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Relationship between Delirium and Night-Time Interruptions in ICU

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Relationship between Delirium and Night-time Interruptions in ICU

By

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A dissertation presented to the

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Dissertation Committee

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Abstract

Background: This dissertation examined the phenomenon of delirium in the intensive care unit (ICU) setting. Delirium is a form of cognitive disturbance with a physiologic etiology and complex, multifactorial mechanisms of causation and risk. Delirium in the ICU patient presents a significant risk for adverse outcomes including increased mortality, length of stay, falls, and restraint use. ICU delirium can lead to persistent cognitive impairment beyond discharge and frequent skilled nursing placement. Identifying delirium requires accurate diagnosis that is optimized when validated instruments are used. Sleep deprivation has been linked to adverse health consequences including delirium. Previous studies investigating the relationship between sleep and delirium have focused on the effects of light, noise, medications, and mechanical ventilation. Limited knowledge existed on the role night-time interruptions caused by routine hospital processes played in the prevalence of delirium.

Objectives: This body of work aimed to determine the prevalence of ICU delirium in a sample of ICU patients and discover if there was a relationship between night-time sleep interruptions and delirium in a subset of patients undergoing cardiac surgery. A secondary purpose was to study the relationship between delirium, falls, and restraint use in adult cardiac surgery patients in ICU. The work will be presented in three manuscripts.

Methods: A data-based retrospective cross-sectional design was used to describe the documentation of delirium in three acute care hospitals with mixed medical, surgical, and trauma ICU's. A descriptive design using a subset of patients from the pre-collected data

was used to identify relationships between independent risk variables and delirium in a sample of cardiovascular surgical ICU patients.

Results: The first manuscript titled *"Preventing ICU Delirium: A Patient-Centered Approach to Reducing Sleep Disruption"* was published in Dimensions of Critical Care Nursing with the purpose of describing the state of the science regarding sleep as a risk factor for developing delirium and research evidence on the ill health effects of sleep loss. A patient-centered approach was introduced to improve sleep in ICU by re-evaluating the necessity of routine processes that disrupt sleep in the critically ill. The second manuscript titled *"Delirium Assessment and Prevalence in Critical Care Patients"*. The article presents the frequency of delirium assessment and the prevalence of ICU delirium. The differences amongst the three hospitals regarding ICU length of stay and assessment percent were also presented. In order to treat delirium, it must first be recognized. This study indicated clinicians may be missing the delirium diagnosis because the assessment was not being done consistently. The third manuscript is titled *"The Relationship Between Delirium and Night-time Interruptions in ICU"*. The final manuscript describes the results of an observational study using retrospective data on the frequency ICU patients are awakened at night for routine laboratory and diagnostic tests. In addition, the relationship between the frequencies of sleep interruptions and delirium prevalence was presented. While no relationship was found, the results suggest ICU patients are awoken frequently at night and more studies are needed to understand if sleep deprivation in critically ill patients leads to poor health outcomes.

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Dedication and Acknowledgments

My dissertation work is lovingly dedicated to my husband Kevin who's steadfast and unbending love, perfectly timed humor, and selfless support of my life's work as a nurse, helped my dream come to fruition. To my children Katy, Drew, James, and Jeff for always encouraging me and surviving having a mom as an ICU nurse. To Brenda Boone, my partner in the PhD journey, for her awesome friendship and always keeping me organized when it mattered most. And lastly, to my parents, for instilling the belief that I could be absolutely anything I wanted to be.

Amy

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Chapter I

Introduction

Delirium in the intensive care unit (ICU) affects up to 30% of critically ill patients and up to 80% of patients requiring mechanical ventilation. Once thought to be self-limiting, recent studies indicate patients experience long-term adverse outcomes including prolonged hospital stay, increased skilled nursing placement, inability to return to prior level of functioning, and increased morbidity and mortality, all contributing to increased healthcare costs (Ely et al., 2004; Inouye et al., 2006; Leslie, Marcantonio, Zhang, Leo-Summers, & Inouye, 2008).

During the past two decades expanded knowledge of ICU associated delirium derived from clinical research has helped to describe many of the poorly understood aspects of delirium. Several landmark studies have examined risk factors, instruments for diagnosis, and pharmacologic and non-pharmacologic interventions for delirium treatment (Ely et al., 2001; Inouye, et al., 1999; Jacobi et al., 2002). Outcome data from numerous studies indicate deleterious short-term and long-term effects of ICU associated delirium, including increased mortality and persistent cognitive impairment with functional decline (Ely et al., 2004; Gottesmann et al., 2010; Pisani et al., 2009; Van Rompaey et al., 2009). According to Mildbrandt et al. (2004), delirium in the ICU results in a 39% increased cost for ICU stay and a 31% increased cost for overall hospital stay. The financial burden is estimated as high as $152 billion annually (Leslie et al., 2008).

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These studies and others suggest once a patient develops delirium in the ICU effective treatment is challenging and outcomes are worse than among patients who never experience delirium. As with many diseases and conditions, prevention holds the key to improving outcomes; yet there are significant gaps in the knowledge regarding primary strategies for preventing ICU delirium.

Background

Delirium is defined as an acute brain failure characterized by a rapid onset of confusion with a fluctuating course, inattention, disorganized thinking, and an altered level of consciousness. In addition to these characteristics, many hospitalized patients report experiencing abnormal sleep-wake patterns, hallucinations, and delusions associated with delirium (Richman, 2000). There are three delirium sub-types: (a) hyperactive, characterized by agitation, (b) hypoactive, characterized by profound lethargy, and (c) mixed, characterized by periods of agitation alternating with lethargy (American Psychiatric Association, 2010).

Delirium is not a new phenomenon but clinicians commonly believed delirium resolved once the critical illness or injury was successfully treated. Research conducted over the last 10 years suggests delirium developing in the acute care setting, particularly in the intensive care unit (ICU), may not fully resolve as once thought (Jackson, Gordon, Hart, Hopkins, and Ely, 2004). Studies have revealed patient's with delirium experience longer ICU and hospital stays, increased discharge to a location other than home, and increased mortality (Thomason et al., 2005; Balas, Happ, Yang, Chelluri, and Richmond,

2009; Pisani et al., 2009). Delirious patients are physically restrained more often than patients without delirium and are more likely to fall (Micek, Anand, Laible, Shannon and Kollef, 2005; Lakatos et al., 2009). While the bulk of research has been conducted on pharmacologic treatment for delirium, a dearth of research exists on strategies to effectively prevent ICU delirium. Innovative ideas are needed to prevent delirium and decrease the severity and duration once delirium is recognized. Delirium is a complex disorder with multiple risk factors. The purpose of this study is to explore one of the risk factors for developing delirium: sleep deprivation. The study also seeks to identify the specific barriers to adequate sleep and rest in the critically ill.

Previous delirium prevention studies have focused primarily on staff education, expert consultation, and protocols targeted toward multiple risk factors simultaneously (Inouye et al., 1999; Marcantonio, Flacker, Wright, and Resnik, 2001; Lundstrom et al., 2005; Robinson, Rich, Weitzel, Vollmer, and Edens, 2008; Vidan et al., 2009). These studies, all conducted in non-ICU settings, have demonstrated some degree of success in decreasing the incidence and duration of delirium. With the exception of Lundstrom, sleep promotion is consistently listed as a component of recommended guidelines for delirium prevention.

Sleep deprivation has been implicated as a risk factor for developing delirium (Inouye, 1999; Weinhouse, 2009). Whether due to the ICU environment, excessive noise, bright lights, frequent interruptions, over-use of sedatives, or mechanical ventilation, experts agree ICU patients sleep patterns and circadian rhythms become disturbed while in ICU. Consequences of prolonged sleep deprivation are well

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documented and include immune dysfunction, impaired respiratory functioning, and

cognitive decline (Benca et al., 2009; Spiegel, Sheridan, and Van Cauter, 2002; Kociuba

et al., 2010). Patients in the ICU are subjected to many processes inherent in ICU care

that include night-time or early morning scheduling of medications, baths, laboratory

tests, EKG's, and X-rays, all of which disrupt sleep.

<div align="center">

Timing of ICU Care: Disrupted Sleep

</div>

Hospital Systems and Processes for Patient Care

Hospital systems and processes for patient care are frequently initiated for

specific reasons, most often related to labor considerations, budgetary constraints, or

medical staff preferences. The original reasons for these processes or systems frequently

evolve or change over time. Such is the case with night-time scheduling of routine

diagnostics and laboratory tests.

Many of the care routines and customs of acute care hospitals has traditionally

been physician centric. Processes were implemented to ensure pertinent physiologic and

diagnostic data were readily available when it best suited physician work flow. Having

results of laboratory and diagnostic tests available first thing in the morning to support

physician's need to round on patients prior to starting office hours is one example. The

intensivist model, present in approximately 20% of ICU's in the US, is designed to have

critical care physicians readily available in ICU's 24 hours a day, seven days a week

(Angus et al., 2006). In these hospitals, physicians are no longer leaving to attend to

office patients and therefore do not have the necessity for early morning test results, yet hospital processes set up for this have remained unchanged.

Physician preference, however, hasn't been the only factor driving early morning lab and diagnostics. Developing x-ray film and processing blood used to take several hours, resulting in the need for routine radiological studies and blood work to be performed in the middle of the night in order to have results available by early morning. With the advent of digital technology in radiology and rapid turn-a-round times for blood work, the need to plan for prolonged processing times has been reduced. Regardless of these changes in physician service models and technology improvements, ICU patients are still interrupted in the early morning hours for routine care, assessments, laboratory tests, and imaging studies. Hospital processes and systems have not changed; but why should it change?

Interrupting night-time sleep in ICU patients is speculated to contribute to sleep deprivation, especially over consecutive nights of interrupted sleep, resulting in negative psychological and physiological disturbances (Patel, Chipman, Carlin, and Shade, 2008). Sleep deprivation has been linked to cognitive dysfunction and physiologic derangement, and implicated as a contributor to the development of delirium in ICU patients (Hardin, 2009). The purpose of this study is to learn if there is a relationship between the frequency of interruptions during the night from routine hospital processes and the incidence of delirium.

Significance

Recent studies suggest ICU delirium may not fully resolve and can contribute to an earlier death (Gottesman, 2009; Leslie, 2008). Treatment modalities are showing some promise in limiting the duration and severity of ICU delirium but preventing delirium from ever occurring would be the first and best option. Published articles list common medications used to treat delirium, ironically these drugs are the same medications that cause or contribute to delirium (Jacobi, 2002). Identifying non-pharmacologic interventions to prevent delirium would limit the need for drugs with undesirable side effects or the potential to cause or worsen delirium.

Caring for critically ill patients who develop delirium, especially the hyperactive or mixed sub-types, can be extremely challenging for ICU nurses, and distressing to patients and families. Delirious patients frequently attempt to remove necessary intravenous lines, endotracheal tubes, and feeding tubes placing them at risk for additional procedures or needing restraints. Delirious patients may also attempt to get out of bed, leading to harm from falling. Nurses caring for delirious patients can become frustrated and exhausted, resulting in patients experiencing neglect or compassionless nursing care caused by overwhelmed nurses.

Promoting sleep in ICU patients presents several challenges. Patient care often necessitates frequent sleep interruptions for diagnostic and laboratory tests, turning, suctioning, medication delivery, and finger sticks to check blood sugar. The effect of these frequent night-time interruptions specifically due to hospital's routine processes is unknown.

Purpose

The purpose of this study is to explore the relationship between night-time interruptions from routine hospital processes in the ICU and the incidence of delirium. The study proposes that increased interruptions of sleep and rest in ICU patients leads to sleep deprivation, especially the longer a patient stays in the ICU. Lack of quality sleep can place critically ill patients at risk for transitioning into delirium.

Specific Aims

Aim I. Examine the relationships between frequencies of night-time interruptions from diagnostics and laboratory tests and delirium in ICU patients.

Aim II. Examine the relationships between use of restraints, episodes of falling, and delirium in ICU patients.

Aim III. Explore factors that increase the probability for delirium in ICU patients.

Research Questions

The research question: Does the frequency of routine night-time hospital processes for diagnostics and laboratory tests correlate with an increased incidence and duration of delirium in ICU patients? Does the incidence of delirium correlate with an increase in falls or the use of physical restraints?

Conceptual Framework

While there are many theories for the mechanisms on how delirium develops and evolves most concentrate on changes or disruptions in brain chemistry, function, or structure. The basic pathoetiologic model of delirium (Maldonado, 2008) illustrates how critical illness triggers neuro-chemical changes in central cholinergic transmissions affecting sleep, arousal, memory, and attention. In this delirium model, a patient experiences stress in the form of critical illness or major surgery and neuro-chemicals, particularly acetylcholine, dopamine and norepinephrine, are released in the brain. The areas of the brain thought to be most adversely affected are the hypothalamic-pituitary-adrenal complex (HPA) (Rigney, 2010). Researchers, operating on the evidence that normal aging brains decrease the synthesis of acetylcholine and have reduced cerebral oxidative metabolism over time, place the elderly at higher risk for developing delirium in the ICU. Combining normal stress response with predisposing factors such as cognitive impairment or dementia, and the precipitating factor of sleep deprivation, the model predicts delirium is more likely to develop. See figure 1.

Significance to Nursing

The problem with performing routine tests during the night is the interruption of sleep occurs during the most vulnerable time when the circadian rhythm drops to the lowest point (Czeisler, Buxton, and Khalsa, 2005; Collop, 2008). Humans are diurnal and inherently require sleep at night. ICU patients already have their sleep disturbed by

necessary interruptions such as medications, frequent neurologic checks, endotracheal suctioning, and turning. Noise from alarms, bright lights, and staff communication is another source of sleep disturbance. Nurses are challenged to design plans of care that eliminate routine interruptions during the time the human brain is most driven to sleep and rest. The results of this study, if the proposition is supported, will provide information for further investigation into whether altering routine night-time processes in order to decrease interruptions will be a potential strategy for preventing delirium in the ICU.

Figure 1
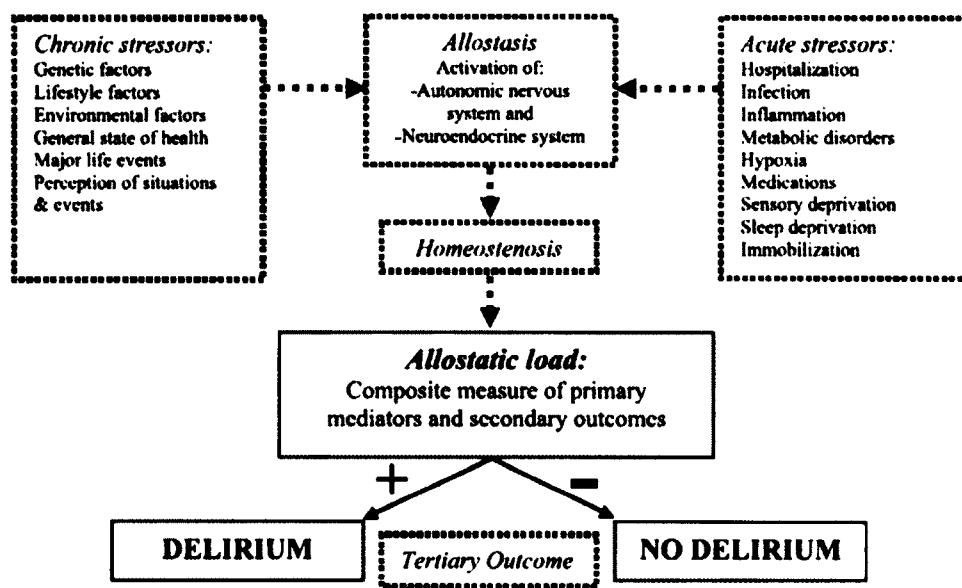
Reprinted with permission from "Allostatic Load and Delirium in the Hospitalized

Patient," by T. Rigney, 2010, *Nursing Research, 59 (5)*, p. 325.

Chapter II

Review of Literature

Delirium has been described in the medical literature for centuries but has only received legitimate attention in the contemporary acute care research community in the last ten years. Historically Psychiatrists have been the predominant professional group to study and describe delirium. Clinicians agreed a common language regarding the medical diagnosis of delirium was necessary in order to propagate the scientific dialogue.

Delirium is defined as an acute organ dysfunction originating from patho-physiologic mechanisms affecting the brain (Diagnostic and Statistical Manual of Psychiatric Disorders IV, 2000). The manual uses the criteria listed below for diagnosing delirium:

1. Disturbance in consciousness with reduced ability to focus, sustain, or shift attention.

2. Change in cognition that cannot be better accounted for by pre-existing, established, or evolving dementia.

3. Development over a short period of time (usually hours to days) and a tendency to fluctuate during the course of the day.

Additionally, there is evidence from the history, physical examination, or laboratory findings that the disturbance is caused by the direct physiological consequences of a general medical condition.

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Delirium, traditionally regarded as an unavoidable side effect of critical illness, is now thought to be a potentially preventable or modifiable condition. Clinicians are familiar with patients becoming confused and agitated, or lethargic and withdrawn as a result of illness or injury. They also believe once the patient's condition improves, the delirium resolves. Empirical findings refute this thinking; rather the evidence points toward paying careful attention to ICU delirium by healthcare providers in order to prevent poor outcomes. Delirium is not unique to the ICU but this study will focus on the phenomenon of delirium primarily in the critical care population.

The majority of early research on delirium was conducted by psychiatrists and published in their specialty journals. Dr. Sharon Inouye of Yale University was one of the first non-psychiatrists to comprehensively study delirium in the acute-care setting. Her landmark studies focused on elderly hospitalized patients. Studies conducted by Inouye and others described the seriousness of the disorder, risk factors for developing delirium, and the recommendations for prevention and treatment (Inouye, 1994; Inouye and Charpentier, 1996; Inouye, Rushing, Foreman, Palmer, and Pompei, 1998; Inouye et al., 1999). These studies became the foundation for research conducted in the ICU population over the next 8-10 years.

The review of literature will first address the prevalence and outcomes of ICU delirium, making a case for why research for effective prevention and treatment needs to continue. Next, the role adequate sleep plays in optimal healing and wellness will be presented, as well as the state of the science regarding sleep deprivation in critically ill patients and the relationship to delirium. The literature regarding the relationship between delirium and restraints and falls will also be presented.

ICU Delirium Incidence and Prevalence

Delirium in the ICU patient gained heightened attention in the critical care literature due to disturbing evidence indicating delirium occurred in near epidemic proportions in critically ill patients, particularly those requiring mechanical ventilation. Researchers began by studying the older medical ICU population (age >70) because earlier research indicated this age group was at the highest risk (Inouye & Charpentier, 1996). McNicoll and colleagues (2003) studied 45 patients over the age of 65 in a medical ICU and found 31% developed delirium. Ely and colleagues (2004) reported nearly 82% of 275 patients requiring mechanical ventilation (MV) screened positive for delirium on at least one occasion while in ICU. This study only looked at medical and coronary ICU patients so study results could not be generalized to surgical or trauma patients. This study also excluded all patients with stroke or other primary neurologic disease, therefore incidence in patients with these diagnoses went undiscovered. Similar methodology was performed by Thomason and associates (2005) only they studied non-mechanically ventilated patients. These researchers found of 261 medical ICU patients, 48% had at least one day of delirium.

Using an alternate methodology, a prospective chart review performed by Pisani et al. (2006), tabulated 80% delirium prevalence in 178 medical ICU patients over the age of 60. Although previously validated methods were employed for both the patient assessment and the chart abstraction, results may have been skewed because two methods were used to collect the same data. Data abstraction involved both a documented score on a validated tool and chart review for key terms and descriptors when no score was

recorded. This could have created the opportunity for variability in the calculations of prevalence.

Dr. Inouye's group from Yale looked specifically at patients undergoing cardiac surgery (mechanically ventilated and admitted to ICU) and found 52% (n=62) developed delirium; however only patients older than 60 were included. Sicker patients requiring emergent surgery or procedures involving the aorta or carotids were excluded. This may account for the lower rates than what other researchers reported.

Further evidence describing the incidence of delirium across other types of ICU patients include studies conducted by Balas et al. (2007), Panharipande and colleagues (2008), and Lat et al. (2009). All reported on the prevalence of delirium in surgical and/or trauma patients. These researchers found between 45-73% of patients suffered at least one episode of delirium while in ICU. Balas' team reported the lowest incidence but like Ely and colleagues (2004) excluded patients with central nervous system injury (stroke, head or spinal cord injury, or any neurosurgical procedure). Researchers note that neurologic injury does not make patients less likely to develop delirium, but may confound an accurate assessment. Pandharipande et al. (2008) had the same exclusions but included all ages and those requiring mechanical ventilation. Lat et al. (2009) did not exclude any age group diagnosis but focused only on patients requiring mechanical ventilation. Mechanical ventilation emerged as the common thread in the studies reporting the highest incidence.

While the aforementioned researchers attempted to represent a cross section of both medical and surgical patients, they were all, with the exception of Lat et al., associated predominantly with the same research team from two large academic

institutions in the eastern United States; therefore results may be unique to this group's epistemology, region, or approach to research questions. Despite limitations, the researchers have mounted strong support that ICU delirium is present in a significant percentage of ICU patients. Next the data showing poor outcomes in delirious patients validates the need for further investigation into ways of preventing delirium or reducing the duration and severity once it occurs.

Long-term Outcomes

Following the acknowledgment that delirium was indeed a problem, the focus on the next wave of studies were questions regarding outcomes of patients who experienced delirium. Studies investigated (a) length of stay, both in ICU and the overall hospital stay, (b) costs associated with delirium, (c) persistence of cognitive dysfunction after leaving the hospital, (d) hospital discharge to places other than home, and (d) mortality. Pertinent studies regarding each of these will be presented in the following sections

Increased length of stay.

When patients develop delirium, studies show patients stay longer in the ICU and the overall hospital stay is prolonged (McCusker, Cole, Dendukuri, and Belzile, 2003). Thomason and colleagues (2005) studied 261 non-ventilated medical ICU patients age 18 and older, comparing delirious versus non-delirious patients, and hospital length of stay (LOS). They reported a 29% greater risk for remaining in the ICU on any given day, and a 41% greater risk for remaining in the hospital in patients who had at least one day of delirium. In patients who required MV, a study of 134 surgical and trauma patients

showed delirious patients stayed in the ICU five days longer than non-delirious patients; overall, hospital stay was up to seven days longer (Lat et al., 2009).

Increased LOS correlates with increased cost. Milbrandt et al., (2005) reported additional costs associated with delirium between $9,000- $11,000 more per patient. According to Leslie, Marcantonio, Zhang, Leo-Sumers, and Inouye (2008), once patients develop delirium, health care costs are two and a half times greater than patients who never develop delirium and range from $16, 303 to $64, 421 per patient. These researchers estimate the annual cost to our healthcare system as high as $152 billion each year.

Salas and Gamaldo (2008) point out patients with acute cognitive changes may also undergo additional neurologic evaluation to rule out other causes (embolism, hemorrhage, or edema). The increased cost from additional diagnostics related to an altered level of consciousness from delirium represents added financial burden.

Persistent cognitive dysfunction.

Perhaps the most unexpected information for clinicians was the finding of persistent cognitive impairment after the patient was discharged from the hospital. In two separate meta-analyses reviewing relevant studies published between 1973 and 2009, researchers used stringent criteria to test the hypothesis that poor outcomes were due to non-recovery from delirium prior to discharge. They found patients with delirium during hospitalization had persistent delirium at discharge; as well as at one, three, and six months after discharge (Cole, Ciampi, Belzile, and Zhong, 2009; Witlox et al., 2010).

The above papers were studying several outcomes, but Girard and colleague's (2010) primary objective was predicting long-term cognitive impairment in survivors of

critical illness. All were medical ICU patients requiring mechanical ventilation. Researchers assessed participants for delirium daily while in ICU and again at three and six months using a comprehensive battery of nine neuro-psychological tests. Results indicated that duration of delirium was an independent predictor of persistent cognitive impairment at three and six months after discharge. The idea that delirium was self-limiting and eventually resolved was being challenged by new data.

Institutionalization.

Patients who experience delirium in the ICU are more likely to be discharged to a location other than home, presenting a significant personal and public health concern. Hospitalized patients who experience delirium are half as likely to be discharged home than patients who never experience delirium (30% vs. 70%, $p < 0.01$) (Marcantonio et al., 2005). Balas, Happ, Yang, Chellure, and Richmond (2009) in a study of surgical ICU patients older than 65 years showed patients were approximately 40% more likely to be discharged to a location other than home (61.3% vs. 20.5%, $p < 0.0001$). Patients may have had successful surgery or full recovery from a medical illness, yet are unable to care for themselves due to persistent cognitive impairments stemming from delirium. Discharging patients to skilled nursing facilities instead of home has implications related to reimbursement from Medicare and Medicaid in an era of healthcare reform.

Mortality

Ely and colleagues (2004) were the first to describe the increase in mortality in patients who experienced delirium in ICU. In a prospective cohort study of 275 mechanically ventilated medical ICU patients, after adjusting for relevant covariates of

age, severity of illness, co-morbid conditions, coma, and use of sedatives or analgesic

medications, delirium was an independent predictor of mortality at 6 months (34% vs.

15%, p= .03). Additionally, a study conducted in Belgium by Van Rompaey and

associates (2009) studied 105 non-intubated ICU patients. The primary aim of the study

was to observe the incidence of delirium using two validated instruments and comparing

incidence identification. The secondary aim was to observe long-term outcomes. After

hospital observation, patients received follow-up contact at three and six months post-

discharge. Using an instrument scoring for mortality and quality of life, researchers

reported greater mortality, as well as decreased quality of life, in patients experiencing

delirium (41% vs. 15%; OR 3.03 (0.57-16.19).

Gottesman and her colleagues (2010) specifically studied mortality from delirium

in patients undergoing coronary bypass surgery. Consecutive patients enrolled from

1997-2007 resulted in a final cohort of 5,034. Researchers assessed patients daily for any

neurologic change and coded them as either (1) stroke, or (2) neurologic injury (broadly

defined as any change in mental status not specifically defined as stroke). Patients were

followed on average three years after discharge. The death rate among those with

delirium was 16 per 100 person-years and 7 per 100 person-years for those without

delirium ($p < 0.0001$). Researchers, however, did not use a validated instrument to assess

for delirium and stroke always took precedence over any other neurologic change.

Results may have represented a broader mortality from neurologic injury and not

mortality specific to delirium.

Duration of delirium also plays a role in increasing mortality. Both Ely and

colleagues (2004) and Pisani and colleagues (2009) used a Cox proportional hazard

regression model to obtain hazard ratios of death at 6 and 12 months respectively. The model controls for relevant covariates such as age, co-morbidity index, and admitting diagnosis of sepsis or adult respiratory distress syndrome (ARDS). Both found an increased risk of mortality of 10% for each day spent in delirium.

In light of the presented literature, research on preventing delirium should be the first objective, but once delirium develops it becomes just as important to learn ways to limit the duration in order to decrease mortality, along with other negative outcomes associated with delirium. Prevention typically starts with identifying patients at risk, then determining which factors can be mitigated or reduced.

Risk Factors for ICU Delirium

ICU delirium is a complex disorder involving many factors. Clinicians need data to evaluate which risk factors are most amenable to interventions; and more importantly, which strategies are most effective at preventing delirium, and at the very least, limiting the severity and duration. While researchers have spent the last few years demonstrating a variety of poor outcomes, earlier researchers wanted to answer questions about what places patients at risk for developing ICU delirium. Knowing risk factors helps researchers to design interventions to modify factors to prevent or treat ICU delirium. Risk factors can be divided into two categories, predisposing and precipitating factors. Predisposing factors are characteristics and/or diagnoses that existed prior to admission to the ICU. Examples of predisposing factors for delirium (Inouye, 2006) include (but not limited to):

- Advanced age (> 65 years)
- Male gender
- Dementia
- Impaired vision or hearing

- Dehydration
- Hypertension
- Diabetes
- Alcoholism

Precipitating factors for delirium comprise both modifiable and non-modifiable factors. These can be divided into several broad categories, (1) the primary illness or disease process, (2) surgery, (3) mechanical ventilation, (4) medications, especially sedatives and opioids, (5) the ICU environment, including noise, lights, and (5) frequent patient interactions or sleep disruptions. All of the aforementioned can affect the ability for patients to get the adequate sleep and rest needed for optimal healing (Pandharipande et al., 2008; Weinhouse & Schwab, 2006).

Each broad category has components that can be modified and some that cannot. For example, if a patient is admitted with respiratory failure and requires mechanical ventilation, this is non-modifiable factor; but optimizing comfort (avoiding over-sedation or under-treatment of pain) through the administration of sedatives and analgesics is modifiable (Weinhouse & Watson, 2009). Risk factors that can be modified have been the focus of research in the last five to seven years and strategies such as sedation guidelines, ventilator weaning protocols, early mobilization, and staff education have shown promise in reducing the incidence of delirium (Ely et al., 2004; Jacobi et al., 2002; Lundstrom et al., 2005; Robinson, Rich, Weitzel, Vollmer, & Eden, 2008).

Delirium prevention guidelines aimed specifically toward ICU patients originate from drug studies indicating increased exposure to medications, particularly benzodiazepines, increase the risk of developing delirium (Pandharipandem et al., 2006). Sedative drugs disrupt sleep architecture, reducing the restorative stages of sleep leading

to cognitive disturbances (Mendelson, 2005). In a study investigating if sedatives and analgesics increased the chance of patients developing delirium, Pandharipande and associates (2006) studied 196 elderly, mechanically ventilated ICU patients. They found a statistically significant correlation, independent of other factors, between lorazepam (a common benzodiazepine used in ICU) and the odds of transitioning to delirium. To reduce the incidence of delirium, current recommendations include a daily interruption of continuously infused sedative medications (Brush & Kress, 2009; Jacobi et al., 2002,).

Guidelines for preventing or managing delirium include both pharmacologic and non-pharmacologic interventions (Jacobi et al., 2002; Potter, 2006; Sendelbach, Guthrie, & Schoenfeld, 2009; Tropea, 2008). The individual interventions, however, vary in the level of evidence supporting their effectiveness. Very few studies test non-pharmacologic interventions targeting a single risk factor. To include a recommendation in a guideline, it would be important to know which interventions have research data supporting their efficacy and which interventions are empirically included. Studies investigating non-pharmacologic interventions to prevent delirium have yet to be conducted in the ICU setting.

Delirium Prevention

Non-pharmacologic intervention studies in non-ICU settings have approached preventing or treating delirium using multimodal strategies (Lundstrom et al., 2005; Milisen et al., 2001; Vidan et al, 2009). Robinson, Rich, Weitzel, Vollmer, and Eden (2008) modeled their delirium prevention study after Inouye and colleague's 1999 landmark study using multiple interventions simultaneously. However, instead of

addressing numerous risk factors (as Inouye did), investigators chose three, (1) mobility, (2) vision and hearing deficits, and (3) pre-existing dementia. Patients over the age of 65 with various combinations of the three study risks factors were enrolled in either the pre-intervention group (n= 80) or post-intervention group (matched group, n=80). The intervention consisted of delirium education for caregivers, as well as prevention measures addressing the specific deficits. Results showed a 22% decrease in the occurrence of delirium between pre and post ($p < .001$).

Many delirium intervention studies exclude dementia patients due to difficulty in evaluating delirium superimposed on dementia. Including dementia patients is important since patients with dementia are at higher risk for developing delirium than patients without dementia (McNicoll et al., 2003). Robinson's (2008) study results support using a multi-modal protocol addressing several risk factors at once; however, the data to support individual aspects of the protocol is limited. For example, the effectiveness of interventions addressing mobility compared to the effectiveness of interventions addressing vision deficits was not analyzed. Also, the study was conducted with elderly medical patients so it is unclear if results could be generalized to other populations or settings, including the ICU.

Contributing to the body of knowledge on how to prevent ICU delirium should clearly be a healthcare priority. The opportunities to study how to alter modifiable risk factors are tremendous. The objective of this proposal will be to address one of the identified risks for developing delirium: sleep deprivation. While the majority of the delirium guidelines advocate strategies to promote sleep, little is known about effective ways to achieve adequate quality and quantity of sleep in the intensive care unit. How

sleep deprivation relates to delirium is also not well documented. Sleep/wake cycle

disturbance has been described as a key feature of delirium but it remains unclear if

delirium precedes sleep disturbance or is caused by it (Weinhouse et al., 2009). The aim

of this proposal will be to increase understanding of how the ICU routines, specifically

disruptions to sleep, correlate with the incidence of delirium.

Sleep Deprivation and Consequences on Health

Deleterious effects of sleep deprivation are well established in the scientific

literature. Studies conducted over the past 30 years (many on healthy volunteers)

indicate sleep deprivation alters respiratory function, disrupts hormone levels, lowers

immune function, and leads to neuro-cognitive changes (Sareli & Schwab, 2008; Sharma

& Kavuru, 2010; Zhong et al., 2005). In ICU patients, these sleep related disturbances

can have significant consequences. Patients may have difficulties weaning from both

non-invasive ventilation and mechanical ventilation, develop impaired immunity making

them more at risk for hospital acquired infections, and they can develop major depression

and anxiety (Knutson, Speigel, Penev & Van Cauter, 2007; Roche et al., 2010; Salas &

Gamaldo, 2008). The importance of patients getting quality sleep is rarely disputed yet

the efforts by clinicians to ensure sleep and rest in critically ill patients is generally not a

recognized priority (Friese, 2008; Salas & Gamaldo, 2008).

Sleep Deprivation and Delirium

While no studies have been conducted indicating a direct link between

interruptions to sleep and ICU delirium, research generally supports a lack of sleep leads

to cognitive dysfunction. Studies on the adverse neuro-cognitive and psychological

effects of sleep deprivation have been conducted predominantly using healthy individuals (Lieberman, 2005, Scott, 2006). One such study by Thomas and colleagues (2000) sought to support the hypothesis that sleep deprivation affects the activity and function of the brain. Seventeen healthy volunteers were deprived of sleep for 85 hours. On each day of the study, patients were injected with Fluorine-2-deoxyglucose (18FDG), a substance that served as a marker for regional cerebral metabolic rate for glucose (CMRglu) and neuronal synaptic activity. Following the injection, participants underwent positron emission tomography (PET) scanning and completed a daily battery of cognitive tests. PET scans demonstrated decreased uptake of 18FDG in the areas of the pre-frontal cortex and posterior parietal-thalamic regions, as well as images indicating global down-regulation of the brain. Adversely affected areas of the brain were regions primarily responsible for attention and higher cognitive functions. Participants also had decreased scores on daily cognitive tests following continued sleep deprivation. These researchers believed this to be further evidence for the biological necessity for sleep. Because participants in sleep deprivation studies are generally healthy, results may not be transferrable to critically ill patients; however, scholars frequently mention in their discussion, the potential relationship between sleep deprivation and the development of delirium.

Sleep dysfunction and delirium are thought to have similar neuro-chemical mechanisms involving acetylcholine and catecholamines. Figeroa-Ramos (2009) eloquently describes the bio-physiological theory well but admits that based on current evidence, it is difficult to know whether sleep deprivation leads to delirium or the reverse. In her review of 17 studies, she found only two demonstrating sleep deprivation as a risk

for delirium. She attributes this to the many technical and methodological limitations of measuring sleep in ICU patients.

Sleep studies conducted in ICU settings have primarily investigated sleep architecture using polysomnography (PSG); a combination of electro-encephalogram (EEG), electro-oculagram, and electromyogram (EMG). Friese, Diaz-Arrastia, McBride, and Frankel (2008) examined 16 trauma and surgical ICU patients, using PSG continuously for 24 hours and found decreased levels of stage 3 and 4 slow wave sleep (SWS) and below normal rapid-eye-movement (REM) sleep (Sareli & Schwab, 2008). These particular stages of sleep have been associated with restoring both physiologic functions (such as tissue healing and protein synthesis) as well as maintaining normal emotional and mental functioning (Honkus, 2003).

The knowledge that ICU sleep patterns were abnormal led researchers to attempt to identify possible causes of the sleep disruption. Noise, light, ventilator asynchrony, and frequent waking of patients were all recognized as potential contributors to disrupted sleep. Researchers agree polysomnography (PSG) is the most accurate way of measuring sleep quantity and quality but acknowledge it is complicated to perform on ICU patients (Bourne, Minelli, Mills & Kandler, 2007; Watson, 2007).

Several studies have focused on reducing light and noise to promote sleep; and although noise and light levels were lower after interventions, no correlation to sleep was attempted or identified (Monson & Edel-Gustafsson, 2005; Walder, Francioli, Meyer, Lancon, & Romand, 2000). In Gabor and colleagues (2003), noise contributed to awakenings only 20% of the time, 10% to patient care activities and the other 70% of

factors was not identified. Further research is needed to discover whether routine processes could be one of the unidentified factors.

In a pilot study, Missildine (2008) sought describe the relationship between sleep and noise and light in hospitalized over the age of 70. The study's purpose was to explore if quantity and quality of sleep were related to light or noise levels. During the first 24 hours of hospitalization, wrist actigraphy was used as the objective measure of sleep; in addition patients completed a sleep quality questionnaire. Although patient's night-time sleep averaged less than 5 hours, was severely fragmented (sleeping on average in 19 minutes increments), and patients self-rated sleep as poor, no significant correlation was found between those who slept poorly and elevated noise/light levels. In the discussion of the results, authors state that disruptions from patient care activities may have been more significant in contributing to decreased total sleep and fragmentation than noise and light.

Disruptions to sleep in ICU

Because the link between sleep deprivation and delirium is poorly understood, research is needed to further explain this link. Disruptions to sleep come from many aspects of the ICU environment. Although Missildine and colleagues did not find a correlation, decreasing noise levels and lowering lights at night are recommended strategies to improve sleep. Whether disruptions come from staff voices, alarms, ventilators, or IV pumps; lights and noise do wake patients up. Treatments, medications, procedures, and staff interactions also disrupt sleep but only two studies could be found in the last 10 years investigating disruptions to sleep in hospitalized patients.

The first, a pilot study by Humphries (2009) set out to determine the frequency and characteristics of sleep disruptions in patients on the medical/surgical unit. Using a descriptive non-experimental design, 22 patients, aged 18- 55, were enrolled on day two of hospitalization. Patients were included if they could read English and had the cognitive ability to complete the survey instrument. Patients completed the Verran and Snyder-Halpern (VSH) Sleep Scale (1987) survey on the morning of day three and four of hospitalization. The survey has 15 items measuring three concepts of sleep, (1) sleep disturbance, (2) sleep effectiveness, and (3) sleep supplementation. Patients also answered additional yes/no questions on current stress, present illness, and routines used to achieve sleep. Patients in this study reported high scores for having their sleep disturbed, low scores on sleep effectiveness items, and reported sleeping during daylight hours to supplement overall sleep. While results support the patient's subjective perceptions regarding high sleep disruptions and poor sleep quality, it does not measure the frequency or type of sleep disruption nor the relationship to cognitive disturbances. In a systematic review by Bijwadia and Ejaz (2009), researchers admit data is lacking linking sleep disruptions and the resulting distortion in sleep architecture to delirium and health outcomes.

In the second study, researchers recognizing the adverse effects of sleep deprivation and concern over long term morbidity. Tamburri (2004) sought to understand the type and frequency of night-time interruptions in ICU patients. These researchers believed if they knew the patterns of patient interactions, they could develop a sleep enhancement protocol. Activities could be clustered to provide longer periods without interruption, offering more time for patients to achieve beneficial levels of

restorative sleep. Records of 50 patients from four medical and surgical ICU's were reviewed and all interactions from 7 pm to 7 am were recorded. Results showed a mean of 43 interactions per 12 hour shift with most occurring at midnight and the least at 3 am. Only 6 % of the studied nights had two to three hour increments without interruptions. Tamburri reiterated it takes approximately 90 minutes to complete a full sleep cycle. The opportunity to achieve a full sleep cycle occurred only 6% of the time. This is consistent with research that shows ICU patients rarely achieve deep sleep (stage III) or rapid eye movement (REM) sleep. The strengths of Tamburri's study were the inclusion of all types of ICU patients making the results more generalizable. Patients, who required constant nursing presence due to continuous renal replacement therapy, intra-aortic balloon pump, and neuromuscular blockade, were appropriately excluded due to the intensive monitoring during these therapies. The first night of hospitalization was also excluded under the assumption more interactions would be occurring during efforts to stabilize the patient.

Weinhouse and Watson (2009) recommended using a patient-centered approach to decreasing the frequency of interruptions in order to improve sleep by individualizing or grouping patient care activities. Unfortunately, no link could be made between specific types of disruptions to sleep (necessary responses to patient problems versus routinely scheduled events) and a correlation with the incidence of delirium. Because the link between sleep deprivation and delirium is poorly understood, further research is needed.

Restraints and delirium

Several of the studies addressing delirium prevention recommend reducing or discontinuing restraints to prevent or decrease the severity of delirium (Hine, 2007; Lundstrom et al., 2005). Only one study was found linking restraint use to delirium. Micek, Anand, Laible, Shannon, and Kollef (2005) studied 93 critically ill medical patients and assessed them daily for delirium. The presence of delirium was associated with an increased use of restraints (77% vs. 50%, $p < .05$). Restraints also remained on longer in the delirious group.

Restraint use in healthcare is highly regulated by accrediting and other government agencies. Violations carry hefty fines and bad press; therefore reducing or eliminating restraints is often a high priority.

Falls and delirium

Beginning in October of 2008, Medicare no longer reimburses for any costs associated with patients who fall while in the hospital. Keeping patients safe is a top priority of healthcare institutions. Fall reduction programs aimed at reducing falls and associated costs can be found in nearly every hospital and long term care facilities. The link between falls and delirium is also not well understood. However, Ferrari and colleagues (2010) described the relationship between one of the key features of delirium: inattention, and falls. Researchers focused on impulsivity and the relationship to seven fall risk factors, and the number of falls. A total of 411 records in patients who fell while in the hospital were analyzed retrospectively. Using logistic regression, inattention emerged as a significant risk factor in impulse related falls. Research is needed to better understand if the inattention related to these falls were associated with delirium.

Conceptual Model

Delirium is a complex neuro-biological disorder with many causes. Over the past 10 years, several complimentary theories have emerged. According to Maldonado (2008) there are at least six theories attempting to explain the pathophysiology of how delirium develops. These hypotheses are briefly described below.

- Neuronal aging hypothesis- with advancing age, changes occur in the stress regulating neurotransmitters.

- Oxygen deprivation hypothesis – abnormalities with neurotransmitters causes a decrease in oxidative metabolism leading to brain dysfunction.

- Cellular signaling hypothesis – intraneuronal signaling conductions are disturbed affecting neurotransmitter production and release.

- Neurotransmitter hypothesis – decreased cholinergic function, increased dopamine, norepinephrine, and glutamate, along with changes in levels of serotonin and gamma-aminobutyric acid leads to cerebral dysfunction.

- Physiologic stress hypothesis – stress in the form of surgery, critical illness, or trauma alters the permeability of the blood brain barrier. Abnormal concentrations of thyroid hormones and increased activity of the HPA leads to delirium.

- Inflammatory hypothesis- stress leads to increased release of cerebral cytokines causing direct damage to neurons.

Maldonado believes a combination of several, or perhaps all of the above theories help explain how delirium develops in hospitalized patients.

Of interest to this study is the neurotransmitter theory due to the role the cholinergic system plays in attention and normal sleep patterns, specifically rapid eye movement (REM) sleep. The volume of acetylcholine producing cells decreases as people age. This could, hypothetically, increase their vulnerability to the adverse effects of sleep deprivation.

Critical illness triggers an acute stress response originating from risk factors that are both precipitating and predisposing. Combining several theories involving a normal stress response with predisposing factors such as cognitive impairment or dementia, and precipitating factor of sleep deprivation, the models predict delirium is more likely to develop.

Rigney (2010) developed a complimentary theoretical model describing stress as *allostatic load (AL)*. Rigney defines allostasis as a continuous process of physiologic adaptation in response to stress and AL as an acute (and chronic) process that diminishes one's capability to maintain homeostasis. Much like Maldonaldo (2008), Rigney's model of allostatic load and delirium in the hospitalized elderly conceptualizes acute and prolonged stress, coupled with environmental and genetic factors, overloads adaptive mechanisms and pathology (delirium) develops. See figure 1.

To test the model of AL, Rigney studied 44 ICU patients, age 65 and older, from three separate units. The demographic data collected upon enrollment included age, gender, diagnoses, medications, and alcohol use. To measure AL, levels of substances designated as primary mediators (determined in a prior study) were measured over a 48-72 hour period of time. The primary mediators were urine cortisol, norepinephrine, and epinephrine; as well as serum dehydroepiandrosterone sulfate (DHEA). Secondary

outcomes were also measured. These were waste/hip ratio, systolic and diastolic blood pressure, glycosylated hemoglobin (HgbA1c), high density lipoprotein (HDL), and triglyceride/HDL ratio. Results showed higher AL scores on the primary mediators predicted delirium (r_{pb} = .31, p < .05) but no significant prediction was found for the secondary outcomes. Since the primary mediators were markers for acute and chronic stress response, the results provide additional evidence for the AL model of delirium. Patients with severe pre-existing dementia, current positive screen for delirium, anuria, steroid administration, and inability to communicate verbally were excluded.

Rigney's study provides important quantitative data on the significance of increased levels of stress chemicals and their relationship to delirium but doesn't provide insight on the practicality of measuring these substances to determine or mitigate risk.

State of the Science

Over the past decade knowledge regarding the definition, diagnosis, and treatment options for delirium has grown. Study results indicating the prevalence and detrimental outcomes associated with delirium, especially in the critically ill have gained the attention of medicine and nursing. Good evidence exists on delirium risk factors, instruments for screening, and medications that are deliriogenic.

A few studies have shown moderate success in preventing delirium using multiple strategies simultaneously in the non-ICU setting but little is known on how to prevent ICU delirium. Even less is known regarding specific individual interventions on prevention.

Almost no evidence exists on the role sleep disruptions play on the development of delirium. If a relationship between sleep deprivation and the development of ICU delirium can be found, intervention studies to investigate strategies to prevent or minimize disruptions and maximize sleep quantity and quality to prevent delirium can be conducted.

Chapter III

Methods

The purpose of this study was to: (1) identify whether delirium in critically ill patients can be predicted from the knowledge of an individual's risk factors (age, gender, race/ethnicity, night-time interruptions (laboratory tests and diagnostics), and (2) examine the relationships in the use of physical restraint, incidence of falls, and delirium in critically ill patients in the ICU.

This chapter includes a description of the design, sample and sampling, data collection, and analytic procedures. The protection of human subjects is also presented.

Specific Aims

Aim 1. Examine the relationships between frequencies of interruptions from diagnostics, laboratory tests, and delirium in ICU patients.

Aim II. Examine the relationships between use of restraints, episodes of falling, and delirium in ICU patients.

Aim III. To explore factors that increases the probability for delirium in ICU patients.

Research Design

A descriptive design using pre-collected data was used to identify relationships between independent risk variables and delirium in a sample of cardiovascular surgical

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ICU patients. Descriptive designs facilitate examination of information not previously explored (Kerlinger & Lee, 2000) as was intended with this population.

Based on the review of the literature, assumptions were made linking sleep deprivation to cognitive changes, but little was known about the association to delirium. Previous studies have established delirium as a serious health problem associated with poor patient outcomes; others have suggested the harmful health effects of sleep deprivation. Additionally, the literature reflects, both restraints and falls have been associated with acute confusion in hospitalized patients but the association with delirium in critically ill patients has not been made. It was proposed that interruptions to sleep, especially during the night, lead to sleep deprivation and a greater incidence of delirium. It was also proposed when patients develop delirium; they have a greater chance of falling or being physically restrained. This study examined whether the number of interruptions from routine hospital processes, such as laboratory tests and diagnostics, positively correlated with the incidence of delirium in ICU patients. Whether there was a relationship between the incidence of delirium and the likelihood of patients falling or being physically restrained was also explored.

Sample and Sampling

Data was abstracted from an existing data base of patients, enrolled in a larger study from January 2011 through March 2011, receiving care from two large hospitals that are part of a five facility health care system located in Southern California. Inclusion criteria: adult patients 18 years of age or older; receiving ICU care in cardiovascular/surgical units following coronary revascularization or valve surgery.

Hospital A is a 332 bed not for profit community hospital with three adult ICU's:
a cardiovascular surgery, trauma/surgical and medical units. The total number of ICU
beds is 40 with the overflow capacity up to 48 beds; 12 beds are designated specifically
for cardiovascular surgical patients. The hospital is a level II trauma center and a Joint
Commission certified stroke center. Hospital B is an academic teaching facility with
approximatetly700 licensed beds situated on two campuses, one urban and the other
community. The urban site has 32 ICU beds consisting of medical, surgical, cardiac, and
trauma patients; twelve beds are designated cardiovascular surgery. The community site
has 24 ICU beds with a mix of medical and surgical patients. The community site does
not perform cardiovascular surgical procedures, so no patient data will be collected from
this site.

Power, Effect, and Sample Size

There is no consensus on the approach to compute the power and sample size with
logistic regression; although as pointed out by Katz (2006), ten outcomes for each
independent variable is appropriate. In logistic regression an estimate of the probability
of a certain event occurring is made, rather than detecting the difference or relationship
that may be present, such as in linear regression. No assumptions are made about the
dependent variable (stage), the relationship is non-linear, and is not normally distributed
(Munro, 2005). Some authors use the likelihood ratio test; some use the test on
proportions; some suggest various approximations to handle the multivariate case. Some
advocate the use of the Wald test since the Z-score is routinely used for statistical

significance testing of regression coefficients (Demidenko, 2008). Since this was a

descriptive study and not focused on hypothesis testing, the Final Logistic Regression

Model, which included significance defined by $p<0.05$, where p is from the Wald test for

Confidence Interval for the Odds Ratio and overall statistical significance was tested by

the likelihood ratio test $p<0.1$, was used to demonstrate logistic regression model fit.

Operational Definitions

Delirium: Any positive screen using the Confusion Assessment Method for ICU (CAM-ICU) any day of hospitalization.

Sleep disruption: Any event that woke up or partially woke up a patient by verbal or tactile stimuli.

Hospital Process: Any process driven by hospital personnel/policy/procedure that was performed at scheduled routine intervals.

Laboratory test: The drawing of blood from a patient either by finger stick, venipuncture or from an intravenous or intra-arterial catheter. Also includes sputum induction for sampling via naso-trachial suctioning.

Diagnostic test: Any radiologic study (x-ray, CT scan, MRI), ultrasound (transthoracic echocardiogram, trans-esophageal echocardiogram, venous Doppler), and EKG.

Restraint use: Any documented episode of physical restraints (soft wrist or ankle, mittens, roll belt, or soft splint) applied to patient in order to restrict movement.

Fall: Any witnessed or un-witnessed descent to the floor, with our without injury

Data Collection Instruments/Measures

The Confusion Assessment Method for ICU (CAM-ICU) (Ely et al. 2001) is the

instrument used for delirium diagnosis. The CAM-ICU was adapted for use on patients

who are non-verbal or unable to speak because of tracheostomies or endotracheal tubes.

The confusion assessment method (CAM) was originally developed by Inouye et al.

(1990) for use in the geriatric population for evaluation of delirium by non-psychiatrists. It was adapted by Ely and associates (2001) for use in the non-verbal mechanically ventilated patient. The CAM and CAM-ICU assess four aspects of delirium, (1) an acute onset of mental status changes or a fluctuating course, (2) inattention, (3) disorganized thinking, and (4) a level of consciousness that is anything other than alert and calm. The CAM-ICU has an interrator reliability ranging between a kappa of 0.79-0.95 ($p < .0001$), a sensitivity of 95-100%, and a specificity of 89-93%.

In the CAM-ICU validation study, patients were screened for delirium daily by three researchers, two nurses and one physician. Their assessments were done at difference times and blinded from each other's assessments. Thirty-eight mechanically and non-mechanically ventilated patients were included in the analysis. Excluded from the sample were any patients with a history of severe dementia, neurologic disease, or underlying psychoses. Results of the study showed 87% of the 38 patients developed delirium (Ely et al., 2001)

Parent Study

Prior to data collection, all nurses received a two hour training session during August and September 2010 on how to use the CAM-ICU to conduct a delirium screen. In October of 2010, nurses began screening patients each shift using the CAM-ICU. During the months of October 2010 through January 2011, periodic validation was conducted by the ICU advance practice nurse to ensure the CAM-ICU was being done correctly and to re-enforce educational principles of delirium screening.

Screening for delirium using the CAM-ICU assesses four distinct features, (1) acute onset of a mental status change or a fluctuating course, (2) inattention, (3) disorganized thinking, and (4) altered level of consciousness (see figure 2). Acute onset of a mental status change is any change from the patient's pre-hospital baseline. Because delirium can fluctuate, the screen asks the clinician to assess if the patient is at their mental status baseline currently and have they been there for the past 24 hours. If the answer is no, this represents a positive screen for this attribute. The second screen is for inattention. The clinician tells the patient they are going to say a series of ten letters and asks the patient to squeeze their hand only when they hear the letter A. The clinician spells out S-A-V-E-A- H-A-A-R-T. (Two A's in haart are intentional to provide adequate A's for squeezing). If the patient misses squeezing on an A or squeezes on a non-A, a point is subtracted from the total of ten. The patient must perform this test not missing more than two to test negative for this attribute. The next attribute tests for disorganized thinking. A series of four yes/no questions and commands are given. The total points possible are five (four points for each question and one point for the command). The patient must get at least 4 points to test negative for this feature. The final screen is for altered level of consciousness. The Richmond Agitation and Sedation Scale (Sessler et al., 2002) is used to evaluate this feature (see figure 3)

Figure 2
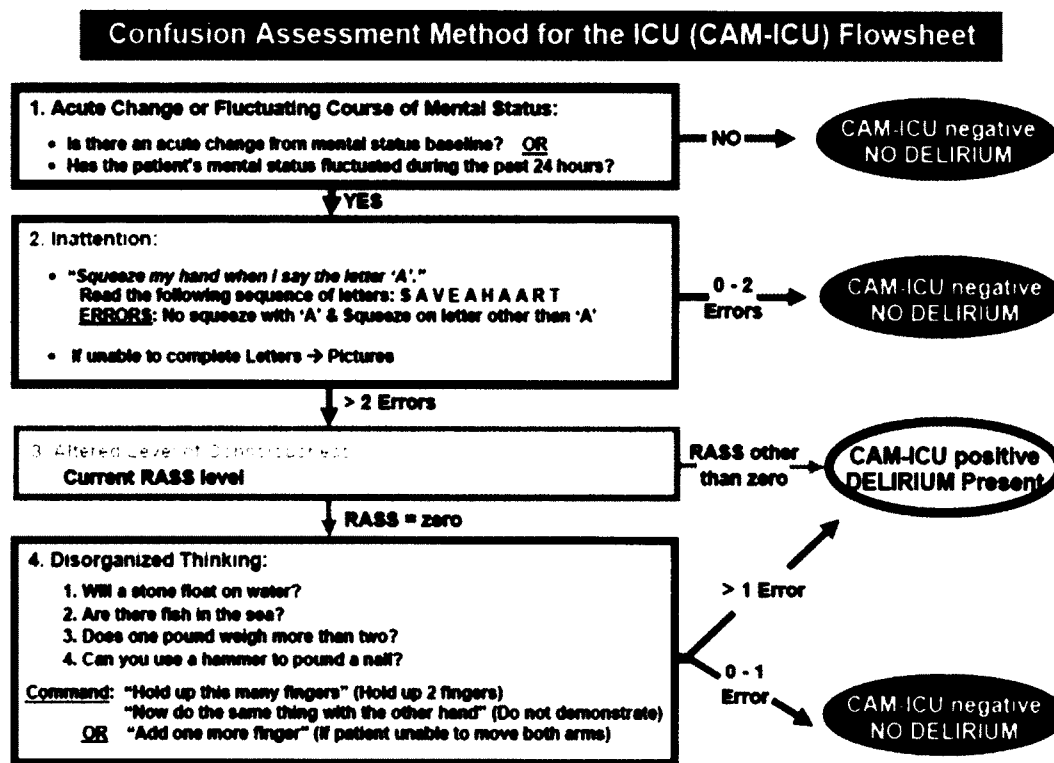
Confusion Assessment Method for the ICU (CAM-ICU) Flowsheet

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The CAM-ICU was used by the primary nurse to screen patients twice a day for delirium (once on the day shift and once on the night shift). The results, either positive for delirium or negative, or unable to assess due to coma (RASS -3 or -4) were recorded on the ICU nurse's flow sheet.

Figure 3

Richmond Agitation Sedation Scale (RASS) *

Score	Term	Description	
+4	Combative	Overtly combative, violent, immediate danger to staff	
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive	
+2	Agitated	Frequent non-purposeful movement, fights ventilator	
+1	Restless	Anxious but movements not aggressive vigorous	
0	Alert and calm		
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* ($\geq$10 seconds)	Verbal Stimulation
-2	Light sedation	Briefly awakens with eye contact to *voice* (<10 seconds)	
-3	Moderate sedation	Movement or eye opening to *voice* (but no eye contact)	
-4	Deep sedation	No response to voice, but movement or eye opening to *physical* stimulation	Physical Stimulation
-5	Unarousable	No response to *voice or physical* stimulation	

Procedure for RASS Assessment

1. Observe patient

   a. Patient is alert, restless, or agitated. **(score 0 to +4)**

2. If not alert, state patient's name and *say* to open eyes and look at speaker.

   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**

   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**

   d. Patient has any movement in response to voice but no eye contact. **(score –3)**

3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.

   e. Patient has any movement to physical stimulation. **(score –4)**

   f. Patient has no response to any stimulation. **(score –5)**

* Sessler CN, Gosnell M, Grap MJ, Brophy GT, O'Neal PV, Keane KA et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care patients. Am J Respir Crit Care Med 2002;166:1338-1344.

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Fall data was abstracted using occurrence reports completed by staff at the time of a fall. Although this required self-report by the healthcare team, the practice of reporting falls is culturally ingrained.

Restraint use was abstracted from electronic documentation. Nursing staff are required to document a minimum of every two hours on a patient in restraints. Documentation included the amount of time the patient was restrained during the prior two hours, the behavior that warranted restraint application, type of restraint being used, including any alternatives the nurses attempted to keep the restraints off.

Data Collection Procedures

A case/record abstraction tool was developed to guide the gathering of information from each participant medical record (See Appendix A).

Data was abstracted retrospectively from the existing data base. Demographic data included:

Age	Documented evidence of pre-existing cognitive impairment	Results of every CAM-ICU screening
Gender		
Medicare status	Hearing or visual deficits	Documented use of restraints during hospital stay
Primary diagnosis		
Secondary diagnoses	Medication and total doses of analgesics and sedatives	Any fall during hospital stay
Surgical procedure		ICU length of stay
American Society of Anesthiologist's (ASA) score	Mechanically ventilation	Hospital length of stay
	Non-invasive ventilation	Discharge disposition

A second abstraction tool was used to count and categorize the patient interruptions from routine or scheduled laboratory or diagnostic tests between 10 pm and 5 am. See Appendix B.

Data Management and Analysis

Secondary data analysis on pre-collected data was used for this study. Initial descriptive statistics (mean, median, mode and standard deviations) was computed for numerical variables. Chi-Square analysis was completed for observed frequencies for categorical predictor variables. Logistic regression analysis was used to determine relationships between independent variables and delirium.

Logistic regression is a multivariate statistical analysis that can be used to predict membership in one dichotomous variable from a set of independent variables. Since the dependent variable is categorical (either has delirium or not) and the explanatory variables are either categorical and or continuous, the logistic regression model can be used to predict membership in one of the outcome categories. The tolerance statistic in the SPSS software can examine multicollinearity among the independent variables to insure that they do not measure the same thing. Tolerance statistics less than 0.10 would suggest a collinearity problem within the identified independent variables (Mertler & Vannatta, p. 169, 2005) and would require re-examination of predictor variables included in the study.

Strengths and Limitations of Methods

Strength of this study is that a homogenous group of cardiovascular surgical patients was included for less potential influence of confounding variables. Patients with

evidence of pre-existing dementia or cognitive impairment were also included. The cardiovascular surgical population is well studied but not on this particular topic. New knowledge generated for this group will be of particular benefit. Many of the previous studies excluded patients with neurologic events either peri-operatively or post-operatively. Excluding patients at high risk for developing delirium limits the ability to find solutions to prevent delirium in those who are most likely to experience it.

Achieving adequate sleep is necessary for optimal physiological and psychological health of all ICU patients. The exclusion of medical, general surgical, and trauma patients provides less insight into the relationships of patients with different diagnoses. This posed a limitation in generalizability to heterogeneous groups.

Conducting a study using pre-collected data reduced the subjectivity of interruptions due to laboratory and diagnostic testing because these events were *time stamped*. Accurate data was obtained rapidly without depending on manual recording of interruptions. A limitation in using existing data is the results of CAM-ICU assessments were incomplete or inaccurate.

Human Subjects Protection

Protection for Human Subjects was obtained through the Institutional Review Board per the protocols of the University of San Diego (Appendix B) and hospital institutional review board (IRB) committees. There were no specific risks or benefits for the patient participants in the study, as this was a secondary analysis of data. No patients were directly participating and data was de-identified for specific patients in the database.

Benefits to future patients were the identification of process improvement opportunities which could result in positive patient outcomes.

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Chapter IV

Manuscript #1
Abstract

Delirium in the ICU is a disorder with multi-factorial causes and is associated with poor outcomes. Sleep-wake disturbance is a common experience for patients with delirium. Care processes that disrupt sleep can lead to sleep deprivation, contributing to delirium. Patient-centered care is a concept that considers what is best for each individual. How can clinicians use a patient-centered approach to alter processes to decrease patient disruptions and improve sleep and rest?

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Manuscript #2

Delirium Assessment and Prevalence in

Critical Care Patients

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Delirium, Prevalence, Assessment, Nursing

Abstract

Background: Delirium in ICU patients has been the focus of research in the past decade due to poor outcomes, including increased risk of death and persistent cognitive impairment. ICU delirium is not a new but remains largely overlooked, under-recognized, and misdiagnosed. Seven delirium screening instruments have been developed and validated but has nursing assessments for delirium become a standard of practice?

Objectives: The study purpose was to determine baseline delirium prevalence for use in the effectiveness of future performance improvement efforts in the care of patients with delirium. The frequency of the delirium assessment and the ICU length of stay were also studied.

Methods: A retrospective cross-sectional design was used to evaluate prevalence of delirium in three mixed medical, surgical, and trauma ICU's. 472 patients admitted to ICU from January 1, 2011 to March 31, 2011 were included. Delirium assessment data was coded as positive or negative for delirium, coma, or not documented.

Results: Delirium was documented on at least one occasion in 12% of patients. Another 3% were comatose. Negative assessments were documented in 46% of the time and 39% were never assessed at any time while in ICU. A post hoc Sheffe indicated nurses in one ICU assessed for delirium more often than nurses at the other 2 hospital's $(F(2, 470)=$

80.855, p=.000). ICU LOS differences between sites was not significant (F (2, 470) =

2.868, p= .058).

Conclusion: Ascertaining delirium prevalence without accurate assessment data is

problematic. The fact that 39% of ICU patients were never screened could mean nurses

are missing the identification of delirium and the opportunity to initiate treatment. Future

studies should address barriers to incorporating routine delirium assessments into bedside

care in ICU.

Introduction

Delirium in the Intensive Care Unit (ICU) patient has been the focus of significant attention from researchers in the past 10 years. The amount of information available to support changes in practice concerning delirium is growing. A number of measures for delirium screening have been developed and recommended, yet delirium remains under-recognized, misdiagnosed, or over-looked.[1]

The diagnosis of delirium, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), is a cognitive disturbance having a primarily physiologic etiology. The syndrome is characterized by acute confusion that develops over a period of hours to days with symptoms that tend to fluctuate over time. Sufferers exhibit deficits in the ability to pay attention, and can have difficulty sleeping. Perceptual disturbances, both visual and auditory hallucinations, can plague the afflicted.[2] After more than a decade of empirical research on the importance of monitoring for delirium, the question remains how adept are critical care nurses at performing the exam and recognizing delirium in their critically ill patients?

Background

Delirium has been described in the literature dating back to the time of Socrates. In writings about the gravely ill, Greek philosophers such as Celsus and Hippocrates believed the changes in behavior to be of physiologic as opposed to a psychiatric origin.[3]

Episodes of confusion, memory loss, hallucinations, and anxiety are well known to be associated with serious illness.

During the Crimean War, Florence Nightingale suffered from a febrile illness, and experienced a confusion which she described her in her diary. The nursing pioneer contracted what was known as the *Crimean fever* and suffered the classic symptoms of delirium, fluctuating between lucidity, disorientation, and coherency; as well as enduring ongoing events she documented as *relapses*. Nightingale subsequently withdrew from public society after her illness. Some historians speculate the aftermath of the febrile illness may have been one of the contributors to her infirmity over the remainder of her life.[4]

Not until the last decade of the 20th century had researchers introduced the idea that delirium was a medical condition (as opposed to psychiatric illness). Health scientists' recognized acute care clinicians lacked the practical tools for accurate diagnosis. As with any medical condition, an accurate diagnosis is necessary to formulate a plan of care. The need for suitable methods for bedside clinicians to diagnose delirium prompted researchers to develop validated screening tools for accurately identifying delirium; as well as differentiate delirium from other neurologic disorders. Table 1 lists the delirium instruments currently available to clinicians. Seven delirium screening instruments have been developed and validated. The most recent and widely used is the Confusion Assessment Method for use in the Intensive Care Unit (CAM-ICU).[5] Adapted from Sharon Inouye's Confusion Assessment Method (CAM)[6] the

CAM-ICU was developed specifically for use in mechanically ventilated or non-verbal patients.

The CAM was the first delirium screening tool published and was designed to assess for delirium in hospitalized geriatric patients. Several years later Geary, a nursing professor with the department of neurosurgical nursing at the University of San Francisco, published the most cited *nursing authored* article on delirium in that decade.[7] It was written for the purpose of teaching critical care nurses, using a case study format, how to recognize delirium. Nearly 20 years later, are ICU nurses yet able to recognize delirium with consistency?

Table 1

Delirium Assessment Tools

Instrument	Year developed	Target population
Confusion Assessment Method (CAM)	1990	Geriatric Acute Care
NEECHAM Confusion scale	1996	Geriatric Acute Care
Confusion Assessment Method (CAM-ICU)	2001	Adult ICU
Intensive Care Delirium Screening Checklist (ICDSC)	2001	Adult ICU
Delirium Observation Screening scale (DOSS)	2003	Geriatric Acute Care
Delirium Detection Score (DDS)	2005	Adult ICU
Nursing Delirium Screening Scale (Nu-DESC)	2005	Oncology

Studies indicate many of the delirium instruments provide an accurate diagnosis; and attempting to recognize delirium employing only clinical judgment reduces the

chance delirium will be identified.[8,9] Indeed, a study by Davis and MacLullich[10]

indicates that physician trainees were aware of how common delirium occurred but were

less knowledgeable of the diagnostic criteria and proper medications to prescribe or

discontinue once delirium was suspected.

Delirium Outcomes

Research has established the importance of monitoring for delirium in critically ill

patients. Poor outcomes associated with delirium have led to recommendations for

regular screening of critically ill patients, especially those on mechanical ventilation.[11]

Detrimental consequences of delirium include persistent cognitive impairment after

discharge and increased risk of death.[12,13] Critical care clinicians generally believed

patients who developed acute confusion while in ICU got better once the critical illness

period passed. Not only have researchers discovered delirium does not always resolve

but may evolve into a more permanent form of cognitive impairment or worsen the

condition of patients who already suffer from cognitive dysfunction.[14] Fong, Jones and

Shi studying patients with Alzheimer's disease, found an acceleration of the disease

following an episode of delirium.[15]

Patients have a greater incidence of being discharged to skilled nursing instead of

going home if they have suffered from delirium while hospitalized.[16] Perhaps the most

disturbing of all the findings may be that delirium increases mortality independent of

other reasons.[17] Consequences of delirium have compelled healthcare researchers and

clinicians alike to search for improved ways to detect, treat, and prevent ICU delirium.

Critical care nurses are in a key position to make a positive difference for patients by

practicing evidence based delirium assessments, as well as prevention and treatment strategies.

Critical Care Nurse Perceptions

According the American Association of Critical Care Nurses[18] (AACN) 2010 member statistics, 69% of ICU nurses practicing in ICU are over the age of 40. When many of these nurses completed basic nursing education programs, little was known about the long term negative consequences of ICU delirium. Seasoned clinicians (nurses and physicians) may still believe confusion in the ICU is a normal and an unavoidable consequence of being critically ill. Antiquated or inaccurate terms are likely still in use (e.g. ICU psychosis, sun downing, confusion, encephalopathy) making accurate communication amongst clinicians less clear. The term *acute brain dysfunction* could possibly be the most accurate umbrella term for delirium, much like the broadly understood terms of acute renal failure or heart failure.

Even if clinicians use the term delirium, many may also still believe delirium is unavoidable and insignificant in relation to the other problems patients experience. Nurses may not be fully aware of the long term consequences, therefore they may de-value the delirium assessment. Devlin,[19] in a survey of ICU nurses working in units with delirium guidelines recommending routine delirium assessments, found the assessment was only done 47% of the time and less than half of the assessments used a validated screening tool. A third of the nurses reported the complexity of the exam as a reason for not conducting the assessment.

Experientially, ICU nurses are acutely aware of the difficulties in caring for patients who predictably begin to exhibit confusion, disorientation, agitation, or lethargy after several days of critical illness. Overt hyperactive delirium is immediately identifiable to any nurse working in the ICU and can lead to nursing fatigue and the potential for burn-out. Patients seem to be in constant motion, pulling at their tubes, trying to get out of bed, unable to be reasoned with, experience impaired short term memory, possess little or no attention span, and occasionally become paranoid and violent. Behaviors fluctuate from agitation to withdrawal and lethargy, leading nurses to believe patients have become exhausted or depressed. One would think nurses would be motivated to assess, diagnose, and treat delirium as early as possible to avoid the exasperation of dealing with a delirious patient.

Role of Professional Organizations

The American Association of Critical Care Nurses (AACN) and The Society for Critical Care Medicine (SCCM) have highlighted the important delirium research findings at national and international conferences in an attempt to inform clinicians.[20,21] Researchers are vigorously attempting to educate the healthcare providers on the deleterious effects of delirium on individuals and families, and on a larger scale, financially burdening our healthcare system. Academic research organizations such as Vanderbilt University have programs of research with websites to disseminate information and provide resources, guidelines, and toolkits to help hospitals change practice and begin to address delirium as a legitimate healthcare crisis in need of dedicated attention on improving the quality of care (www.icudeleirium.org).

Researchers along with clinical experts within AACN and the Society for Critical Care

Medicine (SCCM) have collaborated on guidelines for critical care professionals in

addressing delirium in their units. Foremost among these is the recommendation for

regular assessments using validated tools for identifying delirium. How successful has

the dissemination of research evidence regarding the importance of delirium monitoring

translated into practice changes at the bedside? Is recognition of delirium by ICU nurses

improving?

The Nursing Process

The nursing process is at the core of how registered nurses are educated to

structure care of patients. Nurses typically begin their shift performing a head to toe

patient assessment. From the information gathered in the assessment, along with other

clinical information, a plan of care is formulated. The ICU care plan should be based on

the best evidence available. Staff implement the plan, and continually re-evaluate the

effect of interventions in addressing the identified problems. Professional nursing care

starts with the patient assessment. Without the assessment, the entire care process is

reduced to a series of tasks without clear direction towards an outcome. Incorporating a

more systematic and standardized assessment decreases the likelihood delirium will be

missed.

Assessing for delirium using validated measures (Confusion assessment method-

ICU, Delirium screening checklist, and others) incorporates many of the assessment

activities ICU clinicians already perform. Level of consciousness, orientation to self and

situation, and the ability to follow simple commands are routinely assessed by nursing many times throughout the day.

Delirium prevalence in select groups of critically ill patients has been established based on the early work of Ely and others.[5,22] Others have studied the ability of clinicians to recognize delirium and barriers to performing the assessment.[8,9,10] Does low compliance or poor performance with the delirium assessment represent lack of adequate education, perceptions the exam is too complex, perhaps incomplete buy- in by clinicians on the significance, or not knowing what to do once a patient screens positive for delirium?

The aim of this research study was to describe the documentation of delirium assessments in intensive care units for the purpose of providing baseline data in a hospital system's effort to improve care for the patient experiencing delirium in critical care.

Methods

Prior to the study, all ICU nurses at the 3 hospitals received either structured classroom education or bedside education on delirium, including how to perform the assessment using the Confusion Assessment Method for ICU (CAM-ICU), an easy and fast to use diagnostic tool with an interrator reliability ranging between a kappa of 0.79-0.95 ($p < .0001$), a sensitivity of 95-100%, and a specificity of 89-93%.[17]

The website ICUdelrium.org was used to guide the implementation of the tool including providing staff with pocket cards to remind them of the sequence and steps of the screening process. Education included the rational for monitoring for delirium,

practice performing the assessment, and the location in the record to document results.

Nurses were also provided with written and on-line resources for strategies to reduce the

severity and duration of delirium by using a combination of pharmacologic and non-

pharmacologic interventions.

Nurses were instructed to screen all ICU patients each shift for delirium and as

needed if mental status changed; and to document whether the screen was positive or

negative in the patient's medical record. They were also encouraged to share any

positive delirium screens with the physician team caring for the patient.

A data-based retrospective cross-sectional design was used to describe the

documentation of delirium in three acute care hospitals with mixed medical, surgical, and

trauma ICU's. The three not for profit hospitals are located in a metropolitan area of

southern California. Hospital A is a smaller community hospital with 12 ICU beds

serving a general medical surgical population. Hospital B is a community hospital with

40 ICU beds serving medical, cardiac surgery, and trauma patients. Hospital C is a large

metropolitan academic medical center with 32 ICU beds consisting of a medical,

cardiovascular surgery, and trauma population. Investigational review board (IRB)

approval was obtained prior to data collection.

Sample, Data, and Data Management

The sample included 472 patient cases with admission dates to ICU from January

1, 2011 to March 31, 2011. All 472 patient records were reviewed for delirium

documentation. Data was collected on consecutive ICU admissions from the three

hospitals from an electronic data base. Delirium assessment data was collected for the

entire ICU stay and was coded as a positive or negative screen for delirium, coma, or not

documented. Duration of delirium was not evaluated. Coma was defined as a Richmond

Agitation Sedation Score (RASS) of -4 or -5, meaning the patient was unable to respond

to verbal stimuli. ICU length of stay was also collected.

Results

Delirium Assessment Documentation

A positive assessment for delirium was documented on at least one occasion

while in ICU for 12% (n=55) of the patient cases. Another 3% (n=16) of the patient

cases were unable to be assessed due to coma. Negative assessments for delirium were

documented in 46% (n=217) and 39% (n=184) of the patient cases had no delirium

assessment documented at any time while in ICU. See table 2.

Table 2

Delirium Assessment	N=472	Percent
CAM-ICU Negative	217	46
CAM-ICU Positive	55	12
COMA	16	3
Assessment not documented	184	39

Additional analysis was performed to determine if there were significant

differences between the three hospital sites with relation to documented delirium

assessment and length of stay. See table 3. A one way ANOVA was performed for

documented assessment and a significant difference was found for hospital site, F (2,

470) = 80.855, p=.000). Sheffe post hoc significance indicated that nurses in Hospital

B's ICU documented assessments for delirium more often than nurses at the two other

hospital's ICU's. Although hospital B also had longer ICU LOS, there was no significant

difference in LOS between the three hospital sites (F (2, 470) = 2.868, p= .058).

Table 3

CAM-ICU Assessment and ICU Length of Stay by Hospital Site				
	Length of stay	**Std Dev**	**Percent Assessment**	**Std Dev**
Hospital A	4.52	6.3	13.8	21.2
Hospital B	5.44	8.6	45.5	27.7
Hospital C	3.31	4.1	10.5	23.2

Note: One way ANOVA ICU LOS F (2, 470) = 2.868, p= .058;

Post hoc Sheffe: Percent CAM-ICU Assessment F (2, 470) = 80.855, p= 0.000

Discussion

The purpose of the study was to establish baseline delirium prevalence using documentation of delirium as a proxy for delirium prevalence. The fact that 39% of ICU patients did not have documented delirium assessments does not mean that assessments were not done, nor does it mean that patients did not have delirium. It is difficult to know, based on documentation alone, if means the clinicians are likely missing the delirium diagnosis and therefore not actively treating or addressing strategies to reduce the severity or duration. Table 4 presents' results of prospective prevalence studies where all patients enrolled were consistently assessed showed 21-46% screened positive for delirium.[9,23,24] Not using a validated tool, physicians missed delirium nearly 75% of the time. Responding to surveys, physicians validated the seriousness of delirium and the relationship to poor outcomes but had little knowledge and skills on how to diagnose or treat delirium.[10,17] In reality, physicians rely heavily on the ICU nurse's assessment (and many times the documentation of the nurse's assessment) in order to make needed treatment decisions.

Table 4

Delirium Recognition

Year	Author(s)	Purpose	Method	Sample	N	Result
2009	Davis & MacLullich[10]	Knowledge and attitudes	Survey	Medical Students	784	Students knew the prevalence but lacked knowledge of diagnostic criteria or appropriate treatment medications
2009	van Eijk[9]	Comparing CAM-ICU vs. ICDSC vs. MD	Prospective	ICU patients	126	CAM-ICU superior (sensitivity 64%), ICDSC (sensitivity 43%), MD's only 29% sensitivity
2009	Spronk[8]	Incidence	Prospective	ICU patients	46	MD recognition=28% sensitive, ICU nurse recognition=35% sensitive

The reasons for the lack of consistency with documenting the CAM-ICU

assessment may be multifactorial. Nurses in this hospital system received a two hour

didactic lecture that included research evidence indicating poor outcomes. Nurses were

also instructed on the use of the CAM-ICU tool and given a pocket card to reference

when performing at the bedside. Two hours may not have been sufficient to assimilate

the information and translate to practice. Gesin[25] found nurse's improved their ability to

identify the symptoms of delirium more effectively following a multifaceted program of

education. Nurses in the Gesin study first had to complete an on-line module, and then listen to a lecture from a pharmacist, followed by individual instruction at the bedside.

Some ICU nurses at the three hospitals reported they were not comfortable performing the assessment independently or felt they did not have the time. Some commented physicians rarely asked for the result of the delirium screen, nor looked for the documentation. Often, when a positive screen was reported, no changes were made in the medical regimen. This may have contributed to poor internalization of the importance of performing the assessment, leading to a lack of buy-in. Further investigation into these possible factors is warranted in order to improve the ability of nurses to complete the delirium assessment, act on the results, and document the entire process.

Other gaps in knowledge and opportunities for research fall into three areas. First, guidelines and algorithms for care have been published with variable levels of implementation. Studies are needed to explore the reasons for the slow adoption of accepted assessment tools and treatment guidelines. With approximately 84% of hospitals not utilizing the best evidence in caring for a pervasive disorder, it is no wonder the prevalence has not decreased over the last five decades. It is hard to believe nurses are not motivated given the intense resources, both physical and mental, required to care for delirious patients.

The second area of proposed research concerns studying the outcomes of the recommended guidelines and delirium treatment algorithms. Despite clinical practice guidelines[2] that have been in place since 1994, and algorithms to support decision

making,[26]outcomes achieved as a result of implementing the guidelines has not been published.

The third matter in need of investigation is in the area of prevention. Much of the literature discusses early identification and risk mitigation as the best ways to prevent or minimize the severity of delirium. While these activities are certainly appropriate and necessary, researchers should be shifting to search for better ways for nurses to prevent delirium from occurring. The question needs to be asked: what are the interventions, non-pharmacologic and/or pharmacologic that can be employed to prevent episodes of ICU delirium?

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Manuscript #3

Relationship between Delirium and Night-time Interruptions in ICU

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delirium, sleep, intensive care

Delirium and Sleep Interruptions

Abstract

Background: Delirium in ICU presents a significant risk for adverse outcomes including increased mortality, length of stay, falls, and restraint use. ICU delirium can lead to persistent cognitive impairment and skilled nursing placement. Sleep deprivation has been linked to delirium. Studies investigating the relationship between sleep and delirium have focused on effects of light, noise, medications, and mechanical ventilation. Limited knowledge exists on the role night-time interruptions caused by routine hospital processes play in delirium.

Purpose: To determine if a relationship exists between night-time sleep interruptions and delirium. A secondary purpose was to study the relationship between delirium, falls, and restraint use in ICU.

Methods: An observational design using a retrospective cross sectional review of pre-collected data. Data from 76 cardiac surgery patients was extracted from an existing data base of 472 patients admitted to ICU from January 2011 through March 2011. Results of the CAM-ICU delirium screen were recorded along with night-time interruptions from routine laboratory and diagnostic tests between 10 pm and 5 am.

Results: Of the 76 patients, 70% (n=53) were assessed for delirium *at least* once during the ICU stay and 30% had no CAM-ICU result documented. Six patients tested positive. Patients were awakened a mean of 5.5 times each night. There were no significant differences in the frequency of interruptions [$F(2, 73) = 0.311, p=0.733$]. Patients with

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delirium received more sedatives/analgesic, spent more time on the ventilator and stayed

longer in ICU.

Conclusion: Patients are awakened frequently at night, exposed to sedatives and

analgesics that can precipitate or worsen delirium, potentially resulting in additional

ventilator days and longer ICU stays. ICU clinicians should re-examination the

necessity, timing, and frequency of night-time interruptions in ICU.

Introduction

Advances in health care, specifically in critical care, have enabled clinicians to decrease mortality and improve outcomes in many conditions that in the past would have been non-survivable. Newer therapies such as early goal directed therapy for sepsis, therapeutic hypothermia post cardiac arrest, and cerebral tissue oxygenation monitoring are just a few examples where research provided the knowledge to support the efficacy of such strategies. Yet many complications patients present with or develop during critical illness remain enigmas. Delirium, a complex medical condition, is a complication clinicians struggle to understand, find difficult to treat, and even harder to prevent. Delirium researchers are striving to find answers in order to improve the health outcomes of patients who develop delirium in the intensive care unit (ICU).

Delirium in the ICU affects up to 30% of critically ill patients and up to 80% of patients requiring mechanical ventilation. Initially thought to be self-limiting, recent studies indicate patients experience long-term adverse outcomes including prolonged hospital stay, increased skilled nursing placement, inability to return to prior level of functioning, and increased morbidity and mortality, all contributing to increased healthcare costs.[1-4]

During the past two decades expanded knowledge of ICU associated delirium derived from clinical research has helped describe many of the poorly understood aspects of delirium. Landmark studies have examined risk factors, instruments for diagnosis, pharmacologic, and non-pharmacologic interventions for delirium treatment.[5-7] Outcome data from numerous studies indicate deleterious short-term and long-term effects of ICU

associated delirium, including increased mortality and persistent cognitive impairment with functional decline.[1,8-11] According to Mildbrandt et al.,[12]delirium in the ICU results in a 39% increased cost for ICU stay and a 31% increased cost for overall hospital stay. The financial burden is estimated as high as $152 billion annually.[3] These studies and others suggest once a patient develops delirium in the ICU, effective treatment is challenging and outcomes are worse than among patients who never experience delirium. As with many diseases and conditions, prevention holds the key to improving outcomes; yet there are significant gaps in the knowledge regarding primary strategies for preventing ICU delirium.

Background

Delirium is defined as an acute brain failure characterized by a rapid onset of confusion with a fluctuating course, inattention, disorganized thinking, and an altered level of consciousness. In addition to these core characteristics, many hospitalized patients report experiencing delusions, hallucinations, and abnormal sleep-wake patterns associated with delirium.[13] There are three delirium sub-types: (a) hyperactive, characterized by agitation, (b) hypoactive, characterized by profound lethargy, and (c) mixed, characterized by periods of agitation alternating with lethargy.[14] Hypoactive delirium is the most common type, the most difficult to recognize, and most associated with poor outcomes.[15]

Delirium is not a new phenomenon. Clinicians commonly believed delirium resolved following successful treatment of the critical illness or injury, yet research

conducted over the last 10 years suggests delirium developing in the acute care setting, particularly in the intensive care unit (ICU), may not fully resolve as once thought.[16,17] Researchers have also discovered cognitive decline is accelerated in patients with Alzheimer's dementia who experienced delirium while hospitalized.[18]

Studies have revealed patient's with delirium experience longer ICU and hospital stays, increased discharge to a location other than home, and increased mortality.[10,19,20] Delirious patients are physically restrained more often than patients without delirium and are more likely to fall.[21,22] While the bulk of research has been conducted on pharmacologic treatment for delirium, a dearth of research exists on strategies to effectively prevent ICU delirium. Innovative ideas are needed to prevent delirium and decrease the severity and duration once delirium is recognized. Delirium is a complex disorder with multiple risk factors. This study explored one of the possible risk factors for developing delirium: sleep deprivation. The study also sought to identify the specific barriers to adequate sleep and rest in the critically ill.

Previous delirium prevention studies have focused primarily on staff education, expert consultation, and protocols targeted toward multiple risk factors simultaneously.[6,23-26] These studies, all conducted in non-ICU settings, have demonstrated some degree of success in decreasing the incidence and duration of delirium. With the exception of Lundstrom, sleep *promotion* is consistently listed as a component of recommended guidelines for delirium prevention.

Sleep deprivation has been implicated as a risk factor for developing delirium.[6,27]. Whether due to the ICU environment, excessive noise, bright lights, frequent

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interruptions, over-use of sedatives, or mechanical ventilation, experts agree ICU patients

sleep patterns and circadian rhythms become disturbed while in ICU. Consequences of

prolonged sleep deprivation are well documented and include immune dysfunction,

impaired respiratory functioning, and cognitive decline.[28-30] Cardiovascular and

endocrine dysfunction from sleep disturbances include increased levels of circulating

catecholamines and cortisol, insulin resistance, and hypertension; all risk factors for

cardiovascular disease and increased mortality.[31-34] Patients in the ICU are subjected to

many processes inherent in ICU care that include night-time or early morning scheduling

of medications, baths, laboratory tests, EKG's, and X-rays, all of which can disrupt sleep.

<div align="center">**Timing of ICU Care: Disrupted Sleep**</div>

Hospital Systems and Processes for Patient Care

The National Institute for Clinical Excellence[35] published guidelines for

preventing delirium, recommending sleep promotion by avoiding medical or nursing

procedures during sleep hours. However, hospital systems and processes for patient care

are frequently scheduled during the night for specific reasons, most often related to labor

or work flow considerations, availability of diagnostic equipment, or medical staff

preferences. Nevertheless, the original reasons for the timing of routine hospital

processes may no longer exist. Such is the case with night-time scheduling of *routine*

diagnostics and laboratory tests.

Many of the care routines and customs of acute care hospitals has traditionally

been physician centric. Processes were implemented to ensure pertinent physiologic and

diagnostic data were readily available when it best matched physician work flow. Having

results of laboratory and diagnostic tests available first thing in the morning to support

physician's need to round on patients prior to starting office hours is one example. The

intensivist model, present in approximately 20% of ICU's in the US, is designed to have

critical care physicians readily available in ICU's 24 hours a day, seven days a week[36,37]

In these hospitals, physicians are less likely to be leaving to attend to office patients and

therefore may not have the necessity for early morning test results, yet hospital processes

set up for this have remained unchanged.

Physician preference, however, hasn't been the only factor driving early morning

lab and diagnostics. Developing x-ray film and processing blood used to take several

hours, resulting in the need for routine radiological studies and blood work to be

performed in the middle of the night in order to have results available by early morning.

With the advent of digital technology in radiology and rapid turn-a-round times for blood

work, and point of care testing, the need to plan for prolonged processing times has been

reduced. Regardless of these changes in physician service models and technology

improvements, ICU patients are still interrupted in the early morning hours for routine

care, assessments, laboratory tests, and imaging studies. Hospital processes and systems

have not changed; but why should they change?

Interrupting night-time sleep in ICU patients is speculated to contribute to sleep

deprivation, especially over consecutive nights of interrupted sleep, resulting in negative

psychological and physiological disturbances.[38] Sleep deprivation has been linked to

cognitive dysfunction and physiologic derangement, and implicated as a contributor to

the development of delirium in ICU patients.[39] This study attempts to determine if there is a relationship between the frequency of interruptions during the night from routine hospital processes and the incidence of delirium.

Significance

Recent studies suggest ICU delirium may not fully resolve and can contribute to an earlier death.[3,9] Treatment modalities are showing some promise in limiting the duration and severity of ICU delirium but preventing delirium from ever occurring would be the first and best option. Published articles list common medications used to treat delirium for, example benzodiazepines and antipsychotics; ironically these drugs are the same medications that can cause or contribute to delirium.[7,40] Identifying non-pharmacologic interventions to prevent delirium would limit the need for drugs with undesirable side effects or the potential to cause or worsen delirium.

Caring for critically ill patients who develop delirium, especially the hyperactive or mixed sub-types, can be extremely challenging for ICU nurses, and distressing to patients and families. Delirious patients frequently attempt to remove necessary intravenous lines, endotracheal tubes, and feeding tubes placing them at risk for additional procedures or needing restraints. Delirious patients may also attempt to get out of bed, leading to harm from falling. Nurses caring for delirious patients can become frustrated and exhausted, resulting in patients experiencing neglect or compassionless nursing care stemming from overwhelmed nurses.

Delirium and Sleep Interruptions

Promoting enough quality sleep in ICU patients presents several challenges. Patient care often necessitates frequent sleep interruptions assessments, diagnostic and laboratory tests, turning, suctioning, medication delivery, and finger sticks to check blood sugar. The effect of these frequent night-time interruptions specifically due to hospital's routine processes is unknown.

Purpose

The purpose of this study was to explore the relationship between night-time interruptions from routine hospital processes in the ICU and the occurrence of delirium. The study proposed that increased interruptions of sleep and rest in ICU patients leads to sleep deprivation, especially for longer patient stays in the ICU. Lack of quality sleep can place critically ill patients at risk for transitioning into delirium.

Secondary aims were to examine the relationships between use of restraints, episodes of falling, and delirium in ICU patients and explore factors that increase the probability for delirium in ICU patients. Falls and restraints are typically viewed as nurse sensitive indicators of quality of care and require tracking and trending by regulatory agencies. Understanding characteristics or circumstances that place patients at higher risk of delirium can lead to surveillance or interventions to reduce the falls and restraints.

Conceptual Framework

While there are many theories for the mechanisms on how delirium develops and evolves most ideas concentrate on changes or disruptions in brain chemistry, function, or

structure. The basic pathoetiologic model of delirium[41] illustrates how critical illness triggers neuro-chemical changes in central cholinergic transmissions affecting sleep, arousal, memory, and attention. In this delirium model, a patient experiences stress in the form of critical illness or major surgery, and neuro-chemicals, particularly acetylcholine, dopamine and norepinephrine, are released in the brain. The areas of the brain thought to be most adversely affected are the hypothalamic-pituitary-adrenal complex (HPA).[42] Researchers, operating on the evidence that normal aging brains decrease the synthesis of acetylcholine, and have reduced cerebral oxidative metabolism over time, place the elderly at higher risk for developing delirium in the ICU. Combining normal stress response with predisposing factors such as cognitive impairment or dementia, and the precipitating factor of sleep deprivation, the model predicts delirium is more likely to develop. See figure 1.

Significance to Nursing

The problem with performing routine tests during the night is the interruption of sleep occurs during the most vulnerable time when the circadian rhythm drops to the lowest point.[43,44] Humans are diurnal and inherently require sleep at night. ICU patients already have their sleep disturbed by *necessary* interruptions such as medications, frequent neurologic checks, endotracheal suctioning, and turning. Noise from alarms, bright lights, and staff communication is another source of sleep disturbance. Nurses are challenged to design plans of care that reduce routine interruptions during the time the human brain is most driven to sleep.

Delirium and Sleep Interruptions

Figure 1. Model of allostatic load and delirium in hospitalized elderly
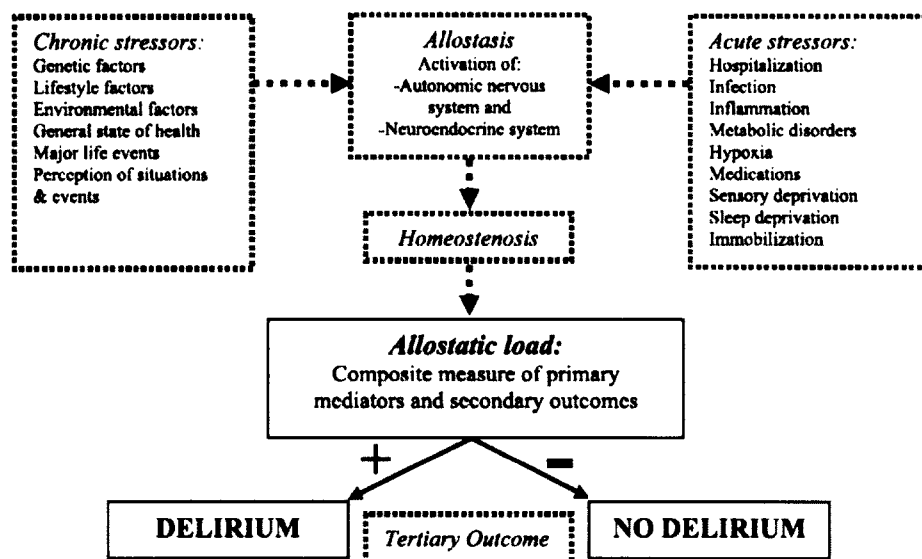
Reprinted with permission from Rigney T. Allostatic load and delirium in the hospitalized older adult. Nurs Res. Sep-Oct 2010;59(5):322-330.

Methods

This study sought to: (1) identify whether delirium in critically ill patients can be predicted from the knowledge of an individual's risk factors (age, gender, exposure to offending pharmacologic agents, night-time interruptions (laboratory tests and diagnostics), and (2) examine the relationships in the use of physical restraint, incidence of falls, and delirium in critically ill patients in the ICU.

Research Design

A descriptive correlational cross-sectional design using pre-collected data was used to identify relationships between independent risk variables and delirium in a sample of cardiovascular surgical ICU patients.

Delirium and Sleep Interruptions

Based on review of the literature, assumptions were made linking sleep deprivation to cognitive changes, but little is known about the association to delirium. Previous studies have established delirium as a serious health problem associated with poor patient outcomes. Others have suggested the harmful health effects of sleep deprivation. Additionally, the literature reflects, both restraints and falls have been associated with acute confusion in hospitalized patients but the association with delirium in critically ill patients has not been made. It was proposed that interruptions to sleep, especially during the night, lead to sleep deprivation and a greater incidence of delirium. It was also proposed when patients develop delirium; they had a greater chance of falling or being physically restrained. This study examined whether the frequency of interruptions from routine hospital processes, such as laboratory tests and diagnostics, positively correlated with the incidence of delirium in ICU patients. Whether there was a relationship between the incidence of delirium and the likelihood of patients falling or being physically restrained was also studied.

Selection and Description of Participants

Protection for Human Subjects was obtained through the Institutional Review Board per the protocols of the University of San Diego and hospital institutional review board (IRB) committees. There were no specific risks or benefits for the patient participants in the study, as this was a secondary analysis of data. No patients directly participated and data was de-identified for specific patients in the database. Benefit to future patients was the identification of process improvement which could result in positive patient outcomes.

Delirium and Sleep Interruptions

Data was abstracted from an existing data base of patients, enrolled in a larger

study from January 2011 through March 2011, receiving care from two large hospitals

that are part of a five facility health care system located in Southern California. Inclusion

criteria: adult patients 18 years of age or older; receiving ICU care in

cardiovascular/surgical units following coronary revascularization, or valve surgery.

Hospital A is a 332 bed not for profit community hospital with three adult ICU's:

a cardiovascular surgery, trauma/surgical, and medical units. All study patients stayed in

the 12 bed cardiovascular surgery unit. Hospital A has Magnet designation, level II

trauma, and a Joint Commission stroke center certification. Hospital B is an academic

teaching facility with approximately 700 licensed beds situated on two campuses, one

urban and the other community. The urban site has 32 ICU beds consisting of medical,

surgical, cardiac, and trauma patients; twelve beds are designated cardiovascular surgery.

Hospital B performed a number of the cardiac surgery cases using a minimally invasive

robotic system, while hospital A began using the minimally invasive techniques after the

time period of this study.

Technical Information

Operational definitions.

Delirium: Any positive screen using the Confusion Assessment Method for ICU (CAM-ICU) any day of hospitalization

Sleep disruption: Any event that woke up or partially woke up a patient by verbal or tactile stimuli

Hospital Process: Any process driven by hospital personnel/policy/procedure that was performed at scheduled routine intervals

Laboratory test: The drawing of blood from a patient either by finger stick, venipuncture, an intravenous, or intra-arterial catheter. Definition includes other types of bodily fluid sampling that disturbs the patient.

Diagnostic test: Any radiologic study (x-ray, CT scan, MRI), ultrasound (transthoracic echocardiogram, venous doppler), and EKG.

Restraint use: Any documented episode of physical restraints (soft wrist or ankle, mittens, roll belt, or soft splint) applied to a patient in order to restrict movement.

Fall: Any witnessed or un-witnessed descent to the floor, with or without injury

Data collection instruments/measures.

The Confusion Assessment Method for ICU (CAM-ICU)[45] was the instrument used for delirium diagnosis. The CAM-ICU is an instrument adapted for use on patients who are non-verbal or unable to speak because of tracheostomies or endotracheal tubes. The confusion assessment method (CAM) was originally developed by Inouye et al[46] for use in the geriatric population for evaluation of delirium by non-psychiatrists. It was adapted by Ely and associates[45] for use in the non-verbal mechanically ventilated patient. The CAM and CAM-ICU assess four aspects of delirium, (1) an acute onset of mental status changes or a fluctuating course, (2) inattention, (3) disorganized thinking, and (4) a level of consciousness that is anything other than alert and calm. The CAM-ICU has an interrator reliability ranging between a kappa of 0.79-0.95 ($p < .0001$), a sensitivity of 95-100%, and a specificity of 89-93%.

In the CAM-ICU validation study, patients were screened for delirium daily by three researchers, two nurses and one physician. Their assessments were done at difference times and blinded from each other's assessments. Thirty-eight mechanically and non-mechanically ventilated patients were included in the analysis. Excluded from

the sample were any patients with a history of severe dementia, neurologic disease, or

underlying psychoses. Results of the study showed 87% of the 38 patients developed

delirium.[5]

Parent Study

Prior to data collection, all nurses received a two hour training session in the late

summer/early fall of 2010 on how to use the CAM-ICU to conduct a delirium screen. In

October of 2010, nurses began screening patients each shift using the CAM-ICU. The

first screening question "has there been an acute onset of a mental status change or any

change from the patient's pre-hospital baseline". Because delirium can fluctuate, the

screen asks the clinician to assess if the patient is at their mental status baseline currently

and have they been there for the past 24 hours. If the answer is no, this represents a

positive screen for this attribute. The second screen is for inattention. The clinician tells

the patient they are going to say a series of ten letters and asks the patient to squeeze their

hand only when they hear the letter A. The clinician spells out S-A-V-E-A- H-A-A-R-T.

(Two A's in haart are intentional to provide adequate A's for a response). If the patient

misses squeezing on an A or squeezes on a non-A, a point is subtracted from the total of

ten. The patient must perform this test not missing more than two to test negative for this

attribute. The next attribute tests for disorganized thinking. A series of four yes/no

questions and commands are given. The total points possible are five (four points for

each question and one point for the command). The patient must get at least 4 points to

test negative for this feature. The final screen is for altered level of consciousness. The

Richmond Agitation and Sedation Scale[47] is used to evaluate this feature.

Delirium and Sleep Interruptions

The CAM-ICU was utilized by the primary nurse to screen patients twice a day for delirium (once on the day shift and once on the night shift) and as needed (PRN) throughout the day. The results, either positive for delirium or negative, or unable to assess due to coma (RASS -3 or -4) were recorded on the ICU nurse's flow sheet.

Fall data was abstracted using occurrence reports completed by staff at the time of the fall. Although this required self- report by the healthcare team, the practice of reporting falls is culturally ingrained.

Restraint use was abstracted from electronic documentation. Nursing staff are required to document a minimum of every two hours on a patient in restraints. Documentation includes the amount of time the patient was restrained during the prior two hours, including the behavior that warranted restraint application, type of restraint being used, and any alternatives the nurses attempted to keep the restraints off.

Data Collection Procedures

A case/record abstraction tool was developed to guide the gathering of information from each participant's medical record. Data from patients who underwent a cardiovascular surgical operation were abstracted retrospectively from an existing data base of 472 patients admitted to ICU from January 2011-March 2011. Patients were included if they'd had coronary bypass grafting, valve replacement, or both, and stayed in ICU at least one day. Patients undergoing any other type of cardiac operation (e.g. aortic dissection, repair of septal defect), or the inability to be assessed using the CAM-ICU due to coma (RASS -4 or -5) were excluded from the study.

Delirium and Sleep Interruptions

Frequency of night-time interruptions from routine laboratory, radiology, and other diagnostic tests were recorded from 10:00 pm to 5:59 am each night while in ICU. These types of interruptions were time-stamped in the electronic record. Events were categorized by type of interruption and the hour when the patient was awakened. Interruptions from all other nursing or medical activities were not collected due to these activities still being recorded on paper at the time of data abstraction, therefore not obtainable electronically.

Results

Results are organized first by presenting the demographic data of the study sample. Next, the results of the analysis on patient's delirium screening exams and the frequency of night-time interruptions will be presented. No falls were reported in the sample during the study time period and too few patients were restrained to perform a statistical analysis. Lastly, risk factors for delirium were analyzed for differences among patients who screened positive for delirium, negative, or were never assessed while in ICU.

A total of 76 patients met inclusion criteria. See table 1. There were more male patients than female, and the sample was nearly equal for primary diagnosis of coronary artery disease versus valvular disease. The mean age was 67 (SD=10.5) and 30% of the sample was Medicare funded. Medicare status was included in the analysis due to proposed reductions in Medicare reimbursement and bundled payments necessitating quality improvement measures to reduce length of stay and cost of care after discharge. No patients had any documented pre-existing cognitive impairments. All sample patients

were on mechanical ventilation for at least 1 day with ventilator days ranging from 1-16

days (mean=2.1, SD=2.8). The majority (70%) were discharged to home.

Delirium and Sleep Interruptions

Table 1

Demographics	N=76
Hospital A	44 (58%)
Hospital B	32 (42%)
Age	67 (SD= 10.5)
Gender	
Female	25 (32%)
Male	52 (68%)
Medicare Funded	25 (32%)
Primary diagnosis	
Valve disease	31 (40%)
CAD	30 (39%)
MI	13 (17%)
CAD +Valve disease	3 (4%)
Secondary diagnosis	
HTN	34 (44%)
Renal insufficiency	18 (23%)
Respiratory insufficiency	6 (8%)
Other	19 (25%)
Surgical procedure	
CABG	41 (53%)
Valve replacement	22 (29%)
CABG +Valve replacement	14 (18%)
ASA score	3.7 (SD=0.47)
Ventilator Days	2.1 (SD=2.8)
NIPPV	10 (13%)
Discharge disposition	
Home	54 (70%)
Skilled nursing facility	9 (12%)
Rehabilitation	2 (3%)
Other	12 (16%)

CAD=Coronary artery disease, MI= Myocardial infarction, HTN=Hypertension, CABG=Coronary artery bypass grafting

ASA= American Society of Anesthesiologist surgical risk score, NIPPV= Non-invasive positive pressure ventilation

Delirium and Sleep Interruptions

Of the 76 patients, 53 (70%) were assessed for delirium *at least* once during the ICU stay, and a positive or negative result from the CAM-ICU was recorded. The remaining 23 (30%) patients had no CAM-ICU result documented at *any* time during ICU admission. Six patients out of the 53 (6%) tested positive for delirium on at least one occasion. Duration of delirium (number of positive days) was not calculated. See table 2.

Table 2

CAM-ICU results	N=76
Positive for delirium	6 (8%)
Negative for delirium	47 (62%)
Not documented	23 (30%)

Note: No cases of coma were documented

Night-time interruption data is presented in figure 2. Patients in the study were awakened for laboratory tests, x-rays, and blood sugar checks a mean of 5.5 times each night between 10pm and 5am (SD= 1.8) while in ICU. Average ICU length of stay was 4.1 days (SD= 4.5) and most frequent interruptions occurred at 3am.

Delirium and Sleep Interruptions

Figure 2

Night-time Interruptions

mean interruptions 5.5/night SD= 1.8

Note: Interruptions recorded only from laboratory tests, blood sugar checks using point-of-care device, bedside radiology or other imaging exam, and EKGs
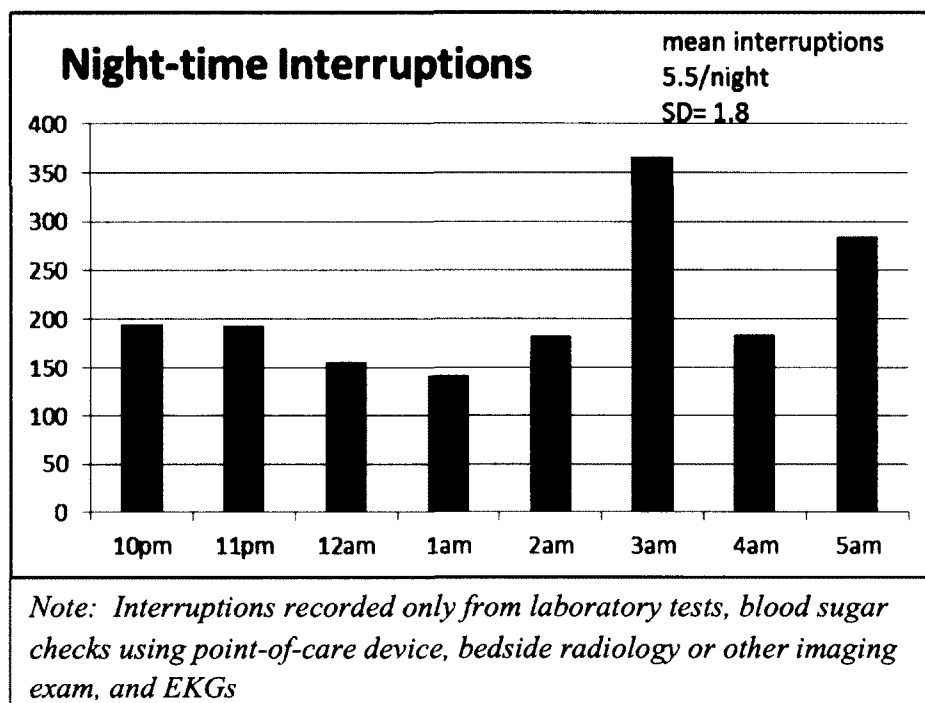
The first aim of the study was to discover if a relationship existed between night-time interruptions and delirium. A one way ANOVA indicated there were no differences in the frequency of interruptions and the 3 groups of patients [F (2, 73) = 0.311, p=0.733]. The second aim was to discover if a relationship existed between delirium and patients falling or being restrained. No falls were reported in the sample, and although 4 of 6 (67%) of the delirious patients were restrained compared to 3 of 47 (6%) in the non-delirious patients, and 3 of 23 (13%) in the patients who were never assessed, too few patients were restrained to perform a Chi Square analysis, which requires each category to have an expected count of greater than five. Two out of the six categories had less than the required number. See table 3.

Delirium and Sleep Interruptions

Table 3

Major Aims

Delirium Screen-CAM-ICU	n	night-time interruptions	Falls	# of Patients Restrained
Positive	6	5.6	0	4
Negative	47	5.6	0	3
Never assessed	23	5.2	0	3

Note: ANOVA CAM-ICU vs. night-time interruptions [F(2, 73)= 0.311, p=0.733]

The third aim of the study was to discover if delirium could be predicted from knowledge of patient risk factors. Again, due to the low number of positive delirium cases, a regression could not be performed. A one way ANOVA was used to study the differences among the 3 groups in relation to risk factors of age, sedative, and analgesic dosages; in addition, ventilator days, ICU, and hospital length of stay was also analyzed for differences. See table 4.

Delirium and Sleep Interruptions

Table 4

Sample Differences				
	n=47	n=6	n=23	
Variable	**Negative Delirium**	**Positive Delirium**	**Not documented**	*p* **value**
Age	67 (SD=11.5)	63 (SD= 10.7)	67 (SD=8.6)	0.715
Ventilator Days	1.7 (SD=2.1)	5.83 (SD=3.4)	1.9 (SD 3.3)	0.003
ICU length of stay	4.3 (SD=4.4)	9.7 (SD=4.9)	2.4 (SD= 3.4)	0.001
Hospital length of stay	11.2 (SD=7.3)	18.8 (SD=11.3)	7.5 (SD=5.1)	0.332
Medications Differences	**Negative Delirium**	**Positive Delirium**	**Not documented**	*p* **value**
Dexmedetomidine	35 (SD= 177)	0	0	0.342
Propofol	1240 (SD=17240	5561 (SD=4465)	1753 (SD= 5083)	0.000
Midazolam	0.40 SD=1.7)	35.5 (SD=80.7)	0.13 (SD= 0.46)	0.001
Morphine	22.9 (SD= 22.1)	47.5 (SD= 49.1)	25 (SD= 28)	0.176
Fentanyl	2.1 (SD=14.6)	1010 (SD=1899)	7.6 (SD=36.5)	0.000
Hydromorphone	6.0 (SD=33.7)	0	0.15 (SD= .481)	0.649
Hydrocodone	39.9 (SD=55.7)	51.7 (SD=38.0)	28.3 (SD=20.1)	0.459
Oxycodone	17.8 (SD= 24.2)	35.8 (SD=58.3)	1.3 (SD=4.5)	0.004

Patients who screened positive (POS) for delirium were significantly different

from the patients who screened negative (NEG), or were never assessed (NA) with

regards to time spent on the ventilator, dosages of particular sedatives and analgesics,

length of stay in the ICU and the hospital. Delirious patients received more milligrams of

propofol [POS-5562, (SD 4465) vs. NEG-1256, (SD= 1738) vs. NA- 1753, (SD=5083)],

midazolam [POS-35.5 (SD=80.7) vs. NEG-0.4mg (SD=1.7) vs. NA-0.13 (SD= 0.46)],

Delirium and Sleep Interruptions

fentanyl [POS-1010 (SD=1899) vs. NEG-2.1 (SD=14.6) vs. NA- 7.6 (SD=36.5)], and

oxycodone [POS-35.8 (SD=58.3) vs. NEG-17.7 (SD=24.2) vs. NA-1.3 (SD= 4.6)] than

patients without delirium or patients who were never tested. Delirious patients spent

longer time on the ventilator [POS-5.8 days (SD= 3.4) vs. NEG- 1.7 (SD=2.1) vs. NA-

1.9 (SD= 3.3)], in the ICU [POS- 9.7days (SD= 4.9) vs. NEG- 4.3 days (SD= 4.4) vs.

NA- 2.3 days (SD= 3.2)], and in the hospital overall [POS- 18.8 days (SD= 11.3) vs.

NEG- 11.2 days (SD= 7.3(vs. NA-7.5 days (SD=5.1)]. All 6 of the delirious patients had

an ASA score of 4 and the majority (4/6) had a valve replacement. There were no

differences in age, or amounts of dexmedatomidine, morphine, hydromorphone,

hydrocodone. Only one of the six delirious patients went to a skilled nursing facility,

4 went home, and the other was transferred to another acute care facility.

When looking at differences between hospital A and hospital B, an independent-

samples t test comparing the mean scores of night-time interruptions found a significant

difference in the frequency of interruptions (t (74) = 2.274, p= .026). Differences were

found between the percentages of the performance of the delirium assessment (Hospital

A-89% vs. Hospital B-44%) but not statistically significant [$x^2(1) = .301$, p= .583]. See

table 5.

Table 5

Site Comparisons		
	Hospital A	Hospital B
N	44	32
CAM-ICU positive	5	1
CAM-ICU negative	34	13
Assessment percent	89	44

Note: The difference in CAM-ICU positive vs. negative was not significant between hospitals, x2(1)= .301, p= .583

Discussion

The primary aim of the study was to examine the relationship between the frequency of interruptions and delirium. While the results tabulating the frequency of night-time interruptions show patients are awoken 5.5 times per night during a seven hour time interval, no significant difference was found between the frequency of interruptions and delirium. This sample of ICU patients was a homogenous group of patients undergoing the same procedures; therefore it is not surprising the frequency of interruptions showed no significance. Post-operative orders for these patients are standardized, and therefore orders for laboratory and diagnostic tests are performed at the same intervals. To find a relationship between these types of interruptions and delirium, future studies should control for the homogeneity of the sample in order to get a variety of interruptions.

The secondary aims were to examine the relationships between the patients who screened positive for delirium and restraints or falls. A greater percentage of delirious patients were restrained compared to the non-delirious or not-assessed patients. There

were no falls reported in the sample. Because only 70% of the patients were assessed for delirium at any time during their ICU stay and only 6 patients tested positive for delirium, finding any relationships was not feasible due to the lack of consistent assessment for delirium and small sample of positive patients. The sample also included patients with less than 3 days in ICU (35 out of 76, 46%). The lack of positive cases of delirium may have been due to the inclusion of patients staying only 1 or 2 days in ICU. Since delirium typically develops after a patient has been in ICU for several days, future studies should consider excluding patients staying less than 3 days in ICU.

A third aim of the study was to explore factors that increase the probability for delirium developing in ICU patients. The results were consistent with previous studies indicating that exposure to narcotics and sedatives, especially benzodiazepines, make delirium more likely.[48,49] Limiting exposure to sedatives through standardized-protocols to allow for more wakefulness and incorporating non-pharmacologic strategies has potential to reduce the incidence of delirium.

Restraints have also been associated with delirium but typically restraints are applied after the delirium develops as opposed to having a causal role.

These findings are of interest because previous studies indicate sleep duration is an important factor in the healing process and that sleep deprivation can lead to deleterious health effects. Analgesics and sedatives are also implicated in the risk for delirium. Delirium is under-recognized by the health care providers (references) and this study adds support to need to re-focus on making sure the screen is performed and an accurate assessment is made. Without an accurate diagnosis, treatments cannot be

implemented to eliminate precipitating factors and reduce the severity and duration of delirium.

The first core component of the nursing process is the assessment. Without an accurate assessment, how can nurses diagnose, plan, or evaluate care? All the nurses at the 2 hospital sites received education on the importance of monitoring for delirium, current evidence on negative consequences, and instruction on using the CAM-ICU. This study perhaps indicates initial educational objectives went unmet. Changing practice patterns is frequently a challenge. Many nurses find it difficult to alter their assessment routines, and incorporate new or different ways of evaluating patients. Perhaps nurses found the assessment difficult to use, or did not immediately see the value in performing and documenting the assessment. A qualitative component may have answered some of these questions.

Advance practice nurses at both sites recognized that delirium monitoring was inconsistent. During the spring of 2011, following the period of this study, bedside reinforcement and re-validation of educational principles was performed.

Strengths and Limitations of Methods

These findings must be interpreted in the light there are several limitations to this study: the short ICU length of stay, and using existing CAM-ICU data assessments. First, patients undergoing uncomplicated cardiovascular surgery usually only warrant an overnight stay in ICU. Delirium typically does not appear until day 2 or 3 in ICU.

Severity of illness scores were not calculated making it difficult to know whether there were differences in how critically ill the patients were.

Second, although conducting a study using pre-collected data reduced the subjectivity of interruptions due to laboratory and diagnostic testing because these are *time stamped, and a*ccurate data was obtained rapidly without depending on manual recording of interruptions, the results of CAM-ICU assessments were incomplete and possibly inaccurate. Nonetheless, a homogenous group of cardiovascular surgical patients, although well studied but not on this particular focus, was included with less potential for the influence of confounding variables.

Notably, the results of this study add to the body of knowledge implicating sedatives and analgesics in the development of delirium, and patients requiring mechanical ventilation are at particularly higher risk. Once delirium develops, restraints are used to prevent the patient from harming themselves or others. While no relationship could be demonstrated between the frequency of interruptions and delirium, the number of interruptions per night is disturbing, especially when this represents consecutive nights of interrupted sleep. Given the detrimental health outcomes from sleep deprivation studies on healthy volunteers, these results should prompt further investigation on the effects of sleep deprivation in the critically ill.

Conclusion

Delirium in the ICU represents a significant health hazard with negative outcomes. Sleep deprivation also presents detriments to health. Both need to be

addressed by ICU clinicians in order to reduce the prevalence of delirium and promote

un-interrupted periods of rest and sleep, especially for stays longer than 2 or 3 days.

Many of the interventions and monitoring performed in intensive care units is necessary

to insure timely interventions, reduce complications, and preserve function. Re-

examining the necessity, timing, and frequency of routine hospital laboratory tests, and

other diagnostics is warranted. However, this study seems to indicate that frequency of

sleep interruptions from laboratory and diagnostic tests is not a risk factor for delirium for

stays of 1 or 2 days.

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Appendix B

Frequency of interruptions per hour

MR#								
Time :00-00:59	10:00 PM	11:00 PM	12:00 AM	1:00 AM	2:00 AM	3:00 AM	4:00 AM	5:00 AM
Laboratory test								
Finger stick BG								
Portable xray								
CT scan								
Ultrasound								
MRI								
other								

Appendix C

IRB Approvals

Scripps

Office for the Protection of Research Subjects

WAIVER OF AUTHORIZATION

April 16, 2011

Principal Investigator or Project Manager:	Amy R Stuck, RN, PhDc
Department:	Scripps Health- Division of Critical Care
Title of Project:	Relationship between Delirium and Night-time Interruptions in ICU
IRB Protocol Number:	IRB-11-5708

The **IRB**, in its capacity as a **Privacy Board**, has determined that the project described above may use or disclose protected health information. The conditions for waiving the need to obtain individual authorization have been reviewed and determined to meet the regulations described in 45 CFR 46.614.512.

It is the responsibility of the Principal Investigator or Project Manager to keep records of how protected health information for an individual has been used and disclosed. You must limit your use of protected health information to the "minimum necessary" to achieve your research purpose.

Documentation of the Waiver will be maintained in the Scripps Office for the Protection of Research Subjects for at least six (6) years.

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Signature applied by Robert Lamar Bjork Jr on 04/16/2011 11:54:49 PM PDT

IRB Officer

Scripps

Scripps IRB

Office for the Protection of Research Subjects

11025 North Torrey Pines Road
Suite 200
La Jolla, CA 92037

Approval Notice

Investigator: Amy R Stuck, RN, PhDc

Department: Scripps Memorial La Jolla - Division of Critical Care

Approved
Research Sites: Scripps Memorial Hospital La Jolla, Scripps Mercy Hospital San Diego

Project Title: Relationship between Delirium and Night-time Interruptions in ICU

Protocol No: IRB-11-5708

Risk Category: Minimal

Type of Review: Expedited – NEW

Your research project indicated above was reviewed and approved by an IRB officer on the review date stamped below. Approval expires *12 months* from this date.

Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form (if applicable) without prior IRB approval.

The IRB may suspend or terminate the approval of research that is not conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.

Thank you for your cooperation.

(Retrospective chart review only)

signature

Signature applied by Robert Lamar Bjork Jr on 04/16/2011 11:54:49 PM PDT

IRB Officer

Scripps

Scripps IRB

Office for the Protection of Research Subjects

11025 North Torrey Pines Road
Suite 200
La Jolla, CA 92037

Approval Notice (Modification)

Investigator: Amy R Stuck, RN, PhDc

Department: Critical Care

Approved
Research Sites: Scripps Memorial Hospital La Jolla, Scripps Mercy Hospital San Diego and Scripps
Memorial Hospital Encinitas

Project Title: Relationship between Delirium and Night-time Interruptions in ICU

Protocol No: IRB-11-5708

Risk Category: Minimal

Type of Review: Expedited

The modification to the protocol above was reviewed and approved by an IRB Officer. This modification
does not extend the expiration date of the protocol's last IRB review.

(Approved to add Delirium Prevalence Performance Improvement data on 472 patients including patients
from Scripps Encinitas)

Signature applied by Barbara G Bigby on 02/10/2012 03:01:00 PM PST

IRB Officer