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The Respiratory Distress Observation Scale (RDOS), Pain, and Agitation

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Dissertation Abstract

The Respiratory Distress Observation Scale (RDOS) is relatively new and has not been extensively evaluated. The purpose of this study was to, a) explore the incidence and severity of respiratory distress in the cognitively impaired adult patient on mechanical ventilation, b) examine the relationships between respiratory distress, pain, and agitation in that same population, and c) compare the differences in RDOS scoring results at a 1 minute versus a 3 minute observation period. This study had Institutional Review Board approval and took place in a large metropolitan medical intensive care unit. Our subjects consisted of 148 cognitively impaired adults on mechanical ventilation.

Our team found that 26% of our subjects experienced respiratory distress for over 5 hours aggregate per day. Patients on mechanical ventilation experience dyspnea even if cognitively impaired. The RDOS slightly correlated with pain as measured by the Critical-Care Pain Observation Tool (CPOT) score (r_s = .15, p = .02). However, restlessness as measured by the Richmond Agitation and Sedation Scale (RASS) as compared to the RDOS score showed differentiation (r_s = -.02, p = .76).

Finally, our findings indicate that 1 minute of observation was as good as 3 minutes in terms of obtaining a score on the RDOS [$r_s(57)$ = .78, p < .001]. This result has practical implications for use and research with this scale since direct care clinicians are more likely to utilize a scale that takes less time.

Our findings recommend further testing of the RDOS in the critical care population. Due to the limited amount of research on respiratory distress in the cognitively impaired patient prior to this research, this manuscript contributes to the body of knowledge on the clinical state of cognitively impaired adults on mechanical ventilation.

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The Respiratory Distress Observation Scale (RDOS), the Critical-Care Pain Observation Tool (CPOT), and the Richmond Agitation and Sedation Scale (RASS) were utilized in this research with permission from the authors.

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Introduction

Every year in the United States, over 5 million hospitalized patients are admitted to an intensive care unit (ICU). The average length of stay is 6-9 days. They are admitted primarily for life support that may include mechanical ventilation (Society of Critical Care Medicine [SOCCM], 2012). In a 2009 multinational cohort study of more than 13,000 adult patients by Metnitz et al., over 53% of patients were mechanically ventilated on admission to a critical care unit. This data is supported by an epidemiological study in 2010 examining over 6 million hospitalized patients in six states. That study found that mechanical ventilation was associated with mortality and significant disability (Wunsch, Linde-Zwirble, Angus, Hartman, Milbrandt, & Kahn, 2010). Future projections show increasing numbers of patients receiving mechanical ventilation in hospitals (Carson, Cox, Holmes, Howard, & Carey, 2006).

The two most common symptoms experienced by all hospitalized patients are shortness of breath /dyspnea, and pain (Banzett, Pedersen, Schwartzstein, & Lansing, 2008). Dyspnea is defined by a number of distinct qualitative symptoms and sensations caused by physiological, psychological, or neuromuscular origins (Banzett et al., 2008: Nishino, 2011: Parshall et al., 2012: Dudgeon & Shadd, 2012). Of all patients admitted to hospitals, 50% have dyspnea (Parshall et al., 2012). Dyspnea in the mechanically ventilated critical care patient has been recognized as an area that has little research {Schmidt, et al., 2014}.

Mechanical ventilation is associated with symptom burden and increased costs (Carson et al., 2006). After an ICU stay including mechanical ventilation,

mortality and morbidity after discharge has a higher probability among patients that have chronic illness, who are elderly, and among patients that have had or who have multiple organ failure (Fischer, Gozansky, Sauaia, Min, & Kutner, 2006: Carson et al., 2006: Wunsch et al, 2010: Ebell & Alfonso, 2011).

Statement of the Problem

The consequences of patients suffering with dyspnea while being mechanically ventilated are serious. In 2011 Schmidt et al. researched dyspnea with mechanical ventilation. Their study found that dyspnea was associated with anxiety and delayed ventilator weaning. Qualitative studies with patients have also shown that dyspnea has been found to be to be one of a number of distressing symptoms experienced during an ICU stay while on mechanical ventilation (Nelson et al., 2001: Li & Puntillo, 2006: Schmidt et al., 2014). Studies on this experience or perception of respiratory distress symptoms have difficulty with quantifying the experience (Bausewein, Farquhar, Booth, Gysels, & Higginson, 2007). One of the difficulties is that dyspnea is associated with up to 20 different sensations from up to 16 different origins (Banzett et al., 2008: Parshall et al., 2012).

Historically most of the studies on the experience of dyspnea have been on patients who could communicate a level of distress in some way (Mularski et al., 2010). Some studies have even induced dyspnea in healthy volunteers in order to discover the mechanism of dyspnea and/or the experience (Banzett et al., 2008). As a result up to 40 dyspnea scales are available for cognitively intact adults to describe their symptoms (Bausewein et al., 2007: Mularski et al., 2010: Parshall et al., 2012).

In 2008 Dr. Margaret Campbell and her team from the Center for Health Research in Michigan completed work in the area of assessing dyspnea on the cognitively impaired patient. The Respiratory Distress Observation Scale (RDOS) was created (Campbell, 2008).

This scale is relatively new and has not been extensively evaluated. The scale was then modified in 2010 by the addition of a paradoxical breathing measurement (Campbell, Templin, & Walch, 2010). The differentiation between respiratory distress as defined by the RDOS, pain, and anxiety has not yet been studied.

Purpose

The overall purpose of this study is to explore the incidence and severity of respiratory distress and the relationships between respiratory distress, pain, and agitation in the cognitively impaired adult patient on mechanical ventilation. In addition, reliability testing of the RDOS will be examined by comparing differences in RDOS scoring results at a 1 minute versus 3 minute observation period.

Research Questions

The research questions this study will answer are:

1. What is the incidence and severity of respiratory distress as measured by the RDOS in the cognitively impaired adult patient on mechanical ventilation?

2. What are the relationships between respiratory distress as measured by the Respiratory Distress Observation Scale (RDOS), pain, and agitation in cognitivel impaired adult patients on mechanical ventilation?

3. What is the difference between scoring results from the RDOS at 1 minute versus 3 minutes when evaluating the cognitively impaired adult patient on mechanical ventilation?

Specific Aims

The specific aims of this study are to:

1. Explore the incidence and severity of respiratory distress in the cognitivel impaired adult patient on mechanical ventilation.

2. Examine the relationships between respiratory distress, pain, and agitation in cognitively impaired adult patients on mechanical ventilation.

3. Compare the differences in scoring results on the RDOS at 1 minute versus 3 minutes when evaluating the cognitively impaired adult patient on mechanical ventilation.

Background and Significance

Patients may be suffering from dyspnea and unable to report their distress. In critical care from 27 to 59% of patients are sedated, comatose, or delirious (Sessler et al., 2002: White et al., 2007). Delirium is an independent predictor for mortality within 6 months as well (Ely et al., 2004). A delirious, sedated, or comatose patient cannot tell clinicians what symptoms bother them the most. In this population, even after discharge, symptoms of confusion, dementia, or delirium may linger for some time (Ely et al., 2004). Thus, it is difficult to directly ask this population of patients what they are experiencing during their critical care stay while on mechanical ventilation.

Researchers have found, in the setting of critical care, palliation of symptoms with full treatment can be cost effective (Smith & Cassel, 2009: O'Mahony et al., 2010). Many believe that full treatment goals of critical care are incompatible with providing palliative care (Smith & Cassel, 2009). Palliative care however, can be compatible with life support therapies such as mechanical ventilation due to the association of mechanical ventilation with patient discomfort. (Payen, Bosson,

Chanques, Mantz, & Labarere, 2009: Schmidt et al., 2011: Schmidt et al,. 2014) In a 2007 study, high-risk patients in the medical ICU who received concurrent palliative care "had significantly shorter lengths of stay… (8.96 vs. 16.28 days, p = .0001)" (Norton et al., 2007). In 2014, in a review of literature by Puntillo et al., it was found that favorable critical care outcomes are linked to control of distressing symptoms such as dyspnea.

Dyspnea has been found to be under-recognized and under-treated (Schmidt et al., 2014). In a study by Puntillo et al. in 2010 only 34% of their 171 subjects on mechanical ventilation were able to express their discomfort while 27% were delirious. Thus, one can conclude that some patients may be suffering from dyspnea while they are cognitively impaired.

Another aspect in the examination of respiratory distress concerns mechanically ventilated patients for whom physicians have deemed as having a "poor prognosis" or for whom care is documented as "medically futile." The relief of pain, dyspnea, and thirst have been deemed as necessary for quality end of life care (Puntillo et al., 2014). Since the mortality of a critical care stay with mechanical ventilation can be greater than 30 percent in the elderly (Schmidt et al, 2014), it is likely that these patients may suffer from respiratory distress during their terminal hospital stay. If so, respiratory distress in a potentially terminal ICU stay would be contrary to generally accepted palliative care goals (Mularski, et al., 2009: U.S.DHH, CDC, NCHS, 2011*:* Puntillo et al., 2014).

The question remains on how to separate the determination of dyspnea from other symptoms of distress and how to obtain information about dyspnea from

those that are cognitively impaired. What we do know from adult patients, is that the subjective experience and objective markers for pain and dyspnea have similarities (Banzett, Gracely, & Lansing, 2007). The sensation of dyspnea in the mechanically ventilated patient has multiple and inter-related causes including the sensation of discomfort and pain (Schmidt et al., 2014).

Pain like dyspnea, is a subjective experience (Schwartzstein, 2012: Puntillo et al., 2014). Both pain and dyspnea are transmitted via nervous system pathways that may or may not relate to an impending threat to the individual (Gracely et al., 2007: Herigstad, Hayen, Wiech, & Pattinson, 2011: Schwartzstein, 2012).

Pain has been very well studied since the 1970 (Gracely, Undem, & Banzett, 2007). Pain, has been studied and evaluated with validated observational scales on the cognitively impaired (Stites, 2013: Puntillo et al., 2014). Critical care observational pain scales use behavioral and/or physiological signs to obtain a conclusion about level of discomfort (AACN, 2013: Stites, 2013). According to Pudas-Tähkä et al., only a few are reliable enough for day-to-day clinical practice (2009). Examples include an observational pain scale utilized with cognitively impaired ICU patients called the Critical-Care Pain Observation Tool (CPOT) created by Gélinas et al in 2004 (Gélinas et al., 2004). This tool utilizes facial expression, restlessness, and ventilator compliance among other things in order to evaluate levels of pain (Gélinas et al, 2004). Another scale, the adult non-verbal pain scale (NVPS) includes restlessness, blood pressure, heart rate, ventilator compliance, and respiratory rate as a means to rate pain in the non-verbal adult (Odhner, Wegman, Freeland, Steinmetz, & Ingersoll, 2003). These scales measure items such as

restlessness and vital signs. Those factors may co-exist with other signs of distress such as agitation/anxiety and shortness of breath.

The study of critical care patient distress is complicated because many patients in intensive care units have pain management and sedation medications that infuse intravenously on a continuous basis (Payen et al., 2007: Puntillo et al., 2014). Optimizing continuous medications with a validated, reliable, and structured method of titration, was the underlying focus for agitation or restlessness scale design (ACCM, SCCM, & ASHP, 2002: Jacobi et al., 2002). Scales on agitation such as the observational Richmond Agitation and Sedation Scale (RASS) (Sessler et al., 2002) or other observational scales for the cognitively impaired have not identified respiratory distress or dyspnea as a separate symptom either (Mularski et al, 2010: Schmidt et al., 2014: Puntillo et al., 2014).

The Respiratory Distress Observation Scale (RDOS) was tested and validated via psychometric testing (Campbell, 2008: Campbell et al., 2010). According to a literature review as of January of 2015, it has been tested and used with very few researchers. These groups have done testing on this scale on either cognitively intact patients or in a non-critical care setting. The RDOS however, is cited in numerous peer reviewed articles including The American Thoracic Society statement on dyspnea and the Improving Palliative Care in the ICU (IPAL) Advisory Board statement (Parshall et al, 2012: Puntillo et al, 2014). Due to preliminary research on cognitively impaired critical care patients experiencing respiratory distress by Dr. Campbell in 2007, it is an appropriate instrument to assess for the prevalence of dyspnea in the sedated or cognitively impaired mechanically

ventilated ICU population (Campbell, 2008: Campbell et al, 2010).

This dissertation will contain 3 manuscripts that will address the three research aims stated previously. Utilizing the RDOS, the first manuscript will describe the incidence and severity of respiratory distress in the cognitively impaired adult critical care patient on mechanical ventilation. Extensive description of our study subjects and characteristics will be included.

The second manuscript will be on the indicator of respiratory distress or dyspnea as measured by the RDOS and the differences between respiratory distress, pain, and agitation in our study population. Our study examines the RDOS and its discriminatory validity as compared to pain and agitation in patients who are unable to communicate their needs.

Finally the third manuscript will address the 3 minute observation time period utilized in the initial psychometric studies which created the RDOS. Previous research on the RDOS included RDOS measurements taken over a 3 minute time period (Campbell, 2008: Campbell et al, 2010). On busy nursing units, it is unlikely that a 3 minute observation period would be utilized by staff nurses.

Currently, there are no other published instruments that can objectively evaluate respiratory distress in the cognitively impaired adult (Parshall et al., 2012: Schmidt, et al, 2014: Puntillo et al., 2014). Thus, a more complete exploration of respiratory distress in this population and the reliability of the RDOS is the next step in knowledge development in this area.

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The incidence and severity of respiratory distress according to the Respiratory Distress Observation Scale (RDOS) in critical care

Abstract

The Respiratory Distress Observation Scale (RDOS) was tested and validated via psychometric testing. However, in spite of its favorable reviews, there is a need for further evaluation of this scale and its use. The purpose of this study was to explore the incidence and severity of respiratory distress utilizing the RDOS in the cognitively impaired medical intensive care adult patient on mechanical ventilation.

This study was a non-experimental descriptive observational study with concurrent and retrospective medical record review. The study took place in a metropolitan medical intensive care unit. Subjects were 141 cognitively impaired subjects on mechanical ventilation that were observed for a total of 309 times throughout the day and night. Multiple diagnoses and problems were noted for our subjects. After excluding resolved problems and eliminating redundancies, our progress notes showed 78% or 116 subjects with 6 or more diagnoses or problems. Of the 141, 26% of the subjects had respiratory distress as measured by a threshold of 3 or higher on the RDOS in at least one observation period.

The medical intensive care patient population is complex. These results cannot be generalized to a surgical or trauma intensive care population. Approximately one in four cognitively impaired adults in our sample met the threshold for respiratory distress. Even if one disagrees with the total amount of time of distress, based on our observations, there were signs of unrelieved respiratory discomfort in the cognitively impaired adult on mechanical ventilation.

Introduction

Overall, in the United States, 1 in 5 Americans die during hospitalization involving ICU with an average ICU length of stay of 12 days (Angus et al, 2004). Of those that are 65 or older, 35.3% die in an acute care hospital as an inpatient (U.S. Department of Health and Human Services [U.S.DHH], CDC, National Center for Health Statistics [NCHS], 2011).

Consensus panels of experts on palliative care in the ICU setting have determined quality indicators for end-of-life care in the ICU. Many are based on qualitative studies with dying cancer and hospice patients who are able to communicate their wishes (Lorenz, Rosenfeld, & Wenger, 2007: Mularski, et al., 2009: U.S.DHH, CDC, NCHS, 2011). Since end-of-life dyspnea is a quality indicator that has not been extensively studied in the ICU population (Campbell, Templin, & Walch, 2010: Schmidt et al., 2014), there is a need for further research in this area (Puntillo et al., 2014).

As healthcare clinicians our goal is to alleviate suffering. There is evidence to support that being a patient in the ICU on mechanical ventilation is associated with significant discomfort and dyspnea (Li & Puntillo, 2006: Schmidt et al., 2011: Schmidt et al., 2014). In addition, due to the nature of an illness or injury that requires ICU monitoring and care, many of these patients will die (Puntillo et al., 2010: Campbell, 2012).

To illustrate the potential end of life issue in hospitals, 35.3% of those 65 or older die in an acute care hospital as an inpatient (U.S.DHH, CDC, NCHS, 2011). Since 50% of patients admitted to hospitals have dyspnea, the conclusion can be drawn

that any particular ICU hospitalization could include a terminal stay that may include discomfort and distress (Campbell, 2012: Parshall, Schwartzstein, et al., 2012: Puntillo, Smith, Arai, & Stotts, 2014).

The Respiratory Distress Observation Scale (RDOS) was tested and validated via psychometric testing (Campbell et al., 2010: Campbell, 2008). According to a literature review as of January of 2015, it has only been rigorously studied with three groups of researchers. These groups have done testing on this scale on either cognitively intact patients, or in a non-critical care setting. The Respiratory Distress Observation Scale (RDOS) however, is cited in numerous peer reviewed articles including The American Thoracic Society statement on dyspnea and the Improving Palliative Care in the ICU (IPAL) Advisory Board statement (Parshall et al, 2012: Puntillo et al, 2014). Review of the literature concludes that respiratory distress in the cognitively impaired ICU adult has not been adequately researched (Schmidt et al., 2014).

In the last 10 years however, research on cognitively impaired critical care patients experiencing respiratory distress was begun by Dr. Campbell starting in 2006, The RDOS was developed. It has been identified as an appropriate instrument to assess for the prevalence of dyspnea in the sedated or cognitively impaired mechanically ventilated ICU population (Campbell et al, 2010: Campbell, 2008a). The purpose of this study was to explore the incidence and severity of respiratory distress in the cognitively impaired medical intensive care adult patient on mechanical ventilation.

Background and Significance

There is evidence to support that being a patient in the ICU on mechanical ventilation is associated with significant discomfort and dyspnea (Li & Puntillo, 2006: Puntillo et al., 2010: Schmidt et al., 2011: Schmidt, et al., 2014). Dyspnea is associated with autonomic behaviors such as increased respiratory rate, increased heart rate, and accessory muscle use (Campbell, 2007: Campbell, 2008a: Parshall et al., 2012). Dyspnea and pain are the two most common symptoms experienced by patients (Banzett, Pedersen, Schwartzstein, & Lansing, 2008). In 2011 Schmidt et al. found that patients on mechanical ventilation with dyspnea have longer ICU stays than patients with less dyspnea. They also found that dyspnea was associated with anxiety and delayed ventilator weaning (2011).

Puntillo et al. (2010) found that for 34% of critical care patients, dyspnea was the most distressing symptom. In addition, when assessing this population of patients about their symptoms, only 10% had the ability to answer all the questions in that study. Schmidt et al. in 2011 found 46% of alert mechanically ventilated patients had substantial dyspnea with sensations of air hunger and increased work of breathing (2011). However, in prior studies, observations for dyspnea or distress took place during the daytime and usually during ventilator weaning times in the morning (Campbell, 2006: Li & Puntillo, 2006: Schimdt et al., 2011). At this point, it is unknown how much respiratory distress may be experienced by our population at times such as in the middle of the night.

Patients in critical care can be sedated, neurologically damaged, or otherwise mentally impaired due to their level of illness. These patients, whether they suffer

from a neurological injury, or are subject to sedation, are cognitively impaired as a result. In fact, in critical care from 27 to 59% of patients are sedated, comatose, or delirious (Ely et al, 2004: White et al, 2007). For the patient on mechanical ventilation in critical care, use of protocol driven assessments and scales as a means to evaluate pain, agitation, and need for sedation leads to improved outcomes (Skrobik et al, 2010: Schmidt et al. 2011).

Some patients may be suffering from dyspnea and unable to report their distress. These patients cannot communicate clearly what they are experiencing while on mechanical ventilation. In a neuroimaging study on pain and dyspnea by Nishino in 2011, results suggest that neural structures for dyspnea and pain might be shared (Nishino, 2011). If a patient is experiencing respiratory distress, they are likely to be having the subjective experience of dyspnea. From an exploratory study in 2007, Campbell found that the autonomic experience of asphyxia could lead to behaviors that could be observed in cognitively impaired patients (Campbell, 2007). After that study, in 2009 Campbell and Walch found that over 50% of patients near death were unable to respond to a yes/no question about dyspnea (2009).

Since many previous studies have excluded patients on mechanical ventilation that are functionally unable to communicate, and since many studies have found that critical care patients on mechanical ventilation do experience dyspnea, a conclusion can be drawn. According to a literature review in 2014 by Schmidt et al., the prevalence of dyspnea and respiratory distress in the population of critical care patients on mechanical ventilation has been understudied. It follows that obtaining new information about respiratory distress in the cognitively

impaired ventilated population in critical care has practical and financial implications in terms of the duration of mechanical ventilation and alleviation of suffering.

Theoretical framework

The theoretical model for this study was created Dr. Margaret Campbell in 2008 (Campbell, 2008b). This model was created as a result of the validity testing and creation of the Respiratory Distress Observation Scale (RDOS)(Campbell, 2008a). The Campbell model is a testable framework that shows observable elements including respiratory distress behaviors that may be seen in critical care patients that are cognitively impaired.

This model provides an appropriate framework for our study since respiratory distress and the RDOS include multiple elements of this model. Our study will be describing the incidence and severity of respiratory distress as measured by the RDOS. Elements that we will examine within the model will include vital sign elements such as tachycardia and tachypnea (Campbell, 2008a: Campbell, 2010: Campbell, et al., 2010). Patient characteristics and demographics will also be examined.

The Instrument

The original 2008 RDOS was a seven item instrument that could be scored by a clinician. The maximum score was 14 with higher scores indicating greater respiratory distress. Each variable was assigned a score between 0 and 2. The items within the scale included; heart rate at or above baseline, respiratory rate at or above baseline, restlessness, accessory muscle use, grunting, nasal flaring, and the

presence of a look of fear (Campbell, 2008a). After 2008 validation studies the presence of a paradoxical breathing pattern added 2 more points to make a new total of 16 as a maximum score for the tested 2010 RDOS (Campbell et al., 2010). Paradoxical breathing was found to be highly correlated with signs of distress upon observation (Campbell, 2008a). The RDOS was scored during a 3 minute observation period which included auscultation for counting heart rate and respirations for one minute. (Campbell, 2010: Campbell et al., 2010).

The RDOS has been shown to have "perfect inter-rater reliability" (Campbell et al, 2010). Convergent validity scores was found to be acceptable when compared to the dyspnea VAS (r_s= 0.404, p= 0.05) (Campbell et al., 2010). Internal consistency was found to be acceptable as well with a Cronbach's alpha at 0.64 and internal consistency correlation coefficient of 0.78 (Campbell et al., 2010). Most recently Campbell & Templin found that for patients on mechanical ventilation, a score of 3 or greater on the RDOS met the threshold for dyspnea (2015).

In a study by Hui et al. in 2013, inter-rater agreement between patients and nurses was 0.09 (p<0.001) indicating that observed dyspnea was less than that reported by patients. However, 47% of the reported dyspnea values were within one point (Hui et al., 2013). The patients in this study were cognitively intact. (Hui et al., 2013).

In 2014, a conference study abstract by Persichini, Gay, Schmidt, Demoule, & Similowski confirmed behavioral evaluation of dyspnea by examining 193 ICU patients and comparing dyspnea with a visual analog scale (VAS). They also found that 73 of those 193 subjects were cognitively impaired and excluded (Persichini et

al., 2014). In that study they found that the RDOS had a 95.5% specificity to predict a VAS score greater than three in 120 ICU subjects (Persichini et al., 2014).

Method

Sample

The site for this research study was a tertiary care metropolitan hospital located in Southern California. This study took place in the 24 bed medical ICU. Members of the critical care team include pulmonologists, physician specialists, nurses, advanced practice nurses, respiratory therapists, physical therapists, dieticians, social workers, and other clinicians. This healthcare system records all health information in electronic medical records. Institutional Review Board (IRB) approval was obtained from the facility and the University of San Diego. Informed consent was waived due to the non-invasive nature of the observations and due to the routine number of patient observations that take place in the study site for quality of care evaluation. Adult participants were screened and included based on presence of mechanical ventilation via endotracheal tube or tracheostomy, cognition as measured by the Glasgow coma scale and other criteria (Table 1). In addition, those that may be agitated due to a severe psychosis were excluded.

This study utilized convenience and purposive sampling. Repeated observations on the same participant were permitted. Observations took place at all hours throughout the day and night.

Procedure

This study was a non-experimental descriptive observational study with concurrent and retrospective medical record review. *A priori* power analysis

determined a goal of 100-200 subjects. Study observations were completed by two critical care nurse observers until an adequate number of samples was obtained. Observation data collection took place through a glass window from the hallway from outside of the room. Subject demographics and characteristics were obtained from the electronic medical record.

Purposive convenience sampling allowed for a representative number of observations to take place at each hour of the 24 hour day (Figure 2). If a subject was re-admitted to the ICU or re-intubated, this was noted at the observation time. Retrospective and concurrent medical record review yielded subject demographics and characteristics. Scoring the RDOS required an assessment of subject heart and respiratory rates. The respiratory rates were obtained from the screen on the mechanical ventilator. The pulse heart rate was obtained from the bedside cardiac monitor during the observation period.

Results

Data Analysis

SPSS version 21 was utilized to analyze the demographics and characteristics of our study population(IBM SPSS, 2012). The key variable of this study was the score of the 2010 RDOS scale taken during an observation period of 3 minutes. Data was screened for patterns of normality and outliers.

Our subjects consisted of 148 patients on mechanical ventilation. There was an average of two separate observations per subject. Data was screened for missing values, outliers, and distribution patterns. For respiratory distress, the results of RDOS scoring for this analysis were extracted from a concurrent study. The first 81

subjects had scores of the 2008 RDOS alone. The following 63 subjects had scoring done for both the 2008 and 2010 RDOS. Out of the original 148, seven subjects were excluded in this study due to missing data. This left 141 subjects.

Observation scores were obtained at every hour of the day and night. (Figure 1 illustrates the observation time distribution). A formal test with Kolmogorov-Smirnov test confirmed that the RDOS observation times did not follow a normal distribution pattern (KS = 0.187, df = 308, $p < 0.001$). The non-parametric Kruskal Wallis testing revealed that there was no time effect on the RDOS scores (χ^2 (23) = 33.447, $p = 0.074$).

The majority of our subjects were men (60%). The mean age was 66 *SD*14 and the mean Glasgow Coma Scale (GCS) score was 8 *SD*2. Artificial airway access was via endotracheal tube (92%) in as opposed to tracheostomy (8%). The mean number of ventilator days of our subjects at the time of observation was 4 *SD*4 with a median number of days of two. (Table 2)

In the daily physician progress notes, intensive care specialists documented a listing of diagnoses and patient problems. For our subjects, almost all had respiratory failure listed (95%). Forty-one percent had a lung problem or some kind or lung based infection. Half of the subjects (50%) had a kidney injury, problem, or some kind of kidney disease. In addition, 52% had some kind of cardiovascular system problem not including minor issues such as a history of hypertension. Diabetes was fairly common with 41% having either controlled of uncontrolled blood sugars, and 22% had a cardiac dysrhythmia such as atrial fibrillation or flutter.

Multiple diagnoses and problems were noted for our subjects. 33% of our subjects had a lung issue or problem combined with kidney damage, injury, or chronic kidney disease. 20% or 30 subjects had sepsis plus a lung issue as well. After excluding resolved problems and eliminating redundancies, our progress notes showed 78% or 116 subjects with 6 or more diagnoses or problems. There were even 11% or 17 subjects with 10 or more problems or diagnoses listed.

Morbid obesity was documented in 11% of the subjects with a few described as "supermorbidly obese." Five percent had a brain injury or dementia and seven percent were status post a cardiac arrest during that hospital stay (Table 3).

In terms of agitation, the median Richmond Agitation and Sedation score (RASS) was -3 with a mode of -3 as well. For the evaluation of pain, behaviors of pain as documented by the nursing staff was categorized as being present or absent.

Regression imputation was utilized in order to obtain a 2010 RDOS 3 minute score from the 2008 RDOS 3 minute score. Spearman's rho correlation showed that the correlation between the results of the 2008 RDOS and the results of the 2010 RDOS was large and statistically significant, ($r_s(99) = .89$, $p < .001$). A regression coefficient relating the 2008 scoring and the 2010 scoring was calculated to change the 2008 RDOS score to the 2010 RDOS score including paradoxical breathing. This regression coefficient was statistically significant, $b = 1.04$, $p < .001$, 95% $CI = .91$ to 1.18. Our equation to predict 2010 scores from the 2008 scores was thus: 2010 RDOS score = 1.04(2008 RDOS score) + .21. Utilizing the above regression modeling, 309 observations became available for analysis on the 141 subjects. The mean score of all the 3 minute 2010 RDOS equivalent scores was 2 *SD*2 with a median score of 1

(95% *CI* = 1.8-2.4). The range of scores was from 0 to 10. Results were positively skewed with most of the scores at the low end of zero to two. Outliers were included with RDOS calculations.

Out of the 141 subjects analyzed, 26% of the subjects had respiratory distress as measured by a threshold of 3 or higher on the RDOS in at least one observation period. Of all 309 observations, 73 observations or 23% indicated respiratory distress.

Discussion

In order to encourage more research on the RDOS and dyspnea scales, one must prove that respiratory distress on mechanical ventilation is a problem for the cognitively impaired. This study supports previous findings from cognitively intact patients that described dyspnea as a distressing sensation while mechanically ventilated (Li & Puntillo, 2006: Schmidt et al. 2011).

This exploration of the incidence of respiratory distress utilizing the RDOS told us that approximately one in four cognitively impaired adults in our population met the threshold for respiratory distress about 23% of the time. In terms of a 24 hour day, this study might indicate that for a mechanically ventilated cognitively impaired patient, a up to five and one-half hours aggregate might include respiratory distress. Even if one disagrees with the total amount of time of distress, based on our observations there exists signs of unrelieved respiratory discomfort in the cognitively impaired adult on mechanical ventilation.

Limitations

The sedation and analgesic components were not included in this study since our researchers were simply looking at subject behaviors. Standard care was provided to all mechanically ventilated patients during observations including continuous intravenous medication for pain and sedation. There might also have been a scrutiny effect whereby the behavior of the patients or staff interactions with the patient changed based on the fact that they were observed by an investigator. It should be noted that previous studies on the RDOS have not indicated whether time of day was a factor in the results. Our investigators, unlike previous studies on ICU patient distress, purposively attempted to avoid observations of ventilator weaning subjects who were most likely to be cognitively intact. Our research found that time of day was not a factor in RDOS results. That further supports the concern about unrelieved respiratory distress in this population.

Subject observations were completed by only two nurse observers on one unit through windows and outside of the patient rooms. Selection bias may have occurred due to the limited number of observers and patient privacy curtains that might have obstructed views during bathing and toileting. However anecdotally, it was noted that restless behavior, respiratory rate, and other signs of distress as measured within the RDOS did seem to increase when patients were turned, suctioned, and bathed. In addition, since observation times occurred around the clock, subjects were selected based on observer convenience.

Finally, the medical intensive care patient population is complex and varied. These results cannot be generalized to a surgical or trauma intensive care

population. Also, it is unknown if a language barrier or an active delusional psychological disorder would affect the RDOS scores.

Implications

Further research on this scale is needed since it is clear from previous research and this exploratory study that respiratory distress is present in mechanically ventilated adults whether they are cognitively impaired or not. It is unknown at this point whether this scale discriminates between respiratory distress, pain, and agitation behaviors. Further examination of the impact of pain and agitation on RDOS scores is warranted and will be analyzed from data collected within this study.

The benefits of having a functional scale such as the RDOS are the following: a) clinicians would have enhanced communication about patient status, b) ventilator settings could be assessed and optimized to prevent ventilator patient dysynchrony, and c) finally patient distress could be alleviated more effectively at end of life.

Table 1. Participant eligibility

Inclusion criteria	Exclusion criteria
Adults age 18 and over	Recent RASS score of 0
On mechanical ventilation via an endotracheal tube or tracheostomy	Pharmacological paralysis
Cognitively impaired as defined by a Glasgow Coma Score of 11 or less	Brain death
Patient's surrogate can read and speak English	Patient with "withdrawal of care" orders who are actively dying,
Patient has a history of English fluency	Patients who are in an active resuscitation or a "code blue,"
	Patients with a previous history of blindness or deafness
	Patients who have a history of a delusional psychological disorder
	Patients on pronation therapy

Figure 2. Q-Q graph of observation times

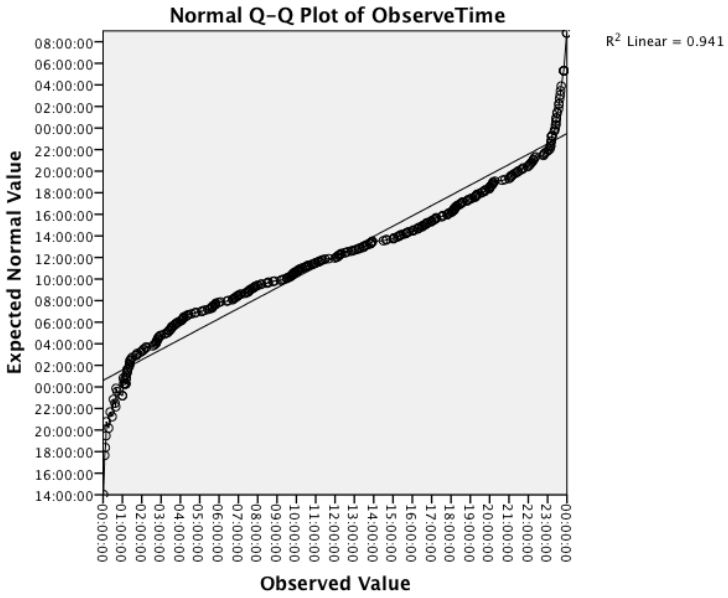

Table 2. Subject Characteristics n=148

	M/F	**% M/F**	
Gender	88/60	60/40%	
	Mean/SD	**Median**	**Mode**
Age	66 *SD*15	67	64
# of observations per subject	2 *SD*1	2	1
# of days on mechanical ventilation*	4 *SD*4	2	1
Glasgow Coma Scale score**	8 *SD*2	8	10
RASS score**		-3	-3
CPOT score**	1 *SD*1	0	0

*First 24 hours on mechanical ventilation (MV) has been noted as Day 1. 2 outliers on MV > 89 days were excluded from calculations.
**Most recent score to time of respiratory distress observation, Subjects with a RASS score of zero were excluded.

Table 3. Subject diagnoses

Diagnosis listed as per physician progress notes	**n=148**	**%**
Respiratory failure	140	95%
Lung injury or lung based infection	60	41%
Sepsis	42	28%
Shock	38	26%
Kidney problem/injury and/or kidney disease	74	50%
Organ failure	26	20%
Electrolyte problem	35	24%
Cardiovascular pathology (except for a history of controlled HTN)	77	52%
Cardiac dysrhythmia such as atrial fibrillation or flutter	33	22%
Diabetes	61	41%
Anemia	44	30%
Obesity/Morbid obesity	23/16	16%/11%
History of substance abuse or psych disorder (unrelated to respiratory failure)	16	11%
Brain injury or dementia	8	5%
s/p cardiac arrest	10	7%

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The Respiratory Distress Observation Scale (RDOS), Pain, and Agitation

Abstract

The Respiratory Distress Observation Scale (RDOS) is cited in numerous research articles including The American Thoracic Society statement on dyspnea and the IPAL-ICU Advisory Board. It was designed for the adult cognitively impaired patient. In the arena of adult critical care, discriminatory analysis of discomfort associated behavioral scales for use in cognitively impaired ICU patients on mechanical ventilation is limited. This study's purpose was to explore the relationships between the RDOS, the Richmond Agitation and Sedation Scale (RASS), and the Critical-Care Pain Observation Tool (CPOT) in the cognitively impaired adult patient on mechanical ventilation.

Thi stud was non-experimental descriptiv observational stud with concurren and retrospectiv medica recor review. Our sample consisted of 148 cognitively impaired subjects on mechanical ventilation from a medical intensive care unit. The RDOS was compared to the CPOT pain scores and RASS agitation scores. Spearman's rho showed a correlation between the RDOS score and the CPOT (r_s = .15, p = .02). Between the RDOS and RASS score there was no significant correlation (r_s = -.02, p = .76). In addition, the CPOT and the RASS however were correlated (r_s = .26, p < .001). The correlation between the RDOS and pain scores (CPOT) are of concern since clinicians utilize these scores as a basis for treatment and evaluation of treatment response. Future research is needed to focus on examination of within scale components in order to increase differentiation between the newer RDOS and the widely used RASS and CPOT scales.

Introduction

In a multinational cohort study of more than 13,000 adult patients by Metnitz et al. (2009), over 53% of patients were mechanically ventilated on admission to ICU. Some patients may be suffering from dyspnea and unable to report their distress (Campbell & Templin, 2009). In critical care from 27 to 59% of patients are sedated, comatose, or delirious. (Ely et al., 2004: White et al., 2007) These patients cannot communicate clearly what they are experiencing during their critical care stay while on mechanical ventilation. One can conclude that some patients may be suffering from dyspnea or respiratory distress while they are cognitively impaired.

In 2008 Dr. Campbell and her team completed work in the area of assessing dyspnea on the cognitively impaired patient. The Respiratory Distress Observation Scale (RDOS) was created (Campbell, 2008a). The original 2008 RDOS was tested and validated on patients during ventilator weaning. It was validated on cognitively intact patients who could fill out a visual analog scales on their levels of shortness of breath (Campbell, 2008a). According to a literature review as of January of 2015, it has had little critical testing outside of the originator team. However, it is cited in numerous research articles including The American Thoracic Society statement on dyspnea and the IPAL-ICU Advisory Board (Parshall et al., 2012: Puntillo et al., 2014). Due to research on cognitively impaired patients experiencing dyspnea by Dr. Campbell starting in 2007, it is a suitable instrument to assess dyspnea in the sedated or cognitively impaired mechanically ventilated ICU population (Campbell, 2008a: Campbell, Templin, & Walch, 2010).

Discriminatory analysis can show the differences between an instrument and other conditions or constructs (Lang & Secic, 2006, p. 246: Waltz et al, 2010, p. 180: Gélinas, Puntillo, Joffe, & Barr, 2013). In the arena of adult critical care, discriminatory analysis of signs and symptoms of discomfort in cognitively impaired ICU patients is weak or limited in most of the research studies in this population (Pudas-Tähkä et al., 2009).

In order for the RDOS to be useful in clinical practice, the RDOS must have discriminatory validity from pain and agitation. To date, no one has completed this research. If this study is able to distinguish between respiratory distress, pain, and agitation, there is a potential to better alleviate suffering and treat patients appropriately. Since this scale is relatively new and has not been extensively studied, further testing of this scale and discrimination of this scale between pain and/or restlessness was warranted. The purpose of this study was to explore the relationships between respiratory distress, pain, and agitation in the cognitively impaired adult patient on mechanical ventilation.

Background and Significance

Every year in the United States, over 5 million hospitalized patients are admitted to an intensive care unit (ICU). The average length of stay is 6-9 days. They are admitted primarily for life support that may include mechanical ventilation (Society of Critical Care Medicine [SOCCM], 2012). Patients with acute respiratory ailments, cancer, or cardiac illnesses are also very likely to be admtted to a critical care unit. Furthermore, the trend is rising. Increased numbers of patients will be on mechanical ventilation in hospitals in the future (Carson, Cox, Holmes, Howard, &

Carey, 2006).

The consequences of patients suffering with symptoms such as respiratory distress or dyspnea while being mechanically ventilated are serious. Dyspnea and pain are the two most common symptoms experienced by patients (Banzett, Pedersen, Schwartzstein, & Lansing, 2008). Shortness of breath or dyspnea is an unpleasant symptom associated with anxiety and distress. Dyspnea is defined by a number of distinct qualitative symptoms and sensations caused by physiological, psychological, or neuromuscular origins (Banzett et al., 2008: Nishino, 2011: Parshall et al., 2012: Dudgeon & Shadd, 2012). In fact, 50% of patients admitted to hospitals have dyspnea (Parshall et al., 2012).

In 2011 Schmidt et al. researched dyspnea with mechanical ventilation. Their study found that dyspnea was associated with anxiety and delayed ventilator weaning. Qualitative studies with patients have also shown that dyspnea has been found to be to be one of a number of distressing symptoms experienced during an ICU stay (Li & Puntillo, 2006: Schmidt et al., 2014).

Nurses use agitation, restlessness, and/or physiological signs as an indication of level of anxiety (Frazier et al., 2002: Frazier et al., 2003). In qualitative studies on nursing perception of agitation in critical care patients, nurses use 48 attributes of patients in planning and treating agitation, and 57 attributes in evaluating the effectiveness of treatment (Aitken, Marshall, Elliott, & McKinley, 2009). In addition, pain may be a cause of agitation (Jacobi et al., 2002, Barr et al., 2013). In the cognitively impaired critical care adult patient, nurses have used observation of signs and symptoms in order to assess pain levels of patients when they are unable

to communicate (Gélinas et al., 2004: Skrobik & Chanques, 2013: Tate et al., 2012).

Restlessness may be associated with respiratory distress, dyspnea, pain, anxiety, and frustration (Abbott et al., 2004). Pain is also associated with restlessness and dyspnea (Li & Puntillo, 2006: Payen et al., 2009: Schmidt et al, 2011). Other confounding co-variables that have been shown to correlate with levels of patient dyspnea are levels of sedation or use of anti-anxiolytics and/or opiods (Campbell, 2010). Qualitative studies with critical care nurses show that administering medications with sedation and/or analgesia for signs and symptoms of dyspnea, pain, and other of many underlying causes depends on clinician judgment in the absence of validated scales (Olson, Thoyre, & Auyong, 2007: Puntillo, Smith, Arai, & Stotts, 2008). Nurses also use the assessment of respiratory rate and heart rate to evaluate levels of pain and sedation in the cognitively impaired patient (Frazier et al., 2002: Gélinas et al., 2004: AACN Evidence-Based Practice Resources Work Group, 2013).

Physiological signs such as tachycardia and tachypnea have multiple causes yet are used in many observational instruments (De Jonghe et al., 2000). These signs correlate poorly with dyspnea, anxiety, and pain (De Jong, Moser, An, & Chung, 2004: Olson et al, 2007: Pudas-Tähkä et al., 2009). It is known from a pathological and psychological standpoint, that pain and dyspnea are slightly different (Gracely et al., 2007: Herigstad, et al., 2011).

Other researchers have started to examine respiratory distress in the ventilated population. In peer reviewed literature on the state of dyspnea in the ICU patient, conclusions state that dyspnea is frequent in the mechanically ventilated

patient and highly associated with pain and anxiety (Pudas-Tähkä et al., 2009: Schmidt et al., 2014). How these three conditions would play out in a cognitively impaired patient has not yet been examined (Schmidt et al., 2014).

The RDOS is the only scale that scores respiratory distress by behaviors alone (Parshall et al, 2012: Barr et al, 2013). Some of the elements within the RDOS are similar or the same as elements used to commonly assess pain or restlessness. The relationships between respiratory distress, pain, and restlessness have yet to be discovered in our cognitively impaired study population. In addition, a complete analysis and summary of the discrimination, reliability, and validity of pain, agitation, and sedation instruments for ICU patients has not been published since 2000 (De Jonghe et al., 2000: Barr et al., 2013).

The Instruments

the Respiratory Distress Observation Scale (RDOS).

The RDOS is a scale that was designed to measure levels of dyspnea on patients who are not able to communicate their distress (Campbell, 2008a: Campbell et al., 2010: Campbell, 2012). Because it is new, it has not been widely used in clinical practice (Parshall et al, 2012). It has the potential of being a very effective tool to evaluate dyspnea within those who cannot speak for themselves (Mularski et al., 2010: Parshall et al., 2012).

After the initial validation study Dr. Campbell next tested the RDOS with 89 palliative care inpatients with various levels of cognition. She found that inter-rater reliability was good and the scale was useful on patients in the cognitively impaired state (Campbell et al., 2010).

The RDOS is an ordinal scale with 8 observer parameters (Campbell, et al., 2010). The parameters are: "heart rate, respiratory rate, accessory muscle use, paradoxical breathing pattern, restlessness, grunting, nasal flaring, and a fearful facial expression." (Campbell et al, 2010) Each parameter is scored with zero to two points for a maximum of 16 points to indicate the most distress (Campbell et al, 2010).

Restlessness, non-purposeful movement, or unusual tension of the upper limbs may be similar to the behaviors observed with sedation and pain monitoring. Restlessness has been associated with respiratory distress, dyspnea, pain, anxiety, and frustration (Abbott et al., 2004: Barr et al., 2013). Pain has also been associated with restlessness and dyspnea (Li & Puntillo, 2006: Payen et al., 2009: Schmidt et al, 2011). Other confounding co-variables that have been shown to correlate with levels of patient dyspnea are levels of sedation, or use of anti-anxiolytics and/or opiods (Campbell, 2010). Qualitative studies with critical care nurses show that administering medications with sedation and/or analgesia for signs and symptoms of dyspnea, pain, and other of many underlying causes depends on clinician judgment in the absence of validated scales (Olson et al., 2007: Puntillo et al., 2008).

Physiological signs such as tachycardia and tachypnea have multiple causes yet are used in many observational instruments (De Jonghe et al., 2000). These signs have been known to poorly correlate with dyspnea, anxiety, and pain (De Jong et al., 2004: Olson et al, 2007: Pudas-Tähkä et al., 2009).

Grunting assessment in a patient on mechanical ventilation would be difficult due to the closed system. In infants and children, nasal flaring, retractions and

grunting are signs of respiratory distress (Deanehan & Nagler, 2012, p. 812: Thygesen, 2013). Seen in sick neonates and infants, grunting is an involuntary end expiration noise caused by vocal chord mechanics for the prevention of alveolar collapse during expiration (Ball et al., 2010, p. 841). Since the endotracheal tube transects the vocal cords (Cairo, 2012, p. 348), there would be no audible grunt in a mechanically ventilated adult.

Accessory muscle use is identified as associated with respiratory distress within the Campbell respiratory distress theoretical model (Campbell, 2008b). In addition, accessory chest muscle movement has not been noted as an element of sedation and pain scales. *Nasal flaring* also is not associated with adult sedation assessment or adult pain assessment literature.

RDOS psychometric testing.

The RDOS was tested for validity and reliability with a 3 minute observation periods during ventilator weaning (Campbell, 2008a). The RDOS was compared to the Dyspnea Visual Analog Scale (DVAS). The DVAS is a validated dyspnea instrument that has been in use since 1921 (Hayes & Pattterson, 1921 {as cited in Campbell, 2006: Mularski et al., 2010: Schmidt et al., 2011}). The Visual Analog Scale requires patient input and is a commonly used test for dyspnea.

In initial studies on the RDOS, it was found to significantly correlate with the DVAS (p= 0.001) (Campbell, 2008). Later testing revealed a Cronbach's alpha of 0.64 and internal consistency of 0.78 (Campbell et al, 2010). RDOS scores were inversely correlated with pulse oximetry and oxygen administration levels. Those results supported construct validity (Campbell et al, 2010). Campbell et al. found that the

RDOS was both valid and reliable for evaluated dyspnea in a cognitively impaired patient (Campbell, 2008a). After 2008 paradoxical breathing presence or absence was included in the scale due to its high correlation with high respiratory distress indicators (Campbell, 2008a). Most recently Campbell & Templin found that for patients on mechanical ventilation, a score of 3 or greater on the RDOS met the threshold for dyspnea as compared to the DVAS (2015).

other studies done with the RDOS thus far. Research outside of the initial creation and testing of the RDOS by Dr. Campbell to date have been done by Hui et al. in 2013 and Persichini, Gay, Schmidt, Demoule, & Similowski, in 2014. In the Hui study, the study subjects were hospitalized with advanced cancer. These subjects were cognitively intact. In this study of 299 subjects, the study team had the subjects self-report their levels of dyspnea using another validated scale. They utilized the RDOS subjective, and physiologic correlates to look for concurrent validity. They found that physiological signs such as respiratory rate did not correlate with the patient's reported level of dyspnea. They also found that the RDOS weakly correlated with the patient's reports of dyspnea (Hui et al., 2013).

The limitation to the Hui study was that the RDOS was completed by a research coordinator, not a nurse or physician. The RDOS was intended as an assessment by nurses on cognitively impaired patients (Campbell, 2010). Since this study was completed outside of the critical care arena (Hui et al., 2013), it cannot be generalized to the cognitively impaired critical care patient.

The Persichini study was a principal component analysis of the RDOS on 193 mechanically ventilated subjects newly admitted to the ICU. It was presented as a

conference abstract in 2014. They compared the RDOS to the DVAS but found that 73 of their subjects were not able to complete the VAS due to cognitive impairment. They did however arrive at a 95.5% sensitivity for the RDOS score level > 3 to dyspnea. Their conclusions were that behaviors are a valid way to evaluate dyspnea (Persichini et al., 2014).

The Richmond Agitation-Sedation Scale (RASS).

The RASS was developed based on clinical guidelines for continuous administration of sedatives and opiates in critical care (Sessler, Gosnell, & Grap, 2002). In critical care, many patients are on medications for pain and sedation that infuse intravenously on a continuous basis (Payen et al, 2007). The underlying focus for the RASS scale design was to optimize medications for pain and sedation that infuse intravenously on a continuous basis with a validated, reliable, and structured method of titration (Jacobi et al, 2002: American Society of Health-System Pharmacists, 2002).

The 10 item RASS is a partial observation scale that measures agitation and sedation levels in adult intensive care patients (Sessler et al, 2002). The RASS scale ranges from +4 combative, zero as "alert and calm," to -5 completely unresponsive (Sessler et al, 2002). The RASS was developed and tested on patients who were without sensory impairment yet who might be cognitively impaired (Sessler et al., 2002). Arevalo et al. completed follow up research and evaluation of the scale in 2012. Their results concurred with earlier validity and reliability testing and stated that "the RASS is one of the best and simplest to use" to evaluate critical care

patients (Arevalo et al., 2012). In addition, the RASS takes less than 20 seconds to complete (Ely et al., 2003).

The Critical-Care Pain Observation Tool (CPOT).

Some critical care observational pain scales use behavioral and/or physiological signs to obtain a conclusion about level of discomfort. (AACN, 2013: Stites, 2013) According to Pudas-Tähkä et al only a few are reliable enough for day-to-day clinical practice (2009).

The Critical-Care Pain Observation Tool (CPOT) was created by Gélinas Fortier, Viens, Fillion, & Puntillo in 2004. This tool utilizes facial expression, restlessness, and ventilator compliance among other things in order to evaluate levels of pain (Gélinas et al., 2004). Validity and reliability of this instrument has been with *k* coefficients ranging between 0.52 and 0.80 (Gélinas, Fillion, & Puntillo, 2009: Pudas-Tähkä et al., 2009: Paulson-Conger, Leske, Maidl, Hanson, & Dziadulewicz, 2011).

In spite of research and clinical guidelines that state that vital signs are not a good method by which to assess pain (Jacobi et al., 2002: Lord & Woollard, 2011: Skrobik & Chanques, 2013), respiratory rate, heart rate, and blood pressure (BP) continue to be utilized by nurses as a method of assessing level of comfort in the cognitively impaired patient (Gélinas et al., 2004). In a 2011 study done on patients assessed with a behavioral pain scale by paramedics outside of the hospital on adults, there were no significant correlations between pain severity score and heart rate or blood pressure (Lord & Woollard). However Lord and Woollard did find a very small but statistically significant association between initial pain score

and respiratory rate (2011).

Method

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The site for this research study was a large tertiary care metropolitan hospital located in Southern California. This study took place in the 24 bed medical ICU. Members of the critical care team include pulmonologists, physician specialists, nurses, advanced practice nurses, respiratory therapists, physical therapists, dieticians, social workers, and other clinicians. This health-care system records all health information in electronic medical records. Institutional Review Board (IRB) approval was obtained from Sharp Healthcare and the University of San Diego. Informed consent was waived. Adult participants were screened and included based on presence of mechanical ventilation via endotracheal tube or tracheostomy, cognition as measured by the Glasgow coma scale and other criteria as seen in Table 1. Potential subjects such as those that may be fearful and agitated due to a severe psychosis were excluded (Table 1).

A priori power analysis determined a goal of 100-200 subjects. Observations were completed by two critical care nurse observers until an adequate number of samples was obtained. Observation data collection took place through a glass

window from the hallway from outside of the room. Subject demographics and characteristics were obtained from the electronic medical record.

Purposive sampling allowed for a representative number of observations to take place at each hour of the 24 hour day. If a subject was re-admitted to the ICU or re-intubated, this was noted at the observation time. Retrospective and concurrent medical record review yielded subject demographics and characteristics. Scoring the RDOS included an assessment of subject heart and respiratory rates. The respiratory rates were obtained from the screen on the mechanical ventilator. The pulse heart rate was obtained from the bedside cardiac monitor during the observation period.

Key variable.

The key variable of this study was the score of the 2010 RDOS scale taken during an observation period of three minutes. For the first 85 subjects the 2008 RDOS score was utilized without the within scale item of paradoxical breath for the purposes of inter-subject and intra-subject comparison. The following 63 subjects were observed with the paradoxical breathing parameter as per the 2010 RDOS scale.

Statistical analysis.

SPSS version 21 was utilized to review the study data. (IBM SPSS, 2012). Data was screened for missing variables and evaluated for distribution patterns. Demographic and characteristics of our study subjects were defined.

An exploratory analysis was run in order to evaluate within subject variability since multiple observations were run on each subject. The 2008 RDOS

scores and 2010 RDOS scores were tested for correlation. Once finding significant correlation and meeting the assumptions for creation of a linear model, a linear regression equation was created to allow for regression imputation or the conversion of 2008 RDOS scores into 2010 RDOS scores. Following the above, each of the 3 variables of the study 2010 RDOS, CPOT, and RASS were described, compared, and contrasted.

Results

Our subjects consisted of 148 patients on mechanical ventilation. There was an average of two separate observations per subject. Data was screened for missing values, outliers, and distribution patterns. Eighty-five subjects had scores of the 2008 RDOS alone. The following 63 subjects had scoring done for both the 2008 and 2010 RDOS. Out of the 148, 7 subjects were excluded for missing data which left 141 subjects for analysis.

Spearman's rho correlation showed that the correlation between the results of the 2008 RDOS and the results of the 2010 RDOS was large and statistically significant,($r_s(99) = .89$, $p < .001$). A regression coefficient relating the 2008 scoring and the 2010 scoring was calculated to change the 2008 RDOS score to the 2010 RDOS score including paradoxical breathing. This regression coefficient was statistically significant, $b = 1.04$, $p < .001$, 95% $CI = .91$ to 1.18. Our equation to predict 2010 scores from the 2008 scores was thus: 2010 RDOS score = 1.13(2008 RDOS score) + .21. Utilizing the above regression modeling, 309 observations became available for analysis on the 141 subjects.

Observation scores were obtained at every hour of the day and night. RASS and CPOT scores were taken from the electronic medical record. The RASS and CPOT scores were recorded at the time closest to the observation within 3 hours. Listwise deletion was utilized for missing data for RASS and CPOT scores.

Subject demographics and diagnoses.

The majority of our subjects were men (60%). The mean age was 66 *SD*14 and the mean Glasgow coma scale score was 8 *SD*2. Artificial airway access was via endotracheal tube (92%) in as opposed to tracheostomy (8%). The mean number of ventilator days of our subjects at the time of observation was 4 *SD*4 with a median number of days of two.

In the daily physician progress notes, intensive care specialists documented a listing of diagnoses and patient problems. For our subjects, almost all had respiratory failure listed (95%). Forty-one percent had a lung problem or some kind of lung based infection. Half of the subjects (50%) had a kidney injury, problem, or some kind of kidney disease. In addition, 52% had some kind of cardiovascular system problem without including a history of hypertension. Diabetes was fairly common with 41% having either controlled of uncontrolled blood sugars, and 22% had a cardiac dysrhythmia such as atrial fibrillation or flutter.

Multiple diagnoses and problems were noted for our subjects. 33% of our subjects had a lung issue or problem combined with kidney damage, injury, or chronic kidney disease. 20% or 30 subjects had sepsis plus a lung issue as well. After excluding resolved problems and eliminating redundancies, our progress notes showed 78% or 116 subjects with 6 or more diagnoses or problems. There

were even 11% or 17 subjects with 10 or more problems or diagnoses listed.

Morbid obesity was documented in 11% of the subjects with a few described as "supermorbidly obese." Five percent had a brain injury or dementia and seven percent were status post a cardiac arrest during that hospital stay. (Tables 2 & 3).

The mean score of all the 3 minute 2010 RDOS scores was 2 *SD*2 with a median score of 1 (95% CI 1.8 to 2.4). The range of scores was from 0 to 10. Results were positively skewed with most of the scores at the low end of zero to two. Outliers were included with RDOS calculations. (Table 4).

In terms of agitation, the median RASS score was -3 with a mode of -3. Scores were positively skewed. For the evaluation of pain, behaviors of pain as documented by the nursing staff was categorized as being present or absent. 69% of our subjects were absent of pain per nursing documentation within 2 hours of the RDOS observation scoring. Our mean CPOT score was 1 *SD* 1.4. Scores were also positively skewed. (Table 4)

When conducting multiple observation samples from individual subjects, there may be an effect within subjects on overall scores. A One-way ANOVA was run and found no significant effect on RDOS scores from taking multiple observations from each subject [F(4.304) = .83, p = .51]. Levene's test confirmed that the homogeneity of variance assumption was met (p = 0.08). The RDOS was then compared to the CPOT pain score. Spearman's rho showed a correlation between the RDOS score and pain (r_s = .15, p = .02). Between the RDOS and RASS score there was no significant correlation (r_s = -.02, p = .76). The CPOT and the RASS however were significantly correlated (r_s = .26, p < .001). (Table 5)

Discussion

This study's findings support previous studies that have stated that pain and dyspnea are similar and associated but different. Our research found a slight correlation between the RDOS and CPOT scores. It was a surprise to find that the RASS score for restlessness differentiated from the RDOS since restlessness is a component within the RDOS scale. The CPOT and the RASS however were found to be correlated as well. Based on this preliminary examination of the correlations between the RDOS, pain, and agitation, our study concludes that the RDOS does not completely differentiate between pain and respiratory distress. However, it should be noted that this is only a preliminary finding. In terms of restlessness, restlessness associated with an RDOS score as opposed to restlessness within the agitation RASS score did seem to differentiate.

Within the RDOS the presence or absence of "grunting" is an item to score (zero to two points). None of our observations had the presence of grunting since the endotracheal or tracheostomy tube prevented that phenomena. However, during the observations on an anecdotal basis, the research team observed a phenomena that was described as "guppy breathing" when higher scores on the RDOS were noted. This behavior was what seemed to be a reflexive dropping of the lower jaw and opening of the mouth around the endotracheal tube that was timed with ventilatory effort. There was expert consensus among our research team clinicians that this behavior was something that should be noted within the scale. However since there were so few subjects with truly high RDOS scores, it was

difficult to pull out objective data for analysis. In the future, perhaps this "guppy breathing" phenomena could be addressed in the literature.

Limitations.

There were three major limitations to this study. The first was that the scores for the RASS and CPOT were obtained from the medical record. Scores were utilized that were within 3 hours or less closest to the time of the RDOS observation. Concurrent scoring by multiple testers would have increased the accuracy of our findings since activities between RASS and CPOT scoring may have influenced the corresponding RDOS score.

Secondly, in the subject group, the RASS score of zero was excluded. The reasoning was that an alert and calm patient was more likely to be cognitively intact and thus be excluded for other reasons. If they were alert and calm (zero RASS score) as opposed to restless or with decreased levels of consciousness our study would be able to identify the differences between the RDOS, pain, and agitation more clearly.

In addition, our study collected a large number of 2008 RDOS scores. It would have been ideal to have all the scoring include the paradoxical breathing component rather than utilizing regression imputation to equalize the 2008 and 2010 scales for analysis. The general consensus of our clinical experts was that a shorter and quicker scale was more likely to be used in clinical practice.

Implications.

The pain (CPOT) and RDOS score correlation should be further examined by research in order to explore what components within the scales are related. The

correlation between restlessness (RASS) and pain scores (CPOT) is also of concern since clinicians utilize these scores as a basis for treatment and evaluation of treatment response.

In this study as in previous studies with the RDOS, RDOS scores have been positively skewed with the majority of the scores at the low end of zero to two. There are 16 points to the scale. While more studies evaluating sensitivity and threshold levels are needed, ideally one might guess that the observation scores would tend to have a more normally distributed outcome pattern. Soon there will be enough RDOS studies that a systematic review may be able to evaluate the data on a larger scale. However different populations of patients, whether ICU, medical, respiratory, or surgical- trauma, may confuse the side by side comparison of scores.

Within the scale components, our research team recommends the close examination of the heart rate scoring. In our medical intensive care patient subjects there was a number of those with atrial fibrillation and atrial flutter. These patients, along with those that might be febrile or have metabolic issues may have higher heart rates in excess of 100 during their ICU stay. These high heart rates in these patients may influence scoring of the RDOS and should be examined by future research. Grunting as a factor for scoring within the RDOS scale also needs close further scrutiny for the ventilated subject.

Finally the benefits of having a functional scale such as the RDOS are the following: a) clinicians would have enhanced communication about patient status, b) ventilator settings could be assessed and optimized to prevent ventilator patient

dysynchrony, and c) finally patient distress could be alleviated more effectively at end of life.

Table 1. Participant eligibility

Inclusion criteria	Exclusion criteria
Adults age 18 and over	Recent RASS score of 0
On mechanical ventilation via an endotracheal tube or tracheostomy	Pharmacological paralysis
Cognitively impaired as defined by a Glasgow Coma Score of 11 or less	Brain death
Patient's surrogate can read and speak English	Patient with "withdrawal of care" orders who are actively dying,
Patient has a history of English fluency	Patients who are in an active resuscitation or a "code blue,"
	Patients with a previous history of blindness or deafness
	Patients who have a history of a delusional psychological disorder
	Patients on pronation therapy

Table 2 . Subject Characteristics n=148

	M/F	% M/F	
Gender	88/60	60/40%	
	Mean/SD	**Median**	**Mode**
Age	66 *SD*15	67	64
# of observations per subject	2 *SD*1	2	1
# of days on mechanical ventilation*	4 *SD*4	2	1
Glasgow Coma Scale score	8 *SD*2	8	10

*First 24 hours on mechanical ventilation (MV) has been noted as Day 1. 2 outliers on MV > 89 days were excluded from calculations.

Table 3. Diagnoses

Diagnosis listed as per physician progress notes	**n=148**	**%**
Respiratory failure	140	95%
Lung injury or lung based infection	60	41%
Sepsis	42	28%
Shock	38	26%
Kidney problem/injury and/or kidney disease	74	50%
Organ failure	26	20%
Electrolyte problem	35	24%
Cardiovascular pathology (except for a history of controlled HTN)	77	52%
Cardiac dysrhythmia such as atrial fibrillation or flutter	33	22%
Diabetes	61	41%
Anemia	44	30%
Obesity/Morbid obesity	23/16	16%/11%
History of substance abuse or psych disorder (unrelated to respiratory failure)	16	11%
Brain injury or dementia	8	5%
s/p cardiac arrest	10	7%

Table 4. RDOS, RASS, & CPOT results

Scale	**Mean**	***CI***	***SD***	**Median**	**Min-Max**	**Mode**
RDOS	2	1.8 to 2.4	2	1	0 to 10	0
CPOT*	1	.6 to .9	1	0	0 to 7	0
RASS*	-2**	-2.1 to -2.5	2**	-3	-5 to 2	-3

*Most recent score to time of respiratory distress observation,
**Subjects with a RASS score of zero were excluded.

Table 5. Spearman's rho correlations

	RDOS	**CPOT**	**RASS**
RDOS			
RASS	.02 $p = .76$	.23 $p < .001$	
CPOT	.15 $p = .02$		

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Testing the observation time requirement when using the Respiratory Distress Observation Scale

Abstract

According to the American Thoracic Society the Respiratory Distress Observation Scale (RDOS) is currently the only scale that can objectively score respiratory distress in the cognitively impaired adult. Research performed in 2008 and 2010 regarding RDOS validity and reliability testing utilized a 3 minute observation period. For use in clinical practice, a shorter observation period is practical. The purpose of this study was to compare the differences in scoring results on the RDOS at 1 minute versus 3 minutes when evaluating the cognitively impaired adult patient on mechanical ventilation.

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Fifty-nine paired observations were completed done on 59 cognitively impaired medical intensive care subjects utilizing the 2010 RDOS. Spearman's rho analysis showed that the RDOS observed over one minute significantly correlated with the observation over three minutes $r_s(57) = .78$, $p < .001$. For the 2010 RDOS, a one minute observation period was essentially as good as a 3 minute observation period for medical intensive care patients on mechanical ventilation. For busy

clinicians, an RDOS requiring less time is more likely to be used in clinical practice in the intensive care unit for adults.

Introduction

The Respiratory Distress Observation Scale is the only behavioral observational scale for respiratory distress (Parshall et al, 2012: Barr et al, 2013). Use of this scale allows clinicians to evaluate objectively the state of respiratory comfort of patients who cannot communicate their distress. However, this scale is has not been extensively evaluated.

The RDOS validity and reliability testing was done during a 3 minute observation period which included auscultating and counting heart rate and respirations for one minute (Campbell, 2010: Campbell, Templin, & Walch, 2010). For use in clinical practice, a shorter observation period is practical. Other observational scales like the Richmond Agitation Scale (RASS) and the Glasgow Coma Scale (GCS) that are used on adults in critical care are validated for scoring in as little as 30 seconds (RASS[Sessler, et al, 2002], GCS [Teasdale & Jennett, 1974]). The purpose of this study was to compare the differences in scoring results on the RDOS at one minute versus three minutes when evaluating the cognitively impaired adult patient on mechanical ventilation.

Background

In a 2009 multinational cohort study of more than 13,000 adult patients by Metnitz et al, over 53% of patients were mechanically ventilated on admission to a critical care unit. Dyspnea and pain are the two most common symptoms experienced by critical care patients (Banzett, Pedersen, Schwartzstein, & Lansing, 2008). In 2011 Schmidt et al. found that patients on mechanical ventilation with dyspnea have longer ICU stays than patients with less dyspnea. Researchers have

also found that dyspnea was associated with anxiety and delayed ventilator weaning (Schmidt et al., 2011: Persichini, Gay, Schmidt, Demoule, & Similowski, 2014). Actually for 34% of critical care patients, dyspnea is the most distressing symptom (Puntillo et al., 2010). Most importantly, when assessing this population of patients about their symptoms, less than half had the ability to answer simple questions asked about dyspnea (Puntillo et al, 2010: Schmidt et al., 2014: Campbell & Templin, 2015).

Up to 40 dyspnea scales are available for cognitively intact adults to describe their respiratory distress symptoms (Bausewein et al., 2007: Mularski et al., 2010: Parshall et al., 2012). Many previous studies have excluded patients on mechanical ventilation that are functionally unable to communicate. Thus, the conclusion can be drawn that obtaining new information about respiratory distress in the cognitively impaired ventilated population in critical care has practical and financial implications in terms of the duration of mechanical ventilation and the alleviation of suffering.

Conceptual framework

Our conceptual framework for this study was created Dr. Margaret Campbell in 2008. (Campbell, 2008b) This model was created as a result of the validity testing and creation of the respiratory distress observation scale (RDOS)(Campbell, 2008a: Campbell et al., 2010). The Campbell model is a testable framework that shows observable elements including respiratory distress behaviors that may be seen in critical care patients that are cognitively impaired.

The Instrument

Many studies on the behaviors of respiratory distress alone in the cognitively impaired adult ICU patient have been completed by Dr. M. L. Campbell between 2006 and the 2014. Early research showed that respiratory distress was observable in a cognitively impaired patient (Campbell, 2006: Campbell, 2007). Campbell also stated that affective or conscious response was not required to perceive a threat to breathing (Campbell, 2006). In 2007 she continued her work in an observational study using capnography and video cameras during ventilator weaning in order to identify behaviors associated with respiratory distress. She found that hypercarbia led to fear behaviors across cognitive states (Campbell, 2007).

These studies on the behaviors of respiratory distress led to the development and testing of the RDOS. The first study on the RDOS was with 210 pulmonary rehabilitation patients. The RDOS was compared with the dyspnea visual analog scale with good results (Campbell, 2008a). The next testing on this scale was with 89 palliative care inpatients with various levels of cognition (Campbell et al., 2010). After 2008 the presence or absence of paroxysmal breathing was added to the instrument since the presence of this behavior correlated strongly with the rest of the scale (Campbell, 2008a). Most recently Campbell & Templin found that for patients on mechanical ventilation, a score of 3 or greater on the RDOS met the threshold for dyspnea when compared with visual analogue scale results (2015).

Currently, the 2010 RDOS is an eight item instrument that can be scored by a clinician. The maximum score is 16 with higher scores indicating greater respiratory distress. Each variable is assigned a score between 0 and 2. The items within the

scale include; heart rate at or above baseline, respiratory rate at or above baseline, restlessness, accessory muscle use, grunting, nasal flaring, the presence of a look of fear, and paradoxical breathing presence or absence (Campbell et al., 2010).

The RDOS has been shown to have good inter-rater reliability (Campbell et al, 2010). Convergent validity scores was found to be acceptable when compared to the dyspnea VAS (r= 0.404, p= 0.05) (Campbell et al., 2010). Internal consistency was found to be acceptable as well with a Cronbach's alpha at 0.64 and internal consistency correlation coefficient of 0.78 (Campbell et al., 2010).

Other studies on the RDOS include a study by Hui et al. in 2013. These study subjects were hospitalized with advanced cancer and were cognitively intact. In this study of 299 subjects, the study team had the subjects self-report their levels of dyspnea using another validated scale. They utilized the RDOS and subjective and physiologic correlates to look for concurrent validity. Results showed inter-rater agreement between patients and nurses was 0.09 ($p < 0.001$) indicating that observed dyspnea was less than that reported by patients. However, 47% of the reported dyspnea values were within one point (Hui et al., 2013).

The limitation to that study was that the RDOS was completed by a research coordinator, not a nurse or physician. The RDOS was intended as an assessment by nurses on cognitively impaired patients (Campbell, 2010). Since this study was completed outside of the critical care arena (Hui et al., 2013), it cannot be generalized to the cognitively impaired critical care patient.

Outside of the initial RDOS validation and creation team, an exploratory validation study on the RDOS was completed by Persichini, Gay, Schmidt, Demoule

and Similowski in 2014. This study was presented as an abstract for the American Thoracic Society International Conference in 2014 (Persichini et al., 2014).

In the 2014 study, 193 critical care subjects were scored per the RDOS on admission. The score was compared to a visual analog scale (VAS) result (Hayes & Patterson, 1921). At the time of the observation, 73 of those subjects were cognitively impaired and unable to complete the VAS scoring. A principal component analysis of the scale was completed. They were able to verify that behavioral signs can indicate respiratory distress in ICU patients (Persichini et al., 2014). No mention is made in the abstract of the observation time period.

Most recently an Evidence Based Practice Project was presented at the 2014 Palliative Care Oncology Symposium. The RDOS was utilized on 56 patients in the oncology acute care setting. Scoring was completed in a two minute time frame. There was no testing provided on the reliability of the two minute time frame for the observation scoring (Scheper, 2014).

None of the previous studies have addressed the time requirement for observation. It is only known that the initial validation studies utilized three minutes to score the subjects for respiratory distress (Campbell, 2008a: Campbell et al., 2010). This represents a gap in the knowledge and utility of the scale for general use in critical care. For busy clinicians, a 3 minute observation time is impractical.

Method

The site for this research study was a tertiary care metropolitan hospital located in Southern California. This study took place in the 24 bed medical ICU. Members of the critical care team include pulmonologists, physician specialists,

nurses, advanced practice nurses, respiratory therapists, physical therapists, dieticians, social workers, and other clinicians. This health-care system records all health information in electronic medical records. Institutional Review Board (IRB) approval was obtained from Sharp Healthcare and the University of San Diego. Informed consent was waived. Adult participants were screened and included based on presence of mechanical ventilation via endotracheal tube or tracheostomy, cognition as measured by the GCS and other criteria. In addition, potential subjects such as those that may be agitated due to a severe psychosis were excluded. (Table 1).

This study utilized purposive convenience sampling. Repeated observations on the same participant were permitted. Observations took place at all hours throughout the day and night. A observatio perio wa 3 minut plus 1 minute observatio takin plac consecutivel withi minutes. Rando orde o whethe 3 minut o minut perio wen firs wa determine b pre-selected randomized design Withi scal measurement o hear rat an respirator rat wer obtained fro th bedsid cardia monito an mechanica ventilator.

Statistical analysis

The key variable for analysis for this study was the score acquired from the 2010 RDOS after one and three minute observation periods. SPSS version 21 was utilized for statistical calculations (IBM SPSS, 2012). Data was screened for missing scores and patterns of normality. The variance of means was not normally distributed between the two scores. Thus, parametric testing could not be utilized.

Results

There were 60 subjects with 59 paired observations done utilizing the 2010 RDOS. Subjects were a mean age of 66 *SD* 16 with a Glasgow Coma Score (GCS) mean of 8 *SD*2. The median RASS score was -3 with a mode of -3 as well. In terms of the medical problems of our subjects and diagnoses, 46 subjects had more than 6 listed. Six subjects had 10 or more serious problems or diagnoses. Almost all had respiratory failure (93%) with majority having a cardiovascular problem (53%). (Table 3)

Q-Q graphing showed that observations were somewhat evenly distributed throughout the day and night (Figure 2). The mean score of the one minute RDOS was 1.46 *SD* 1.57, 95% *CI 1.05-1.87* while the mean score of the three minute RDOS was 1.54 *SD*1.42, 95%*CI* 1.18-1.91. (Table 4) Spearman's rho analysis showed that the 2010 RDOS observed over one minute significantly correlated with the 2010 RDOS observed over three minutes $r_s(57) = .78$, $p < .001$. (Table 5)

Discussion

A 1 minute observation period is not significantly different from a 3 minute observation period. A shorter observation period for behavioral scales used in critical care is common for the cognitively impaired. Examples of scales that can be rapidly scored are the GCS and the RASS. Due to the nature of the multiple simultaneous demands on clinician's time in critical care, it is unlikely that any behavioral scale would be utilized in isolation. It is more likely that use of an observation scale might be accompanied by a physical assessment, conversation

with others in the setting, or even a critical task such as preparing for medication administration.

Limitations

Patients that were intubated for behavioral management or substance abuse withdrawal were excluded. In addition, patients that had a language barrier due to inability to understand English were also excluded. These exclusions, limit the generalizability of the results. Surgical intensive care patients were not included in this study. The surgical intensive care adult may have some characteristics that might affect the RDOS scoring results if the scale would be utilized in that population. Also, due to logistic constraints, the majority of the observations were done by one observer.

Implications

It has been recognized by many critical care researchers and palliative care groups that dyspnea and associated respiratory distress is under-diagnosed, under-documented, and under-treated (Mularski, et al., 2009). This condition has been particularly under-recognized in the cognitively impaired (Schmidt et al., 2014). The management and documentation of dyspnea is a quality of care goal particularly at end of life (Mularski, et al., 2009: U.S.DHH, CDC, NCHS, 2011*:* Puntillo et al., 2014).

According to the literature in the last year or so, the RDOS is starting to be utilized by clinicians even though it has not been widely tested. Since this is the only observational scale to measure respiratory distress and assumed dyspnea in the cognitively impaired, it behooves scientists to critically examine all components of the scale and ensure that it meets the needs of patients and clinicians. Anecdotal

findings during the collection of data for this study support a possibility that the RDOS may need adjustment or modification for the intensive care ventilated population. In addition, generalizability of the scale to the adult population with a variety of diagnsoses needs to be addressed in research. Further work with the RDOS and other scales on respiratory distress for the cognitively impaired should be fostered.

This scale is unique and meets a previously unmet need. Further scientific refinement and examination of the RDOS is essential. It would be interesting to examine whether the presence of family members or nursing staff has an effect on respiratory distress or even agitation scores. Future research could also focus on principal component analysis of data collected from RDOS observations. Analysis on each scored item within the scale will be helpful to identify the key components of the scale to both strengthen and shorten it. Finally, the RDOS would benefit from critical evaluation to improve ease and efficiency of scoring for busy clinicians.

Table 1. Participant eligibility

Inclusion criteria	**Exclusion criteria**
Adults age 18 and over	Recent RASS score of 0
On mechanical ventilation via an endotracheal tube or tracheostomy	Pharmacological paralysis
Cognitively impaired as defined by a Glasgow Coma Score of 11 or less	Brain death
Patient's surrogate can read and speak English	Patient with "withdrawal of care" orders who are actively dying,
Patient has a history of English fluency	Patients who are in an active resuscitation or a "code blue,"
	Patients with a previous history of blindness or deafness
	Patients who have a history of a delusional psychological disorder
	Patients on pronation therapy

Table 2. Subject Demographics and Characteristics n=60

	M/F	**% M/F**	
Gender	42/18	70/30%	
	Mean/SD	**Median**	**Mode**
Age	66 *SD*16	68	68
# of days on mechanical ventilation*	4 *SD*16	2	1
Glasgow Coma Scale score**	8 *SD*2	8	10
RASS score**		-3	-3
CPOT score**	1 *SD*1	0	0

*First 24 hours on mechanical ventilation (MV) has been noted as Day 1. 2
**Most recent score to time of respiratory distress observation, Subjects with a RASS score of zero were excluded.

Table 3. Subject diagnoses

Diagnosis listed as per physician progress notes	**n=60**	
Respiratory failure	56	93%
Lung problem or lung based infection	43	72%
Sepsis	18	30%
Shock	17	28%
Kidney problem/injury and/or kidney disease	29	48%
Organ failure	7	12%
Electrolyte problem	15	25%
Cardiovascular pathology (except for a history of controlled HTN)	32	53%
Diabetes	21	35%
Anemia	33	55%
Obesity/Morbid obesity	10	16%
History of substance abuse or psych disorder (unrelated to respiratory failure)	2	3%
Brain injury or dementia or encephalopathy	29	48%
s/p cardiac arrest	2	3%

Figure 1. Time of observations.

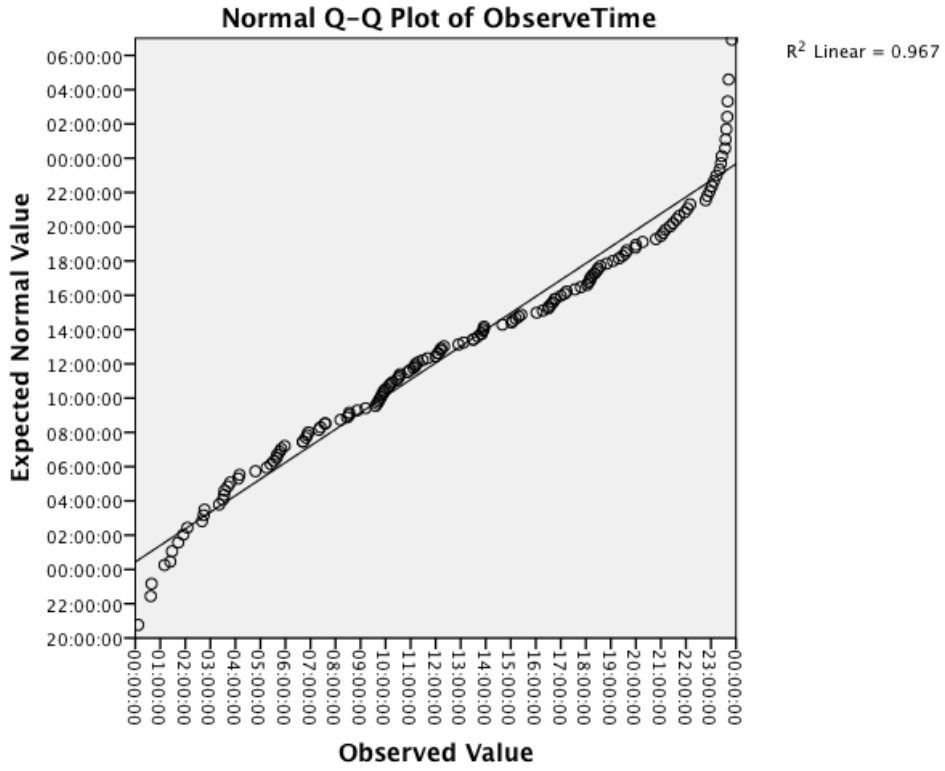

Table 4. RDOS score results

	N	Mean	95% *CI*	*SD*	Median	Minimum	Maximum
RDOS one minute	65	1.46	1.05-1.87	1.57	1.00	0	7
RDOS three minutes	60	1.54	1.18-1.91	1.42	1.00	0	6
Valid n (listwise)	59						

Table 5. Spearman rho correlation

	RDOS 3 minute
RDOS 1 minute	.78 p < .001

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Conclusion

This manuscript has identified a research gap in the ongoing scale refinement and validation of the Respiratory Distress Observation Scale (RDOS). There have been three research goals met within this manuscript. This section will summarize each research aim and the conclusions found.

The first research aim was to identify the incidence and severity of respiratory distress in our cognitively impaired adult patient on mechanical ventilation. Our team found 26% of our subjects experienced respiratory distress for over 5 hours aggregate per day. This finding supports previous research on cognitively intact adults. Patients on mechanical ventilation experience dyspnea even if cognitively impaired.

Our second aim was to find out if the RDOS differentiated between pain and agitation. This conclusion would provide further validity for the respiratory distress construct of the RDOS. Our team found that the RDOS slightly correlated with pain as measured by the CPOT score. This indicates that use of RDOS results in order to determine the effectiveness of interventions for the critical care patient may be problematic. However, restlessness as measured by the RASS as compared to the RDOS score showed a significant difference. The RASS is an agitation scoring scale, whereas restlessness is just one component to be scored within the RDOS scale. In spite of the statistical differentiation between the two, restlessness as a scoring item within the RDOS may need further evaluation as a factor in the behaviors for respiratory distress.

Finally our third aim dealt with the practical use of the RDOS in a clinical setting. The research question was to find out if the 3 minute observation period that was used in the initial validation studies was equal to observing for 1 minute. Our findings indicate that 1 minute of observation was as good as 3 minutes in terms of obtaining a score on the RDOS. This result has practical implications for use, research, and study with this scale since direct care staff is more likely to utilize a scale that takes less time.

Due to the limited amount of research on respiratory distress in the cognitively impaired patient prior to these studies, this manuscript contributes to the body of knowledge on the clinical state of cognitively impaired adults on mechanical ventilation that may or may not have respiratory distress. Clinical practice guidelines for critical care recommend that agitation sources be addressed in order to minimize sedation and its subsequent complications (Barr et al., 2013). Unaddressed dyspnea has been linked to agitation (Schmidt et al., 2014). At a national level, the Agency for Healthcare Research (AHRQ) supports research on the "development of scientifically rigorous research that provides new knowledge for informing health care decisions" (Velentgas, Dreyer, Nourjah, Smith, & Torchia, 2013, p. 17). In addition, an analysis of National Institute of Health (NIH) funding completed in 2011 concluded that the NIH has been funding support for the development of unbiased research on disease burden in the United States (Gillum et al., 2011). It should be noted that funding in the NIH analysis was tied to disease diagnoses rather than a condition such as dyspnea that crosses many disease states.

Finally, because dyspnea is such a complex condition, evaluating this state in those that are cognitively impaired is difficult. That may be the reason that a behavioral observation scale for respiratory distress has not been developed until the 21st century. As clinicians, the observation of a patient gasping for breath in spite of mechanical ventilation is heart wrenching. End of life clinical organizations such as the Improving Palliative Care in the ICU (IPAL-ICU) Advisory Board (Puntillo, et al.,2014) have disseminated guidelines that dyspnea be addressed, documented, and treated. In the cognitively impaired adult, further work in addressing dyspnea and respiratory distress is not only good healthcare, but is the right thing to do.

The RDOS is the only scale able to evaluate the cognitively impaired adult for dyspnea (Parshall et al, 2012: Barr et al, 2013). Even though this scale may need further refinement, it is a commendable accomplishment by Dr. Margaret Campbell as she began her research trajectory on this issue in 2008 (2008).

In the future, this scale could be as common or as generalizable as any of the observational pain scales or agitation scales utilized in critical care. Since it known that patients on mechanical ventilation suffer from dyspnea (Li & Puntillo, 2006: Schmidt et al., 2011: Schmidt et al., 2014), further RDOS validation research is warranted by health science researchers worldwide in order to refine this scale. The RDOS could be used to measure the effectiveness of mechanical ventilation interventions such during ventilatory weaning or changes in ventilator settings. The RDOS could also be a useful instrument for ancillary healthcare workers such as respiratory therapists or paramedics.

There is data to support that mechanical ventilator treatment interventions can decrease respiratory distress, and by doing so, decrease intubation time. (Branson, Blakeman, & Robinson, 2013). Utilizing the RDOS in order to enhance ventilator settings for cognitively impaired adults on mechanical ventilation has patient centered comfort as well as fiscal implications. Finally the RDOS could be used at end of life to identify respiratory discomfort and allow for effective medication interventions.

As a research tool, the availability of a validated RDOS allows for multi-center trials and interventions involving the effectiveness of respiratory care on the cognitively impaired adult. Research on the RDOS leads to the ultimate goal of improvement in patient outcomes and lessening of patient suffering.

Conclusion

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