2020

Effects of post ICU debriefing on the development of depression, anxiety, and PTSD symptoms

BOSTON UNIVERSITY

SCHOOL OF MEDICINE

Thesis

EFFECTS OF POST ICU DEBRIEFING ON THE DEVELOPMENT OF DEPRESSION, ANXIETY, AND PTSD SYMPTOMS

by

OLIVIA SHEERIN

B.S., University of Vermont, 2014

Submitted in partial fulfillment of the

requirements for the degree of

Master of Science

2020

Approved by

First Reader _____

Michael Ieong, M.D.
Assistant Professor in the Department of Medicine

Second Reader _____

John Weinstein, Ph.D.
Director of Research in the Physician Assistant Program

ACKNOWLEDGMENTS

I would like to offer my sincerest thanks to Dr. Michael Ieong for his time and expertise, to Dr. John Weinstein for his guidance, to my parents, Mary and Christopher Gross, for their support, always, and to my husband, Jack Sheerin, for his unconditional love.

EFFECTS OF POST ICU DEBRIEFING ON

THE DEVELOPMENT OF DEPRESSION, ANXIETY, AND

PTSD SYMPTOMS

OLIVIA SHEERIN

ABSTRACT

Due to advances in medical care, the number of patients surviving critical illness is on the rise. As a result, our healthcare system has a new and growing subset of patients dealing with a variety of issues related to survivorship. These issues, called post-intensive care syndrome, fall into three pillars: physical, cognitive, and psychiatric. While targeted efforts have begun to attempt to manage the physical and cognitive deficits, how to treat the psychiatric deficits remains unclear.

So far, the handful of studies attempting to treat these psychiatric outcomes via a variety of approaches have had only limited success. Further, there is an inadequate understanding of the patient perception of these experiences and to better grasp this may help target future studies.

The proposed study is a randomized, non-blinded, longitudinal controlled trial with the goal to limit the development of psychiatric symptoms following ICU admission. The intervention, conducted by a trained, Licensed Clinical Social Worker will take place in

the form of a one time, in hospital debriefing of the ICU experience. Following the intervention, the patients will be surveyed to identify the presence of PTSD symptoms at various time intervals following hospital discharge. In addition, a number of interviews will be recorded and undergo qualitative analysis to identify cohesive themes and develop a better understanding of the patient perception of their experience.

If successful, this study would lead to an improved quality of life for this patient population, as well as lessen their dependence on the healthcare system, reducing the associated financial burden following ICU admission.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

Within any hospital, ICU patients require more frequent monitoring, more invasive treatments, and have higher mortality rates than other patients.[1] According to the Society of Critical Care Medicine there are more than 5.7 million ICU admissions in the United States per year. Of these patients, approximately 10-29% of them will die as a result of their illness, around 900,000 annually.[2] While these mortality figures are significant, there is a new and growing emphasis that attention must also be paid to the majority of patients that survive their hospitalization and may experience adverse sequelae from their ICU stay. Importantly, the proportion of patients surviving the ICU is growing as medical advances allow medical teams to intervene for longer and to prevent the loss of life more often.[2] The result is a health care system with a new subset of patients – those who have survived and were discharged from the hospital with new and often times life-long physical, cognitive, and psychological deficits. It is in this context that survivorship has been identified as the defining challenge of critical care in the 21st century.[3]

STATEMENT OF THE PROBLEM

The deficits of survivorship, collectively referred to as post-intensive care syndrome (PICS), have proven to be challenging to manage and, as such, the medical community has yet to establish a standard of care with which to approach them. These deficits are multifaceted and variable, affecting any part of a patient's mind or body. Recently, hospitals have begun to focus more attention on understanding and attempting to manage

some of the long-term physical and cognitive deficits, however there remains little focus on the prevention, mitigation, or management of the psychological components of this phenomenon.

The limited number of studies examining the potential modification of these psychological deficits to date have taken a variety of approaches. Researchers have utilized various interventions, protocols and timing with only limited success. However, upon a review of the existing literature on this subject, there has yet to be a randomized clinical trial that directly analyzes and evaluates the effect of a post-ICU debriefing in close proximity to ICU discharge. A study like this may be valuable in determining how to effectively modify the patient perspective of their ICU experience and their Post-Traumatic Stress Disorder (PTSD) symptoms at discharge, and long-term.

HYPOTHESIS

A post-ICU debriefing in close proximity to ICU discharge will reduce the number of troubling psychologic / PTSD symptoms at various intervals following hospital discharge.

OBJECTIVES AND SPECIFIC AIMS

In conducting this research, the overall goal is to determine whether a post-ICU intervention in the form of a debriefing, conducted in close proximity to ICU discharge, can help patients better understand their ICU experiences and the normalcy of their

emotional process and, potentially, limit the development of negative feelings and PTSD symptoms. Secondarily, the goal is to better understand the psychological components of post-intensive care syndrome, to consolidate the research that has already been done, and to focus on the aspects of these studies that proved to be successful, in order to better elucidate where the medical community can thoughtfully invest efforts moving forward.

Specific aims of this study include:

- To determine whether a post ICU debriefing by a trained social worker reduces the prevalence of negative feelings and PTSD symptoms measured via survey at one week, three months, and 12 months after discharge from the hospital.

- To better understand the experiences, memories, and perspectives of patients recently discharged from the ICU via qualitative interview methods.

REVIEW OF THE LITERATURE

OVERVIEW

In the United States, there are approximately 5.7 million ICU admissions per year.[2] Within any hospital, patients in the ICU are among the sickest, being treated for diseases and complications known to be associated with higher morbidity and mortality.[1] For this reason, these patients require more frequent monitoring and invasive interventions. In order to facilitate this level of care, the ICU has generally been regarded as a device and technology laden area of medicine. Historically, this related well to the primary goal of patient care in the ICU -- to prolong the life of the patient at whatever cost. Recently, however, the medical community has begun to acknowledge that this intervention-focused paradigm of patient care may have grown excessive at times as knowledge on the plethora of negative outcomes from these interventions has emerged. This has forced clinicians to modify their approach to balance the potentially negative outcomes of the patient's illness with those that may be iatrogenic, a result of the hospitalization. These negative ICU-related consequences are broadly called post-intensive care syndrome. The following sections will serve to elaborate upon the background of ICU care, its evolution, and the concept of post-intensive care syndrome and its management.

Evolution of ICU Care

Focus on Devices for Acute Management

Different sources credit a variety of different historical events with the creation of critical care medicine or the Intensive Care Unit (ICU).[145] Some attribute it to the cholera

epidemic of 1830 when intravenous fluid therapy was used to resuscitate patients,[1] while others credit the Crimean War of the 1850s when nurses created a separate area for critically injured solders. Others credit Dr. Walter Dandy of Johns Hopkins Hospital who arranged a special area for increased monitoring of post-operative neurosurgical patients in 1927.[4]

What has remained consistent since the beginning, though, is the focus of ICU medicine on the use of tools and then machines to support the lives of the very ill. For example, the tank respirator, or "iron lung," was introduced in 1927 and maintained artificial respiration in patients with polio until they were able to breathe independently again.[6] Today, the medical community uses medications to support a patient's blood pressure, continuous dialysis machines to replace kidney function, breathing tubes for mechanical ventilation, and sedative medications to allow these interventions to be performed without pain.

While the physical restoration achievable with critical care medicine is impressive, many of these interventions can be as traumatic as they are essential. Intubation, the process of inserting a plastic tube into a patient's airway for mechanical ventilation, can cause patients to feel as though they are being suffocated.[7] Additionally, many medications used on ICU patients can skew their perception of reality and the events occurring around them.[7] Furthermore, both intubation and sedative medication use limit a patient's ability to communicate effectively. For this reason, and because patients often appear only semi-

conscious, necessary life-saving interventions are frequently performed on these patients without explanation or consideration of the fact that patients can hear and perceive what is going on around them.

Thus, these interventions are associated with a cadre of negative consequences – physiologic, cognitive, and psychological. While it is likely that these consequences have been occurring since the beginning of intensive care medicine, they have only recently gained widespread attention and the shift in patient care to address these consequences remains ongoing.

Outcomes Focused Care

As the historically under-recognized negative consequences of these life-saving interventions have gained attention over the past decade, there has been a parallel shift in approach to the care of the critically ill patient. Clinicians no longer solely focus on prolonging the lives of their patients but, rather, also consider the unintended consequences of their hospitalization, their quality of life, and their ability to return to the lives they had before their acute illness.

Despite this shift toward outcomes focused care, the medical community has continued to fall short. This focus is new, evolving, and only just beginning to gain traction. And, even with this movement, physicians are primarily focused on the long-term physical well-being of patients and their return of functionality, often neglecting their patients' mental

health and psychologic needs.[8]

While research tends to precede practice, there has been a recent focus in the scientific literature on not only managing patients' physical needs but also evaluating and addressing their mental health and psychologic needs after hospital admission. With this, it is likely that the assessment and treatment of these less tangible, previously ignored problems will become standard practice within the practice of intensive care medicine moving forward. How this will be best achieved, however, remains unknown.

Post-Intensive Care Syndrome

Early Observations

The psychologic impact of ICU admission was first widely disseminated in a paper out of Johns Hopkins in 2008, which summarized and critically reviewed data from the studies on the subject at that time. They found that across papers the median point prevalence of Post-Traumatic Stress Disorder (PTSD) measured via a standardized Impact of Events Scale (IES) questionnaire was 22% among Intensive Care Unit patients, while the median point prevalence of clinician-diagnosed PTSD was 19% . Consistent predictors of post-ICU PTSD included prior mental health diagnoses, greater benzodiazepine use during admission, and post-ICU memories or in-ICU experiences that were frightening or psychotic. Female sex and younger age were also found to be predictive, though less consistently so. They concluded that post-ICU PTSD is common and negatively impacts the health-related quality of life of survivors[9].

The subject received more wide-spread attention after a study by Johns Hopkins in 2013 examined ICU survivors of acute lung injury who required mechanical ventilation and found that approximately 1/3 of these patients experienced PTSD symptoms – including avoidance, intrusive memories, and anxiety – for up to two years after discharge from the ICU[10].

While this study was limited to patients with acute lung injury, a specific subset of the ICU patient population, further studies out of Johns Hopkins determined that about ¼ of all patients that leave the ICU experience PTSD symptoms. The proportion was greater among those who were mechanically ventilated (1/3 of patients) or with any degree of delirium during their hospitalization[11].

Formal Recognition of Post-Intensive Care Syndrome

Researchers have been documenting clinically meaningful psychological symptoms experienced by patients after ICU discharge for more than a decade. However, it was not until more recently, as the number of studies supporting these findings continued to grow, that the Society of Critical Care Medicine formally named this syndrome Post-ICU Syndrome.

Post-Intensive Care Syndrome, or PICS, was first defined by the Society of Critical Care Medicine in 2010 as the complex of health problems that remain after critical illness,

involving any aspect of the patient's body, thoughts, feelings, or mind.[12] PICS can present in a variety of different ways in different patients and can last for a few months to many years post-recovery.[10] Post-intensive care syndrome is an umbrella term but can be separated into three pillars - cognitive, psychiatric, and/or physical deficits. Some patients may experience symptoms that fall under only one of these pillars, while others may be affected by all three[13].

Physical Deficits

Physical deficits are common and arguably the most addressed by our current healthcare system, as physical therapists and occupational therapists routinely visit and evaluate patients prior to discharge to ensure that they are safe to return home. Most commonly, patients experience neuromuscular weakness, found in more that 25% of survivors. This can present in the form of poor mobility, falls, or paresis. Prolonged mechanical ventilation, deep sedation, sepsis, and multi-organ failure are risk factors for ICU-acquired weakness.[13] Recently, trials have evaluated the potential for early mobility efforts like getting patients out of bed to work with physical therapy sooner, for example, to limit the development of these physical deficits with some success but further research is still needed.

Cognitive Deficits

While some studies report that an average of 25% of ICU survivors have some degree of cognitive impairment, others have found an incidence of up to 75%.[13,14] One study,

published in the New England Journal of Medicine in 2013, found that 25% of ICU survivors had cognitive impairment similar in severity to that of patients with mild Alzheimer's disease and that 33% of patients had cognitive deficits typically associated with moderate traumatic brain injury.[14] The major risk factors for development of cognitive impairment include duration of delirium in ICU, acute brain dysfunction, severe sepsis, hypoxia, hypotension, glucose dysregulation, requirement of prolonged mechanical ventilation, acute respiratory distress syndrome, and prior cognitive impairment.[13] While many of these may be regarded as unavoidable characteristics of critical illness, some of them may be effectively avoided. For example, glucose dysregulation can be managed by ensuring appropriate insulin regimen during admission.

Psychologic / Psychiatric Deficits

A more recent study, conducted in the UK in 2018, confirmed the high proportion of ICU patients with PTSD symptoms as initially reported by Johns Hopkins and suggested this may be a greater problem than initially appreciated. Researchers surveyed more than 13,000 ICU patients and found that more than half of them reported severe anxiety, depression or PTSD three or 12 months after discharge with 17% of patients experiencing all three.[15] The risk factors overlapped with those for cognitive impairment but also included female gender, use of sedation and analgesia in the ICU, and preexisting psychiatric disability.[13].

While PTSD has generally been associated with real-life traumatic experiences, this condition can result from delusional events or situations perceived by the patient, even those that did not actually happen, as is often the case in the ICU.[8] Experiences in the ICU can be traumatic, scary, painful, confusing, emotional, and delusional. As previously noted, many necessary procedures can result in pain, difficulty breathing, and limited ability to communicate. This, compounded by the skewed reality induced by sedative medication use, can result in a state of altered perception and the development of PTSD symptoms.

First-Hand Accounts of Traumatic Memories of the ICU

Upon review of patients' first-hand reports of their ICU experiences, the importance of an investment in this area of research becomes increasingly clear. While these accounts reflect the patient's perception of their experience, it becomes apparent that these memories are not in concordance with the reality of their medical care:

> Bill, who was admitted to Conquest Hospital in 2010 and placed on a ventilator for 19 days recalls many vivid dreams, "some of which were seeing the grim reaper, a nurse saying to me 'do you know you are dead' and another dream that the nurses were trying to kill me." [16]

> Anthony, who was admitted to John Radcliffe hospital in Oxford describes that even three years after being discharged from the hospital, his nightmares were

"clear as ever." He recalls that, "they revolved around me fighting for breath, fighting to stay with my family, believing many of my friends and family had died due to a global pandemic, travelling to far flung corners of the world to try to get treatment and on several occasions believing that I had run out of options and so having to come to terms with death."[16]

Sarah, a British doctor who was intubated and sedated in the ICU at the age of 25, described the hallucinations experienced after a severe medication reaction as, "blood seeping through holes and cracks in my skin, forming a puddle of red around me." She explained that these fragmented and delusional memories prevented her psychological recovery and led to her development of PTSD after ICU admission.[7]

Management of Post-Intensive Care Syndrome

Treating post-intensive care syndrome has been difficult with multiple promising strategies showing no benefit.[17] Most recently, post-ICU clinics have shown some promise. These are multidisciplinary clinics that patients can attend after discharge from the ICU to have their various needs assessed, evaluated, and treated by a care team who specializes in this area of practice. While the organization of these clinics varies between different institutions, they all share a commitment to improve patients' quality of life by allowing convenient and easy access to the necessary multidisciplinary care.[18] James Jackson PsyD, the assistant director of the ICU Recovery Center at Vanderbilt, explains

that the goal of these clinics is to help patients thrive within the context of their limitations, rather than to fully improve their functioning, as often this is neither attainable nor realistic.[18]

Despite some success within these clinics, researchers have begun to focus on preventing PICS, rather than treating it. One method they identified is that limiting the use of deep sedation and encouraging early mobility in ICU patients with physical and occupational therapy can help prevent the functional disabilities associated with PICS. Following this, a practice strategy was created called the ABCDE bundle with the aim to reduce PICS by: Awakening (using light or minimal sedation); Breathing (spontaneous breathing trials); Coordination of care and communication among various disciplines; Delirium monitoring, assessment and management; and Early ambulation in the ICU. Notable, however, is the fewer intervention efforts to prevent the development of psychologic impairment compared to the other two pillars of this syndrome. While this is possibly related to the fact that the psychologic outcomes are often difficult to measure, the patient's perspective, experience, and mental health are paramount to their overall recovery and re-entry into the life they led prior to admission.

Currently in the United States, there are no standard practice guidelines to address the prevention, treatment or mitigation of post-ICU syndrome and its various sequelae, specifically those related to mental health. There has been some research conducted in this area but much remains unknown about the efficacy and generalizability of practices

trialed. Further efforts to prevent the development of the psychological consequences of ICU admission as part of a holistic approach to PICS prevention may serve to significantly improve the quality of life of ICU survivors and their loved ones.

EXISTING RESEARCH

The following section will attempt to lay out the variety of approaches researchers have taken to prevent or mitigate the negative psychological consequences of ICU admission as a component of post-intensive care syndrome. In doing so, our goal is to better understand which aspects of different research studies have shown promise, the generalizability of these studies, and the consistent limitations across studies to better elucidate in which areas the medical community can thoughtfully invest efforts to target this understated public health issue moving forward.

PICS and, specifically, its psychologic components are known to be resistant to change[17], as many efforts have been trialed to treat this phenomenon without success. What remains less clear, however, is whether or not the psychological components of PICS can be effectively prevented or mitigated by intervening prior to their development. If this were possible, difficulties in treatment may become less relevant. While prevention, rather than treatment, has the potential to be more effective in solving this problem, there remain many questions about the optimal approach.

In studying the prevention of the psychological components of PICS, researchers have utilized different interventions, including support offered by a psychologist[19], counseling by a nurse[20], eye masks and earplugs during sleep[21], and ICU diaries.[22] These studies also utilized a variety of different timelines. Some studies initiated their intervention during ICU stay[23], while others didn't intervene until well after discharge from the hospital.[2022] Some studies evaluated the effects of their intervention three months post-discharge and others waited until one year following discharge.[19] And, finally, they utilized a variety of patient cohorts with some studies investigating only trauma patients[19], only cardiac patients[21], or only patients with a certain length of stay, duration of intubation, or level of consciousness. We will take a look at these various approaches below, determining the strengths, weaknesses, and generalizability of the current research.

The RAPIT study by Jensen et al [20], published in 2016, was a non-blinded randomized controlled trial that investigated the effectiveness of a post-ICU recovery program compared to standard care during the first year after ICU discharge. It was conducted in 10 ICUs across Denmark and included 386 adult patients (190 in the intervention group, 196 in the standard care group) who received mechanical ventilation for 48 hours or more. Patients were excluded if they had any baseline dementia, delirium, or if researchers were unable to confirm that they were oriented to self/person for any other reason, such as through being nonverbal. The intervention group received three post-ICU consultations by trained study nurses. The first was in person within one to three months of discharge and focused on supporting the patient in constructing an illness narrative.

The following two consultations occurred via telephone at five and 10 months after discharge from the ICU. Unfortunately, the results of this study found no differences in health-related quality of life at 12 months after discharge, the primary outcome, nor in the secondary outcomes of self-reported sense of coherence, anxiety, depression or PTSD. It is important, though, to consider the many limitations of this study. First, only 88% of the surviving 154 patients in the intervention group received at least one consultation, while only 71% of patients received all three as intended. Second, it is important to consider the weaknesses associated with the timing of initiation of the intervention, as well as the infrequency of the subsequent consultations. The first consultation was not until the patient had been out of the ICU for at least one month during which time it could be argued that these troubling memories are most vivid and potentially troubling, without any secondary contact for two to four months after that. Additionally, the results of this intervention could have been potentially influenced by baseline differences in health-related quality of life as there was no evaluation of this in the trial. Finally, the trial utilized questionnaires that researchers themselves suggested may not have been able to effectively capture the existential issues that many ICU survivors deal with. Taking all of this into account, it appears that the study design was flawed in itself with the results further restricted by additional limitations.

An observational study by Peris et al [19], published in 2011, used a different approach. Researchers observed patients before and after an institution implemented, early intra-intensive care unit clinical psychologist intervention to determine whether this decreased

the prevalence of anxiety, depression and PTSD at 12 months after ICU discharge. To be included in this study, participants were: adults aged 18-75 years old; in the ICU for >72 hours; required mechanical ventilation; admitted for trauma with "severe" or "critical" injuries, as measured by an injury severity score[24]; and able to participate in an interview during their ICU stay. Patients were excluded if they had a history of psychiatric illness, previous critical illness or previous psychiatric medication use and/or any drug abuse or addiction. The study took place in the ICU of the Emergency Department of a tertiary referral center in Florence, Italy. There were 376 patients included in the study and two study arms: a standard care group, admitted before institutional initiation of psychologist intervention, and an intervention group, admitted following the initiation of psychologist involvement. The intervention included services available 24 hours daily with an array of educational interventions, counseling, and stress management efforts at bedside initiated after the patients had regained consciousness. On average, patients received five or six interventions from the clinical psychologists during their stay. The outcome of this study was a measure of quality of life, assessed via the Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-Revised Questionnaires (IES-R) by trained nurses 12 months after discharge. The study found no significant reduction in depression and anxiety in the intervention group. What was significant between the groups, however, was the reduction in the number of patients deemed to be high risk for development of PTSD (21.1% vs. 57%; $P < 0.0001$), also measured via questionnaire. Additionally, the percentage of patients who needed psychiatric medications at 12 months was significantly higher in the control group than in the intervention group (41.7% vs. 8.1%;

P < 0.0001). Finally, and perhaps most importantly, the control group was found to have a fivefold increased odds of developing PTSD at 12 months, measured by the IES-R Questionnaire (OR, 5.463; 95% CI, 2.946 to 10.13; $P < 0.001$).

While these findings are somewhat encouraging, one cannot ignore the short-comings of this study. First, this study specifically used trauma patients with a high injury severity score. This is problematic for a few reasons, including that head trauma itself can cause physiologic changes to the brain which could lead to some of the psychologic changes observed after ICU discharge, and, additionally, one cannot confidently determine whether the traumatic event which led to their admission was responsible for their development of PTSD rather than their ICU experience itself. In fact, other studies have purposely excluded trauma patients for this reason.[25] Second, the intervention was not standardized, as the protocol investigated was already being implemented, and was not designed for the sake of the research study. The protocol covered a wide range of activities with each patient receiving a different amount and type of support which could result in some patients receiving more or less support than others, even within the intervention group. Perhaps most importantly, the timing of this study, both in terms of the intervention and evaluation must be discussed. The intervention was initiated during ICU admission. ICU admissions, especially in those requiring mechanical ventilation, rely heavily on sedative medications known to obscure reality.[7] While the researchers reported that the intervention was conducted in patients who were able to communicate, they offered no additional information about how this was determined, whether this

referred to verbal communication or otherwise, and whether there was any standardization of how long one was required to be off of sedative medications prior to the start of the intervention. Thus, the patients may not have received the intervention at the appropriate time or in a lucid state of mind. As a result, one cannot confidently exclude the possibility that differences in sedative drug administration between patients may have partially influenced the results.

Additionally, the evaluation of the intervention did not occur until a year after discharge. This, combined with the fact that the intervention took place at such a potentially overwhelming and confusing time for the patients, makes it unclear what of the ICU stay patients remembered at that time, if anything. While it could be argued that whether or not the patient remembers the intervention is irrelevant – only whether or not it had any measurable effect is important – the 12 months after ICU discharge are crucial and the lack of follow-up during this time could have led to a lack of important results being captured. Perhaps harder to avoid, but worth noting, is that the study did not account for pre-existing depression or anxiety in their patients, which could have further modified the study's findings.

Even overlooking the potential study limitations, the results would be difficult to generalize across all ICU populations. This study investigated a homogenous cohort of patients and additionally, took place in an ICU where family members are allowed

24-7, which is not often the case and could contribute to psychologic recovery long-term.

A more recent study, a cluster randomized clinical trial, published in 2019 by Wade et al[23], took a similar approach. Researchers investigated the effect of a preventive psychological intervention initiated during ICU admission with the goal to reduce patient symptom severity after discharge. The study included 1458 ICU patients, randomized in a 1:1 ratio to the intervention or control group. While there is overlap between this study and Peris et al, differences include that this study was led by nurses, rather than clinical psychologists, and that the evaluation took place sooner, at six months rather than 12 months after discharge. Patients included in this study were at least 18 years old; in the ICU for more than 48 hours; receiving advanced respiratory monitoring and support or monitoring and support for two or more organ systems; who scored -1 to +1 on the Richmond Agitation Score [26]; and had a Glasgow Coma Score (GCS) of 15.[27] The intervention included creating a therapeutic ICU environment, utilizing music, for example, plus three stress support sessions (30 minutes each over the course of one week by the same trained ICU nurse) with the goal to alleviate stress and memories of troubling ICU experiences such as hallucinations, paranoid delusions, and nightmares.

This study found no significant difference in PTSD symptom severity at six months in comparison to the standard of care group, as measured by a self-report questionnaire.

Additionally, there was no statistically significant change in secondary outcomes including anxiety, depression, or health-related quality of life.

Despite the fact that this study also began during ICU admission, this study standardized their population and approach more than Paris et al. Further, they took steps to ensure that their patient population was appropriate for intervention. Their patients needed to have a GCS of 15 which equates to spontaneous eye opening, orientation present, and the ability to obey commands. Patients also had a Richmond Agitation Score of -1 to +1, which ensures that these patients were neither overly combative, nor sedated, at time of intervention. They also specified that all patients were able to communicate orally. And finally, the intervention itself was more structured than Peris et al, designed for the sake of the research study.

Despite all of this, there were some weaknesses to the study. For one, this study was randomized at the ICU (cluster) level, so one must consider that there may have been differences not only between specific nursing care provided within institutions but also between institutions. Standard of care at one hospital may resemble the intervention care at another and this was not accounted for. This study attempted to combat this issue through sufficient training of staff, however, they were unable to effectively achieve this. Only 58% of the nursing staff had completed the online training for the intervention at the time that the intervention period began and, even by the third month of the intervention, only 80% of nurses had completed the training. Even those that did do the

training reported that they found it difficult to deliver the intervention when working with complex needs and authors further suspected difficulties in delivery due to existing practice habits and resistance to change in the units. Additionally, and perhaps in part because of these obstacles, the intervention itself was not successfully implemented. Only 66% of patients received all three sessions and only 80% received even two. The authors found that there was some reduction in anxiety in those who received all three sessions, suggesting that with better execution there could have been a greater effect captured.

However, it is important to consider the many strengths of this study. While the results were not what the researchers had hoped for, this study, conducted in 24 ICUs, served to highlight some of the challenges that are likely to be faced in any ICU.

Other studies, recognizing the challenges of interventions targeting patients' psychological states or emotions while still in the ICU, have taken alternative approaches.

A study conducted in Iran, for example, evaluated the effect of using eye masks and earplugs on the risk of PTSD development.[21] The study was made up of 64 patients who were admitted to a cardiac surgery ICU for open heart surgery. There was no requirement regarding mechanical ventilation or severity of illness but patients needed to be 18 years old without any history of mental illness, drug or alcohol addiction, or recent stress aside from the need for cardiac surgery. Patients were randomized to either the intervention group, which wore eye masks and ear plus during sleep, or the control group which did

not. All patients had their PTSD symptoms evaluated by the Impact of Event Scale – Revised (IES-R) on the day of surgery and again 2 months after discharge. IES-R evaluates intrusive memories, hyperarousal, and avoidance individually on a 5-item Likert scale. On the day of surgery total scores for the control and intervention group were 10.41 ± 5.25 and 10.71 ± 5.10, respectively. As expected, the difference between groups was not statistically significant ($p = 0.82$). Two months later, the total scores were 29.50 ± 5.90 and 11.72 ± 6.48, respectively. This difference was statistically significant ($p < 0.001$). With this, the authors concluded that the use of eye masks and ear plugs worn during sleep regulated light and sound exposure, improving sleep quality and, subsequently, reducing the risk of PTSD after ICU discharge. While encouraging, this was a small, homogenous patient population in a unique setting, where ICU beds were separated by paravans. Thus, additional studies are needed to determine the generalizability of these results.

Taking yet another approach, studies investigating the usefulness of ICU diaries[22] have, arguably, offered the most promise in this area of research over the past decade. One study, by Jones et al published in 2010[22] evaluated 352 patients in a randomized controlled trial to determine whether a prospectively collected diary of a patient's ICU stay could reduce the development of new onset PTSD when used during convalescence following critical illness. The study included patients admitted to the ICU for >72 hours and excluded patients with pre-existing, chronic PTSD. The intervention group received their ICU diary at one month following critical care discharge and the assessment of

PTSD was conducted at three months. The incidence of PTSD was reduced in the intervention group compared to the control group (5% vs 13%, $p = 0.02$). This study interestingly noted that approximately 40% of patients in both groups reported that they found their experiences in the ICU to be traumatic. One strength of this study was that it was conducted across 12 ICUs, increasing the generalizability of results. It has generally been regarded as an exciting step for the use of ICU diaries in the management of ICU-related PTSD.

Following this study, a study was conducted in Paris, France in 2012, which evaluated the impact of an intensive care unit diary on psychological distress in patients and relatives.[28] Garrouste-Orgeas et al conducted a prospective, single-center study with a sequential design, where an intervention period occurred between two control periods. Patients included in the study were admitted for four or more days and were excluded if they had any baseline dementia. While the team also collected data on psychiatric history, patients were not excluded on this basis alone as their post hoc analysis excluding these patients yielded similar results. The study utilized a diary, to which family and staff could contribute throughout ICU admission to document information about the patient's hospitalization. The study evaluated depression and anxiety in relatives of the patients at time of discharge from the ICU, as well as the patient's anxiety, depression, and PTSD symptoms at three and 12 months after discharge, via telephone. The study ultimately concluded that an ICU diary significantly affected post-traumatic stress-related symptoms in surviving patients and their relatives 12 months after ICU discharge with a larger effect

in relatives than in patients. For patients, the posttraumatic stress related symptoms scores were 34.6 +/- 15.9 pre-diary, 21 +/- 12.2 during the diary period, and 29.8 +/- 15.9 post-diary ($p = 0.02$).

Some limitations acknowledged by the writers of this study were the fact that this took place in one ICU with a history of emphasizing family involvement, making the results less generalizable across ICUs, as well as the use of a before-after-before study design. The writers stated that they chose to do this to prevent cross-contamination between groups through family interaction in the ICU and included a second control period after the intervention period to increase reliability. Nonetheless, one cannot guarantee that unmeasured confounders were equally distributed across the three groups or that aspects of patient care or institutional approach did not vary across time periods.

A few other potential shortcomings of this study include that patients were not given their diary until hospital discharge (which can be weeks after ICU discharge in some cases), there was no debriefing on the diary or what its intent was for the patient, and, as we have seen consistently across the studies reviewed thus far, there was no patient follow-up or contact prior to three months after discharge from the hospital.

While there have been multiple studies that have found similar benefits of the implementation of ICU diaries and while these diaries have already long been a part of standard practice in many European countries[29], the exact method to go about

implementation, the potential inclusion of debriefing, and the possible addition of other interventions for synergistic effect remain less clear and in need of further investigation. As research in this field continues to show promise, it is likely that efforts will be focused here, at least in part, moving forward.

Taking a more global view, one consistent limitation across studies is the time gap between intervention and follow-up, leaving it unclear what the results would look like if the intervention and/or evaluation occurred in closer proximity to ICU discharge. It is possible that utilizing aspects of successful interventions, in combination with a change in the timing of intervention initiation, may lead to a more promising outcome.

Through a review of this sparse yet diverse and representative group of studies on this subject, it becomes clear that additional, more comprehensive, standardized studies are needed to investigate the prevention of the negative psychological outcomes experienced by patients after being discharged from the ICU.

METHODS

Study design

This will be a randomized, non-blinded, longitudinal controlled trial. The control group will receive normal, standard care and the study group will receive the intervention, a one-time verbal debriefing conducted by a trained social worker after transfer to a general medicine unit from the ICU. Allocation to each study arm will occur in a 1:1 ratio. The effect of the intervention will be measured by survey at one week, three months, and 12 months following hospital discharge. Those who did not receive the intervention will be evaluated using the same survey at the same time intervals as the study group.

Study population and sampling

The study cohort will include patients who were intubated and pharmacologically sedated in the ICU at either Boston Medical Center, Massachusetts General Hospital or Tufts University Medical Center for 48 or more hours during their current hospital admission but who are extubated, no longer sedated and have been transferred to a regular medical floor greater than 24 but less than 72 hours prior. This timeframe will allow researchers to be confident that patients are no longer influenced by sedative medications, which could limit the patient's ability to receive the intervention, but is still timely enough to ensure that any memories of the ICU remain in the forefront of the patient's mind. Patients included in this study will not have other medical factors that could result in abnormal cognition or psychiatric outcomes, independent of ICU stay. Abnormal cognition may inhibit one's ability to receive the information, while any unrelated

psychiatric issues may further confound the results. To ensure this, exclusion criteria will include the following: previous history of PTSD diagnosis; known altered baseline mental status or encephalopathy related to unmanaged liver failure, renal failure, dementia, current brain tumor, previous stroke or hypoxic brain injury; and any suspicion of new neurologic deficit related to the admission, such as intracranial bleed, head trauma, or traumatic brain injury. In addition to being appropriate to receive the intervention from a cognitive standpoint, patients must also be able to hear and verbally reply to partake in this study. Otherwise, there will be no restrictions on the diagnosis requirement for inclusion in this study to ensure that our population is heterogeneous and, thus, the results of our study will be generalizable to a larger patient population. In order to detect a significant difference in mean survey scores with an alpha value of 0.05, beta value of 0.2, and a Cohen's D value of 0.2, which equates to a small effect size, we will need to include at least 786 patients for analysis in our study. We will use this small effect size as any change appreciated may be clinically significant for our patients, while the potential risks associated with this study are minimal – there is no drawing of blood, collection of urine, or administration of medication involved. Allowing for a loss of 10% of participants related to poor response or other unpredictable circumstances and an additional 10% loss related to annual expected loss of retention in a study with a prolonged follow-up, the number of patients to recruit will be 983 patients.

Intervention

The intervention will take place in the form of an in person, one-on-one debriefing, conducted by a trained, Licensed Clinical Social Worker (LCSW). For training, the LCSW will attend a one day, eight-hour course where they will receive training on PTSD and PICS, learn about the study, and role-play an intervention and receive feedback for improvement. The intervention will take place no less than 24 hours, but no more than 72 hours, after the patient is transferred to a regular medical floor from the ICU. The LCSW conducting the intervention will visit the patient in their hospital room. They will ask any family members or friends present to excuse themselves so that the session can take place in private. Over the course of approximately one hour the social worker will assess the patient's current understanding of their ICU stay, will discuss what brought them to the hospital – their presenting problem and ultimate diagnoses – and review a timeline of the events that took place during their ICU admission. To do this, the LCSW will utilize the patient's electronic medical record (EMR) to obtain the necessary information related to their admission. They will also inquire about how the patient is currently feeling about the events that have transpired. These prompts will be semi-structured but open ended and give the patient a chance to freely discuss their perception of events and their current emotional state. As appropriate, they will validate feelings of fear or confusion and offer information about the prevalence of confusing memories or feelings, as well as post-traumatic stress disorder, in people that have been intubated and sedated in the ICU. Patients will receive information about the process of intubation and sedation and the fact that sedative medications have the capacity to obscure one's perceptions, possibly

contributing to memories they might be grappling with. Patients will be advised that even if they are not currently experiencing troubling or bothersome memories, it is important that they understand that some psychologic effects of their ICU stay may arise later – even weeks or months after ICU discharge. The potential for flashbacks and nightmares will also be discussed, as well as the normalcy of these should they occur. They will receive information about resources available should they find themselves in need of additional support and will be given an opportunity to ask any questions about their experience to help align their memories with the reality of events that occurred.

Study variables and measures

The primary outcome of this study will be measured via a standardized survey one week, three months, and 12 months following hospital discharge. The survey will also be taken just prior to the intervention, at time zero, to determine if there are any differences between groups prior to the intervention. The survey used will be the Impact of Event Scale – Revised (IES-R) (Appendix 1). This is a 22-question survey initially created in 1996 to assess subjective distress caused by traumatic events. The revised version was adapted from the original Impact of Event Scale (IES), which was similar but did not capture the hyperarousal symptoms (difficulty sleeping, abnormal dreams, and heightened startle response) included under the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for PTSD (Appendix 2). This survey is not considered diagnostic for PTSD, but rather is utilized to

measure the subjective response to a specific traumatic event as a preliminary assessment tool.[31,32]

Responses on the IES-R are presented as a scale ranging from 0 ("not at all") to 4 ("extremely"). The survey is designed such that patients are to target their responses to the symptoms experienced over the past seven days specifically. Individual responses are aggregated for a numerical score such that a total score on the IES-R may range from 0 to 88 points, with a higher score more concerning for PTSD and, in our case, for the presence of psychologic consequences of ICU admission.[31]

Secondarily, the qualitative information obtained from patients during the course of the intervention will be collected to help us better understand the perception of the ICU experience in these patients and to better appreciate the prevalence of feelings of fear, confusion, or reduced clarity of mind following ICU discharge regardless of intervention.

Recruitment

Patients will be recruited from the participating ICUs. Patients will be approached by the trained, LCSW for enrollment just prior to ICU discharge. As the included hospitals utilize Epic software for patient medical records and documentation, formal orders to transfer a patient to the regular floor from the ICU will be entered here electronically. There is typically a delay between order entry and physical transfer, often a day or more. It is common for orders to be linked and, in this instance, we will have the Information

Technology personnel in each hospital link orders within the software such that any order for transfer to the regular floor from the ICU will automatically trigger a consult to the LCSW, specific to the study. Only those patients who meet inclusion requirements will be approached as there will be an electronic medical record screen prior to recruitment to ensure that a patient is eligible to participate in the study (see Study Population and Sampling). At recruitment, patients will first be asked a number of screening questions pertaining to exclusion criteria if not apparent to the LCSW on review of the EMR. Once deemed appropriate, patients will be asked if they would be willing to partake in a study evaluating memories and the psychologic toll of ICU admission. The study approach will be explained in general terms and the patient will have the opportunity to ask any questions. If willing to participate, they will sign a consent form and basic demographic information (age and gender) will be obtained. Additional information including length of intubation, primary diagnosis, and possible relevant medical history will have already been obtained from the EMR when it was reviewed to determine that the patient met the study's inclusion requirements. The LCSW will later return to conduct the intervention, greater than 24 hours but less than 72 hours after transfer to a regular unit.

Data collection

Basic demographic data will be collected at time of recruitment (See Recruitment) and primary outcome data will be collected via IES-R survey (see Study Variables and Measures). The data at time zero, prior to the in-hospital intervention, will be collected through an in-person, verbal delivery of the survey, while the data collection at the

remaining time points will be conducted via telephone. A trained research assistant will contact participants via telephone numbers (primary and alternative) given to study personnel at the time of the intervention. The study staff will call the participant and ensure that they have ten minutes to talk by phone. The phone call will be at least partially scripted and begin with an explanation of the survey format, the multiple-choice selections, and their significance. Patients will be informed that they can either reply via number, i.e. "zero," or by associated words, i.e. "not at all." Then, the survey will begin. The staff member will read each question and the associated answers to the participant. As necessary, the staff member may repeat the options after reading a question, such as, "as a reminder, I want to know how troubling or bothersome you find this – zero, not at all; one, a little bit…" and so on. After the survey is complete, the patient will be given the opportunity to share with the research assistant anything else related to the psychologic toll of the ICU experience that they feel a researcher interested in this should be aware of.

At the end of the call, the participant will be thanked for their time and participation. They will be informed of the time frame of the next telephone call and survey and will be asked if they would be interested in receiving information about resources available for further support. If requested, the staff will have a list of resources and contact information available for participants.

In addition to the data collected via survey, there will be qualitative data collected during the intervention period (see Intervention). To enable this, the intervention will be recorded. Of the total recorded interviews, 50 will be randomly selected for data analysis. The goal is that this data will be utilized to help researchers better understand the patients' perception of their experience.

Data analysis

The primary analysis will be a comparison of mean IES-R scores between the study and control groups to determine if there is a statistically significant difference in survey scores between groups at a given time interval. We will compare the total mean survey scores via a student's T-test. Given the multiple time points, will use the Bonferroni adjustment to alpha to account for the increased risk of an alpha error when performing multiple comparisons. We will also compare mean IES-R scores within each group at various time points to assess how the prevalence of PTSD may change over time. For this portion of our data analysis we will use the repeated measures ANOVA.

As for the analysis of the secondary qualitative data, 50 recorded intervention transcripts will be transcribed and then methodically reviewed and coded by our research assistants. Prior to reading the transcripts, our research assistants will create a list of approximately 50 codes as a starting point. Upon review of the transcripts they may choose to modify this list. They may review less than the total transcribed if they reach theoretic saturation earlier in their analyses, such that further interviews would not lend additional

contributory information. The goal is that through this coding process, themes will begin to emerge. Both the coding data and cohesive themes will be presented with a goal of better understanding of the patient perception of the ICU experience. Whether or not consistent themes are not evident, this data may be used to target future studies.

Timeline and resources

This study will take place over the course of approximately three and a half years, taking Institutional Review Board (IRB) approval, recruitment, data collection and analysis into account. Following IRB approval, which should take about one month, patient recruitment and data collection will begin. These activities will overlap, given the nature of the study. As patients are being discharged and receiving their surveys, other patients will be recruited. In order to achieve the desired sample size for this study, there will need to be at least nine or ten patients recruited every week (over 104 weeks, this will provide our necessary minimum of 983 total participants). This means, all patients will be recruited and have received the intervention within the first two years of the study. Therefore, the last recruited patient will complete their 12-month survey at three years from the study start date. This leaves approximately five months for data analysis.

For this study, we will hire one trained LCSW at 30 hours weekly. Generally speaking, they will split their time equally between the three included hospitals but will have the flexibility to work wherever patient volume dictates. This individual will receive consult orders triggered by transfer-to-floor orders within the EMR (see Recruitment). They will

then screen the patient, determine if appropriate for the study, and obtain consent. They will later return and complete the one-hour assessment. Having all of the recruitment and intervention conducted by the same person will be cost effective and will also limit any possible confounders related to variation in delivery of the intervention.

Second, a research assistant will be hired to manage calling patients, conducting the surveys at the appropriate time intervals, and later, data analysis. This person may work remotely to collect data, calling patients on the telephone. Each survey should take no more than 15 minutes – 45 minutes total for all three surveys. This means that over the course of the three years, the total time required to collect all of the necessary data for the maximum number of participants, that is the total recruited number of 983, would be five hours weekly (45 minutes x 983 patients / 156 weeks – 3 years). Following this, there will be five months for data analysis. During this time, the research assistant may continue to work remotely but will increase their hours to 40 hours weekly to allow for adequate time to analyze and interpret both quantitative and qualitative data (800 total hours for data analysis).

The necessary funding to complete this study would include paying a LCSW for 30 hours per week for three years and a research assistant for five hours per week for three years and 40 hours per week for 5 months. In addition to staffing costs, we will pay a third-party company to transcribe our recorded interviews. Beyond this, the budget required to conduct this study would be minimal.

Institutional Review Board

This study will submit an application to the Boston University Medical Campus Institutional Review Board (BUMC IRB) for expedited review under Category 7, which involves studies utilizing survey data. Full review is unlikely to be necessary as this study poses minimal risk to subjects, does not utilize any deception, and does not include vulnerable patient populations such as the cognitively impaired or children.

CONCLUSION

Discussion

To date, there have been numerous studies attempting to better describe and investigate methods to alleviate the negative effects of ICU stay or post-intensive care syndrome. The results of these studies have led to the creation of targeted efforts like the ABCDE bundle and other hospital specific policies, though there have been far fewer studies focusing on the psychologic toll of ICU stay specifically. To date, there has not been a randomized trial, including a heterogeneous cohort of patients, investigating the effect of a one-time, hour-long debriefing of ICU experience by trained clinical social worker with the intent to better elucidate and/or mitigate the psychological toll of these experiences following ICU admission. Should our hypothesis prove true, we would find that there is a statistically significant lower incidence of troubling memories, nightmares, flashbacks, and the interference of these with daily life in patients who received the intervention compared to the control group.

Noting the weaknesses of existing studies helped us design our study and as such, there are many strengths of our study design by comparison. First, our study population will be significantly more heterogenous that many of the existing studies, including patients with any diagnosis from the ICUs of our three designated large Boston area hospitals, while others studies have included only patients with a particular diagnosis. At the same time, our study will not be so heterogenous or include patients from such vastly different hospitals that their experiences are not comparable. One of our critiques of Wade et al

was that the standard of care at one hospital may differ from the standard of care at another, but it is likely that the standard of care at our three selected hospitals is similar. Further, we included numerous relevant exclusion criteria, where many existing studies fall short. For example, some excluded those with significant head trauma but not prior psychiatric diagnoses, while others excluded those with prior psychiatric diagnoses but not those admitted for significant head trauma. Considering the many criteria that could potentially obscure the efficacy of the intervention if not used as basis for exclusion, we took care to include numerous exclusion criteria to ensure that our data is not affected by these. Another strength of our study design is the time-course of intervention and evaluation. We found that existing studies tended to intervene too soon, for example, when a patient may still be affected by sedative medications in the ICU, and evaluated their effect too late with the first patient contact coming more than a month after discharge from the hospital in some instances. Taking this into account, we specified that our intervention should take place greater than 24 hours but less than 72 hours after transfer from the ICU to the regular medical floor and designed our evaluation of effect to take place as soon as one week following hospital discharge.

Despite our efforts, there remain some areas of potential weakness. One possible weakness is that patients will need to be consented to participate in this study while they are still in the ICU. This is a weakness for the same reason that beginning the intervention in the ICU would be a weakness and why we decided to avoid this. Patients in the ICU are often confused, related to medications and possible delirium. Asking

patients to participate in a study while they are in this mental state could lead to poor retention later, if a patient is not in fact interested or doesn't totally understand the implications of agreeing to participate in a study like this. Second, the simple fact that we must ask patients to participate in the study means that when they receive the intervention, they will know that they are part of the intervention group and thus there is no blinding. With this, there is risk for the Hawthorne effect as patients will know that they are expected to have had a positive outcome as a result of the one-time debriefing. Additionally, people may find answering survey questions over the phone to be difficult. However, the scripted verbiage of the evaluation, the simplicity of the answers, and the ability to answer via number or word choice should serve to limit this.

Despite these, our study design and its strengths far outweigh the weaknesses or risks and if our hypothesis holds true, our study may change the standard of care and improve the quality of life of the millions of ICU survivors in the United States annually.

Summary

Many patients experience some degree of functional, cognitive, or psychologic impairment following ICU admission. Post-intensive care syndrome, the collective name for these deficits, has proven to be difficult to treat and, as such, focus has begun to shift toward prevention. Despite some strides made in the prevention of the functional and cognitive deficits of this syndrome, the psychologic components have been more difficult to understand and address. To date, there are a limited number of studies investigating

whether these psychologic effects can be prevented, or mitigated, by intervening prior to their development and the optimal approach to doing so remains unclear. This study aims to take the promising aspects of existing studies, modifying those things that did not work well, to create an intervention that may reduce the development of psychologic symptoms including anxiety, depression, nightmares, and flashbacks following ICU admission, while also helping us to better understand the prevalence and perception of these in our patients.

Clinical and/or Public Health Significance

If our hypothesis proves true, we will not only improve the quality of life of the millions of survivors of ICU admission annually but we will create a new standard of care for the management of the psychological complications of post-intensive care syndrome in patients recently discharged from the ICU. In doing so, we could also potentially reduce the financial burden on the healthcare system associated with the need for further psychiatric evaluation, medication, and management at multidisciplinary clinics and other healthcare outlets for these patients. Beyond this, we will also be gathering data on the prevalence and patient perception of these psychologic symptoms, which will aid us in designing studies to investigate strategies to prevent their development moving forward.

APPENDIX 1

IMPACT OF EVENTS SCALE-Revised (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to _____ _____(event) that occurred on _____(date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Total IES-R Score:_____

INT: 1, 2, 3, 6, 9, 14, 16, 20
AVD: 5, 7, 8, 11, 12, 13, 17, 22
HYP: 4, 10, 15, 18, 19, 21

APPENDIX 2

Criterion A: Stressor (one required)

The person was exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, in the following way(s):

Direct exposure
Witnessing the trauma
Learning that a relative or close friend was exposed to trauma
Indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g. first responders, medics)

Criterion B: Intrusion Symptoms (one required)

The traumatic event is persistently re-experienced in the following way(s):

Unwanted upsetting memories
Nightmares
Flashbacks
Emotional distress after exposure to traumatic reminders
Physical reactivity after exposure to traumatic reminders

Criterion C: Avoidance (one required)

Avoidance of trauma-related stimuli after the trauma, in the following way(s):

Trauma-related thoughts or feelings
Trauma-related external reminders

Criterion D: Negative Alterations in Cognition and Mood

Negative thoughts or feelings that began or worsened after the trauma, in the following ways

Inability to recall key features of the trauma
Overly negative thoughts and assumptions about oneself or the world
Exaggerated blame of self or others for causing the trauma
Negative affect
Decreased interest in activities
Feeling isolated
Difficulty experiencing positive affect

Criterion E: Alterations in Arousal and Reactivity

Trauma-related arousal and reactivity that began or worsened after the trauma, in the following way(s):

Irritability or aggression
Risky or destructive behavior
Hypervigilance
Heightened startle reaction
Difficulty concentrating

Criterion F: Duration (required)

Symptoms last for more than 1 month.

Criterion G: Functional Significance (required)

Symptoms create distress or functional impairment (e.g. social, occupational)

Criterion H: Exclusion (required)

Symptoms are not due to medication, substance use, or other illness.

REFERENCES

1. Modrykamien AM. The ICU Follow-Up Clinic: A New Paradigm for Intensivists. *Respiratory Care*. 2012;57(5):764-772. doi:10.4187/respcare.01461

2. Critical Care Statistics. Society of Critical Care Medicine (SCCM). https://sccm.org/Communications/Critical-Care-Statistics. Accessed June 4, 2019.

3. Iwashyna TJ. Survivorship will be the defining challenge of critical care in the 21st century. *Annals of Internal Medicine*. 2010;153(3):204-205. doi:10.7326/0003-4819-153-3-201008030-00013

4. History of Critical Care | New England Journal of Medicine Resident 360. https://resident360.nejm.org/content_items/277. Accessed June 5, 2019.

5. Kelly FE, Fong K, Hirsch N, Nolan JP. Intensive care medicine is 60 years old: the history and future of the intensive care unit. *Clinical Medicine*. 2014;14(4):376-379. doi:10.7861/clinmedicine.14-4-376

6. National Museum of American History | Polio: The Iron Lung and Other Equipment. https://amhistory.si.edu/polio/howpolio/ironlung.htm. Accessed June 18, 2019.

7. Hoffman J. Nightmares After the I.C.U. *Well*. July 2013. https://well.blogs.nytimes.com/2013/07/22/nightmares-after-the-i-c-u/. Accessed June 5, 2019.

8. A New Awareness of Mental Health in ICU Patients - Johns Hopkins Medicine. http://clinicalconnection.hopkinsmedicine.org/news/a-new-awareness-of-mental-health-in-icu-patients. Accessed June 5, 2019.

9. Davydow DS, Gifford JM, Desai SV, Needham D, Bienvenu OJ. Posttraumatic stress disorder in general intensive care unit survivors: a systematic review. *General Hospital Psychiatry*. 2008;30(5):421-434. doi:10.1016/j.genhosppsych.2008.05.006

10. Treating the trauma of intensive care. The Hub. Summer 2013. https://hub.jhu.edu/magazine/2013/summer/ptsd-intensive-care/. Published June 3, 2013. Accessed June 5, 2019.

11. Roberts BL, Rickard CM, Rajbhandari D, Reynolds P. Factual memories of ICU: recall at two years post-discharge and comparison with delirium status during ICU admission--a multicentre cohort study. *Journal of Clinical Nursing*. 2007;16(9):1669-1677. doi:10.1111/j.1365-2702.2006.01588.x

12. SCCM | Post-intensive Care Syndrome. Society of Critical Care Medicine (SCCM). https://sccm.org/MyICUCare/THRIVE/Post-intensive-Care-Syndrome. Accessed May 28, 2019.

13. Rawal G, Yadav S, Kumar R. Post-intensive Care Syndrome: an Overview. *Journal of Translational Internal Medicine*. 2017;5(2):90-92. doi:10.1515/jtim-2016-0016

14. Pandharipande PP, Girard TD, Jackson JC, et al. Long-Term Cognitive Impairment after Critical Illness. *New England Journal of Medicine*. 2013;369(14):1306-1316. doi:10.1056/NEJMoa1301372

15. Hatch R, Young D, Barber V, Griffiths J, Harrison DA, Watkinson P. Anxiety, Depression and Post Traumatic Stress Disorder after critical illness: a UK-wide prospective cohort study. *Critical Care*. 2018;22(1):310. doi:10.1186/s13054-018-2223-6

16. Kay - ICUsteps. https://icusteps.org/patients/patient-experiences/kay. Accessed June 5, 2019.

17. Mikkelsen ME, Jackson JC, Hopkins RO, et al. Peer Support as a Novel Strategy to Mitigate Post-Intensive Care Syndrome. *American Association of Critical Care Nursing Advanced Critical Care*. 2016;27(2):221-229. doi:10.4037/aacnacc2016667

18. Kuehn BM. Clinics Aim to Improve Post-ICU Recovery. *The Journal of the American Medical Association*. 2019;321(11):1036-1038. doi:10.1001/jama.2019.0420

19. Early intra-intensive care unit psychological intervention promotes recovery from post traumatic stress disorders, anxiety and depression symptoms in critically ill patients | Critical Care | Full Text. https://ccforum.biomedcentral.com/articles/10.1186/cc10003. Accessed June 3, 2019.

20. Jensen JF, Egerod I, Bestle MH, et al. A recovery program to improve quality of life, sense of coherence and psychological health in ICU survivors: a multicenter randomized controlled trial, the RAPIT study. *Intensive Care Medicine*. 2016;42(11):1733-1743. doi:10.1007/s00134-016-4522-1

21. Azimian J, Assar O, Javadi A, Froughi Z. Effect of Using Eye Masks and Earplugs on the Risk of Post-traumatic Stress Disorder Development in Patients Admitted to Cardiac Surgery Intensive Care Units. *Indian Journal of Critical Care Medicine.* 2019;23(1):31-34. doi:10.5005/jp-journals-10071-23109

22. Jones C, Bäckman C, Capuzzo M, et al. Intensive care diaries reduce new onset post traumatic stress disorder following critical illness: a randomised, controlled trial. *Critical Care London England*. 2010;14(5):R168. doi:10.1186/cc9260

23. Wade DM, Mouncey PR, Richards-Belle A, et al. Effect of a Nurse-Led Preventive Psychological Intervention on Symptoms of Posttraumatic Stress Disorder Among Critically Ill Patients: A Randomized Clinical Trial. *The Journal of the American Medical Association*. 2019;321(7):665-675. doi:10.1001/jama.2019.0073

24. Stevenson M, Segui-Gomez M, Lescohier I, Scala CD, McDonald-Smith G. An overview of the injury severity score and the new injury severity score. *Injury Prevention*. 2001;7(1):10-13. doi:10.1136/ip.7.1.10

25. PTSD Common in ICU Survivors - 04/20/2015. https://www.hopkinsmedicine.org/news/media/releases/ptsd_common_in_icu_survivors. Accessed June 12, 2019.

26. Sessler CN, Gosnell MS, Grap MJ, et al. The Richmond Agitation–Sedation Scale. *American Journal of Respiratory and Critical Care Medicine*. 2002;166(10):1338-1344. doi:10.1164/rccm.2107138

27. Teasdale G, Jennett B. ASSESSMENT OF COMA AND IMPAIRED CONSCIOUSNESS: A Practical Scale. *The Lancet*. 1974;304(7872):81-84. doi:10.1016/S0140-6736(74)91639-0

28. Garrouste-Orgeas M, Coquet I, Périer A, et al. Impact of an intensive care unit diary on psychological distress in patients and relatives. *Critical Care Medicine*. 2012;40(7):2033-2040. doi:10.1097/CCM.0b013e31824e1b43

29. Garrouste-Orgeas M, Flahault C, Fasse L, et al. The ICU-Diary study: prospective, multicenter comparative study of the impact of an ICU diary on the wellbeing of patients and families in French ICUs. *Trials*. 2017;18. doi:10.1186/s13063-017-2283-y

30. Milton A, Brück E, Schandl A, Bottai M, Sackey P. Early psychological screening of intensive care unit survivors: a prospective cohort study. *Critical Care*. 2017;21(1):273. doi:10.1186/s13054-017-1813-z

31. Impact of Event Scale - Revised (IES-R) for DSM-IV - PTSD: National Center for PTSD. https://www.ptsd.va.gov/professional/assessment/adult-sr/ies-r.asp. Accessed January 2, 2020.

32. Weiss D, Marmar C. *Assessing Psychological Trauma and PTSD: A Practitioners Handbook*. 2nd ed. Guilford Press; 1997.

CURRICULUM VITAE