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Aromatherapy for Preoperative Anxiety among Female Breast Surgery Patients: A Feasibility Study

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Aromatherapy for preoperative anxiety among female breast surgery patients: A feasibility study

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“If I have seen farther than others,

it is because I was standing on the shoulders of giants”

Abstract

Purpose: This dissertation addresses the use of complementary therapies in the perioperative period for acute situational anxiety. The aim of this dissertation was to explore the concept of relief from anxiety, to describe instruments used to measure preoperative anxiety, and to evaluate the feasibility of using aromatherapy patch for preoperative anxiety among female breast surgery patients.

Design: This dissertation includes a principle-based concept analysis on relief from anxiety using complementary therapies in the perioperative period, an integrative review on instruments used to measure preoperative acute situational anxiety, and a feasibility study using the RE-AIM framework to evaluate the feasibility of providing lavender aromatherapy through a sustained-release patch and the use of a Visual Analog Scale (VAS) to measure anxiety levels during the preoperative period for female breast surgery patients.

Conclusions: This dissertation provides a greater understanding of relief from anxiety using complementary therapies. This knowledge will allow perioperative providers to modify and specify the incorporation of complementary therapies to the plan of care for surgical patients experiencing acute situational anxiety. However, if providers wish to implement a plan of care for preoperative acute situational anxiety, a reliable and valid instrument should be used for measurement. A feasible and convenient option for measuring and treating preoperative anxiety are a VAS and a sustained-release lavender aromatherapy patch.

Clinical Relevance: The ideas for this dissertation arose directly from my clinical practice as a Certified Registered Nurse Anesthetist and my personal appreciation for the use of

complementary therapies to relieve or reduce anxiety or stress. Numerous deleterious effects can occur from untreated anxiety in the perioperative period. Therefore, this dissertation explores options, beyond the traditional anxiety treatment, for patients and providers to use for perioperative anxiety. Aromatherapy was shown to be a feasible and potentially efficacious intervention to reduce preoperative anxiety. The next step is to conduct a randomized controlled trial to determine whether the aromatherapy patch demonstrates efficacy compared to a placebo patch on perceived reductions and bio-behavioral decreases in anxiety (i.e., anxiety scales, heart rate variability, skin conductance, physiological biomarkers of stress) among patients in the preoperative period.

Introduction

Anxiety is a ubiquitous problem in the health care setting. The focus of this dissertation is acute situational anxiety among surgical patients, specifically female patients undergoing breast surgery, in the preoperative period. Acute situational anxiety is a subjective feeling of an unpleasant, fearful emotion or uneasiness that is influenced by an immediate situation (Acar, Cuvas, Ceyhan, & Dikmen, 2013, Maranets & Kain, 1999, Merriam-Webster.com, 2015, Waltz, Strickland, & Lenz, 2010). The intensity and duration of acute situational anxiety can vary among patients and is estimated to affect 11 to 80% of adult surgical patients in the preoperative period (Maranets & Kain, 1999, Caumo et al, 2001). A number of studies report that female surgical patients experience more preoperative anxiety compared to their male counterparts (Matthias & Samarasekera, 2012, Mitchell, 2012, Sears, Bolton, & Bell, 2013, Yilmaz, Sezer, Gurler, & Bekar, 2012). Furthermore, female breast surgery patients are at an increased risk for anxiety attributable to a surgical procedure that has a known or the potential for a diagnosis of breast cancer (Binns-Turner, Wilson, Pryor, Boyd, & Prickett, 2011, Caumo et al, 2001).

As a Certified Registered Nurse Anesthetist caring for this patient population, I traditionally use anxiolytics such as midazolam for anxiety, which has been shown to produce negative physiological effects (Binns-Turner et al, 2011). Thus, I found myself searching for a more holistic and patient-centered approach to perioperative anxiety. The Institute of Medicine (2010) defines patient-centered care as an assessment of negative bio-behavioral changes associated with stress and the implementation of strategies to alleviate those changes. Complementary therapies such as music, acupuncture, acupressure, relaxation techniques, and aromatherapy are non-pharmacological

interventions that are used for therapeutic purposes and have been shown to reduce and/or alleviate anxiety without sequelae (Acar et al, 2013, Binns-Turner et al, 2011, Ni et al, 2013).

After being introduced to a new and innovative aromatherapy product from Bioesse® Technologies, Inc. (2013), aromatherapy became the focus of this dissertation research. Aromatherapy uses natural, plant essences (e.g. lavender, spearmint, peppermint, citrus) for therapeutic purposes (Stea, Beraudi, & De Pasquale, 2014; Perry, Terry, Watson, & Ernst, 2012). Through olfactory scent inhalation, these essential oils may provide a more gentle treatment option with significant psychological and physiological benefits (Bioesse® Technologies, LLC, 2013; Perry et al., 2012). The addition of complementary therapies, such as aromatherapy, in the perioperative period is a budding area of research.

Gaps in Knowledge

Although studies over the last decade have demonstrated that aromatherapy positively affects surgical patients in the preoperative setting, additional research is needed to provide further insight into successful methods of participant recruitment, anxiety measurement, and intervention delivery modalities. In a review of the literature of aromatherapy studies that targeted preoperative patients, the surgical patient population and recruitment methods varied among the three studies (Braden, Reichow, & Halm, 2009, Fayazi, Babashahi, & Rezaei, 2011, Ni et al, 2013) included in the review. The instruments used to measure anxiety also varied among these studies (Braden, Reichow, & Halm, 2009, Fayazi, Babashahi, & Rezaei, 2011, Ni et al, 2013). For example, the instruments included a visual analog scale (VAS), that uses a single rating on a numerical scale and the State-Trait Anxiety Index (STAI), which is a 40-item questionnaire that provides a summative score

(Braden, Reichow, & Halm, 2009, Fayazi, Babashahi, & Rezaei, 2011, Ni et al, 2013). In these studies, various physiological indicators of anxiety such as heart rate and blood pressure were used to measure anxiety (Braden, Reichow, & Halm, 2009, Fayazi, Babashahi, & Rezaei, 2011, Ni et al, 2013). The intervention delivery modalities differed among all three studies ranging from topical application of the essential oil lavandin to inhalation with a handkerchief containing lavandula to the aromatic diffusion of bergamot oil using an ultrasonic aroma diffuser device (Braden, Reichow, & Halm, 2009, Fayazi, Babashahi, & Rezaei, 2011, Ni et al, 2013). The plethora of measurement models, intervention delivery approaches and outcomes demonstrate several methodological gaps. However, the positive finding serves as evidence that aromatherapy holds promise for anxiety reduction in the preoperative period. Thus further research is needed to add to the body of knowledge in the field of symptom science related to aromatherapy.

Exploration of the Concept of Anxiety

First, a principle-based concept analysis as described by Penrod and Hupcey (2005) was performed to analyze and clarify the concept of relief from anxiety using complementary therapies in the perioperative period. The concept was explored through the tenets of a principle-based analysis to describe the maturity and boundaries of the epistemological, pragmatic, linguistic and logical principles to advance the concept according to the current state of the science. The objective of this analysis was to explore relief from anxiety for patients through complementary therapy. The overall outcome added to a better understanding of anxiety with the goal of enhancing nursing care in the perioperative period.

Second, a focused integrative review was conducted on instruments that have been used to measure acute situational anxiety for adult surgical patients in the preoperative period of hospitalization. The stress response theory guided this review of five manuscripts that reported the use of instruments to determine acute situational anxiety in the preoperative period of hospitalization. The objective was to synthesize and describe the instruments used to measure preoperative anxiety and discuss their psychometric properties (Jaruzel & Gregoski, ND).

Third, a feasibility study was conducted to evaluate several processes such as recruitment and implementation of providing a lavender aromatherapy through a sustained-release patch applied to the chest using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (Glasgow, Vogt, & Boles, 1999). The measurement model included the use of a VAS to measure anxiety levels during the preoperative period; the target population was female patients schedule for breast surgery. The General Adaptation Syndrome Theory of Stress was the underlying theoretical framework for the study (Melnyk, & Morrison-Beedy, 2012, Rice, 2012). The aims of this study were to: 1) evaluate and determine the feasibility of using an aromatherapy patch in the preoperative period of surgery for anxiety using the RE-AIM framework by assessing recruitment, retention, adherence, and adoption, and 2) collect data on preliminary signals of efficacy on anxiety measured with a VAS and physiological signs of anxiety including heart rate and mean arterial blood pressure.

Theoretical Frameworks

The Stress Response Theory was used as a guide to define acute situational anxiety in the preoperative period of hospitalization and formed the basis of the theoretical

approach within the integrative review. The Stress Response Theory postulates the breakdown of acute situational anxiety as: the threat (i.e., stress); the individual reaction (i.e., fear, anxiety, elation); and physiological fight or flight response of health and survival that includes the central nervous system and hormonal responses (Rice, 2000, Rice, 2012, Jaruzel & Gregoski, ND). The theoretical definition of acute situational anxiety, guided by the Stress Response Theory is, a subjective fearful feeling of emotion influenced by an immediate situation which is variable in intensity and duration among patients in the preoperative period of hospitalization (Acar et al, 2013, Maranets & Kain, 1999, Merriam-Webster.com, 2015, Rice, 2000, Rice 2012, Waltz, Strickland, & Lenz, 2010, Jaruzel & Gregoski, ND).

Seyle's General Adaptation Syndrome Theory of Stress was used as the underlying theoretical framework to determine if an aromatherapy intervention was a feasible option to assist with adaptive coping for preoperative anxiety among female patients scheduled for breast surgery. Seyle's model describes a three-stage response to a stressor: alarm with activation of the sympathetic nervous system leading to physiological changes; resistance with activation of the parasympathetic nervous system in an attempt to restore homeostatic balance; and, exhaustion with susceptibility to disease and death if homeostatic balance could not be restored (Rice, 2012). The goal of the General Adaptation Syndrome Theory of Stress is adaptive coping in response to the stressor (i.e. surgery, diagnosis, fear, etc.) to balance the biological, physiological and social processes to resolve the stress response (Rice, 2012).

Description of Manuscripts I, II, and III

Presented in this dissertation are three manuscripts related to acute situational anxiety in the perioperative period and complementary therapies that showcase the trajectory of my research. The first manuscript is an analysis and clarification of the concept of relief from anxiety using complementary therapies in the perioperative period. The second published manuscript is a synthesis and description of the instruments used over the last decade to measure preoperative anxiety. The final manuscript is a report of a feasibility study conducted on aromatherapy for preoperative anxiety among female breast surgery patients.

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Manuscript I

Relief from Anxiety Using Complementary Therapies in the Perioperative Period: A Principle-based Concept Analysis

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Relief from Anxiety Using Complementary Therapies in the Perioperative Period: A Principle-based Concept Analysis

Abstract

Aims and objectives. To analyze and clarify the concept of providing relief from anxiety using complementary therapies in the perioperative period utilizing the epistemological, pragmatic, linguistic and logical principles of a principle-based concept analysis to examine the state of the science.

Background. The majority of patients scheduled for surgery experience anxiety in the perioperative period. Anxiety has the potential to limit a patient's ability to participate in his or her care throughout their hospitalization. Although medications are the conventional medical treatment for anxiety in the perioperative period, the addition of a complementary therapy could be an effective holistic approach to providing relief from anxiety.

Design. Principle-based concept analysis.

Methods. In 2015, strategic literature searches of CINHAL and PUBMED using keywords were performed. Fifty-six full text articles were assessed for eligibility.

Results. Twelve studies were used in the final analysis to clarify the concept of relief from anxiety using complementary therapies in the perioperative period.

Conclusion. This analysis has clarified the maturity and boundaries, within the four principles of a principle-based concept analysis, of the concept of relief from anxiety using complementary therapies in the perioperative period. A greater understanding of relief from anxiety using complimentary therapies in the perioperative period as an adjunct to conventional medicine will allow perioperative nurses and anesthesia providers to modify and specify the plan of care for their surgical patients. The use of complementary therapies

for relief in the perioperative period appears to be an area of promising research and treatment for patients, families and providers.

Keywords: relief, anxiety, perioperative care, perioperative period, complementary therapy

Introduction

One of the top priorities of Registered Nurses and Certified Registered Nurse Anesthetists is to prevent and/or manage anxiety in the perioperative period. Unfortunately, there is no consensus on conceptual and operational definitions of relief from anxiety, and there are a limited number of definitive measures specific to anxiety for surgical patients receiving care in the perioperative period. These gaps make it difficult to have a comprehensive understanding of what it means to the patient to have relief from anxiety and to identify the best approaches to anxiety relief in patients undergoing surgery.

The term *relief* has been used in numerous settings throughout history. Relief of anxiety for surgical patients in the perioperative period is a topic of interest to those providing perioperative care. *Anxiety* is defined as "a feeling of worry, nervousness, or unease, typically about an imminent event or something with an uncertain outcome".[1] To date, no studies have directly reported relief in regard to anxiety in the perioperative period. Instead words and phrases, such as *prevention*, *reduction*, *minimization*, *effects of*, and *decreased levels,* concerning anxiety for surgical patients are the terms used in various studies in the preoperative and postoperative setting.

The definition of *relief* in *The Oxford English Dictionary*[1] is "ease or alleviation given to or received by a person through the removal or lessening of some cause of distress or anxiety; deliverance from what is burdensome or exhausting to the mind; mental relaxation; ease from, or lessening of, physical pain or discomfort; an agreeable change of object to the mind or one of the senses." *Tabor's Cyclopedic Medical Dictionary* [2] defines *relief* as "the alleviation or removal of a distressing or painful symptom." Kolcaba's mid-range theory of comfort defines relief as a state of having a specific discomfort mitigated or

relieved.[3,4] Thereby, to provide relief an action must be taken to relieve. *Relieve* is defined as: "to raise (a person) out of some trouble, difficulty, or danger; to rescue, succor, aid or assist in straits; to deliver from something troublesome or oppressive; to ease or free (a person, the mind, etc.) from sorrow, fear, doubt, or other source of mental discomfort; to give (a person, part of the body, etc.) ease or relief from physical pain or discomfort; to ease or mitigate (what is painful or oppressive); to render less grievous or burdensome".[1]

Complementary therapies combined with conventional medical treatment could offer an effective, holistic, and beneficial approach to provide relief from distressing symptoms, especially anxiety, a common distressful symptom experienced by up to 80% of surgical patients in the perioperative period.[5] Using a principle-based method of concept analysis as described by Penrod and Hupcey[6], the purpose of this manuscript is to explore the concept of relief from anxiety using complementary therapies for surgical patients within the perioperative period. Exploration of the concept through the tenets of a principle-based analysis to clarify the maturity and boundaries of the epistemological, pragmatic, linguistic and logical principles will assist in the advancement of the concept of relief from anxiety using complementary therapy according to the current state of the science.[6] A principle's maturity is described by the concept's level of development based on the current state of the science. Concepts are mature within a principle when they are clearly defined and differentiated from other concepts (epistemological) and are applicable and useful for scientific inquiry (pragmatic).[6] A principle's boundaries describe a concept within a context. A concept will *hold its boundaries* if it is used consistently and appropriately within a context (linguistic) or be unable to *hold its boundaries* when the concept becomes blurred when positioned with other concepts (logical).[6]

Specifically, this concept analysis aims to clarify the concept of relief from anxiety in the perioperative period using complementary therapies as an adjunct to conventional medical treatment for surgical patients. A clearer understanding of the concept of relief from anxiety would allow anesthesia and perioperative providers to modify the plan of care for surgical patients experiencing anxiety. The objective is to add a better understanding of relief from anxiety for patients through the use of complementary therapies to enhance nursing care in the perioperative period.

Methods

Search Questions

The questions that guided the review of the literature to address the concept of relief from anxiety in the perioperative period using a principle-based concept analysis are as follows: How would clarifying the concept of relief from anxiety using complementary therapies in the perioperative period change health care for both the patient and the provider? In surgical patients, has the addition of complementary therapies in the perioperative period compared to conventional medical treatment alone led to relief of anxiety or better outcomes? What have previous researchers used to define and measure relief? What complementary therapies to date have been investigated to relieve anxiety in the perioperative period?

Data Sources

The Cumulative Index of Nursing and Allied Health Literature (CINAHL) and PUBMED databases were searched. Search terms used in CINAHL were *anxiety*, *perioperative care* and *alternative therapies*. Each term was "exploded" to include all major subheadings. The MeSH database for PUBMED was searched using *anxiety* [MeSH],

perioperative period [MeSH], and *complimentary therapies* [MeSH]. PUBMED Clinical Queries was also searched using the terms *anxiety*, *complimentary therapies*, and *preoperative care*. Inclusion criteria for each database/search engine included: scholarly journals, research studies, and publication within the last 15 years. Exclusion criteria for each database/search engine that led to the final sample included Adult (19 – 44 years) and English language. A final result of 56 scholarly journal articles were retrieved for review. Twelve studies utilizing complementary therapies in the perioperative period for anxiety and published within the last 15 years were selected for inclusion to review for this analysis (Figure 1).

Method

The most recent research on anxiety relief with complementary therapies in the perioperative period was analyzed using a principle-based concept analysis.[6] Findings of the 12 studies (7 randomized control trials, 1 quasi-experimental, 1 prospective experimental pretest/posttest, 1 group assignment study, 1 experimental 3-group design, and 1 questionnaire) were categorized by each principle (Table 1. Epistemological, Pragmatic, Linguistic, and Logical) as they contribute to the understanding of the strengths and limitations of the concept.

Results

Epistemological Principle

The epistemological principle focuses on a clear definition and differentiation of a concept.[6] Relief from anxiety was described and measured by the researchers in each study reviewed (Table 1). Descriptions of relief included words such as *decline*, *decreased*, *lowered*, *reduced* and *reduction*. No conclusive definition of relief from anxiety using

complementary therapies in the perioperative period was defined. In each of the 12 studies analyzed, relief from anxiety using complementary therapies in the perioperative period was not specifically differentiated from other concepts such as pain, Bispectral Index (BIS) technology to monitor level of anesthesia, and vital sign changes (i.e. heart rate, blood pressure, mean arterial pressure, respiratory rate). Measurement instruments included State Trait Anxiety Index (STAI), State Anxiety Index (SAI), Visual Analog Scales (VAS), Amsterdam Preoperative Anxiety and Information Scale (APAIS), urine epinephrine levels, and BIS (Table 1).

Pragmatic Principle

The pragmatic principle focuses on the applicability and usefulness within the scientific realm of inquiry.[6] Each study reviewed described the applicability and usefulness of anxiety relief using complementary therapies within the perioperative period. In the perioperative period, Mitchell[7] found that while the majority of patients experience anxiety, it is more prevalent in female patients and those undergoing general anesthesia.

A number of complementary therapies are used in the perioperative setting that range from minimally invasive acupuncture to noninvasive music or guided imagery. Finding from two studies suggested that the use of acupressure points in the preoperative setting was statistically significant in decreasing anxiety and BIS ($p < 0.001$)[8] and reducing anxiety levels ($p < 0.001$)[9]. Acar, Cuvas, Ceyhan, and Dikmen[10] found that acupuncture at the yintang point was statistically significant in reducing preoperative anxiety ($p = 0.018$) and Bispectral index levels ($p < 0.0004$). The use of the essential oil, lavandin, for therapeutic sensation was also found to be statistically significant in lowering preoperative anxiety ($p = 0.01$) at the time of transfer to the Operating Room.[11] In addition, Gonzales et

al.[12] found that guided imagery performed preoperatively resulted in statistically significant ($p = 0.002$) decreases in anxiety levels in the postoperative period.

Furthermore, findings from three additional studies suggested that music lowered anxiety levels ($p < 0.001$) throughout the perioperative period.[13-15] Brunges and Avigne[16] did not report statistical significance but reported findings suggesting that music therapy resulted in lower epinephrine hormone levels, the neuroendocrine response to stress, in the perioperative period. Additionally, Johnson, Raymond, and Goss[17] did not report statistical significance but reported findings that suggested perioperative music and noise-blocking headsets both resulted in decreased anxiety scores in the perioperative period.

Seers, Chrichton, Tutton, Smith, and Saunders[18] studied relaxation techniques and found there were no statistically significant ($p = 0.20$) decreases in anxiety from pre-intervention to immediately post intervention and 1, 2, 3, and 4 hours later. Anxiety was measured with the State-Trait Anxiety Index (STAI). Although the findings were not statistically significant, the investigators reported decreased levels of anxiety in the surgical patient population.

Linguistic Principle

The linguistic principle evaluates the appropriate use of the concept in context.[6] The initial literature review using the keywords, *relief*, *anxiety*, *perioperative care*, *perioperative period*, and *complementary therapy* in CINAHL and PUBMED yielded 143 studies. The terms *reduced*, *lowered, decline* and *decreased* are consistently used in health care and research contexts in regards to relief from anxiety. Acar et al.[10], Cooke et al.[14], and Valiee et al.[9] reported *reduced* anxiety with a complementary therapy. Agarwal et al.[8], Gonzales et al.[12], Johnson et al.[17], and Seers et al.[18] reported *decreased* anxiety following a complementary

therapy. Binns-Turner, et al.[13] found a perioperative *decline* in anxiety with a music intervention and both an essential oil[11] and music[15] intervention *lowered* preoperative anxiety.

Logical Principle

The logical principle refers to the integration of the concept with related concepts.[6] If the concept becomes blurred when positioned with other concepts, then the concept is unable to *hold its boundaries* within the logical principle.[6] All 12 studies aimed to assess relief from anxiety using complementary therapies; however, they also described and measured other concepts such as pain and pain score changes[9-13, 18], vital signs and vital sign changes[9, 13, 15], length of stay[12, 16] and Bispectral index (BIS) measurements[8, 10].

There is limited research on relief of anxiety using complementary therapies in the perioperative period. However, from the data generated within the framework of this analysis, complementary therapies have provided relief from anxiety for surgical patients in the perioperative period. Reductions in anxiety indices, vital sign measurements, pain scores, length of hospitalization, and BIS index values are indicative of relief.

Discussion

Relief is a dynamic concept, and each researcher has described and measured relief of anxiety utilizing complementary therapies differently. For this analysis, relief was defined as the reduction, decrease, or lowering of anxiety through the use of a complementary therapy in the perioperative period. This definition of relief is not epistemologically mature but does provide clarity to the concept of relief from anxiety using complementary therapies for perioperative providers.

The concept of relief from anxiety using complementary therapy in the perioperative period is shown to be both pragmatically and linguistically mature. Pragmatic maturity was shown by each study describing the applicability and usefulness of anxiety relief using complementary therapies such as acupressure, acupuncture, essential oils, guided imagery, and music within the perioperative period. Additionally, each study led to a better understanding of the applicability and usefulness of the current complementary therapies being used in the perioperative period, which may, in turn, enhance health care for both patients and providers. Linguistic maturity was shown by the appropriate use of the terms *reduced*, *lowered, decline* and *decreased* in the current body of research to describe relief from anxiety using complementary therapies in the perioperative period. The use of these terms to describe relief from anxiety in patients receiving a complementary therapy in the perioperative period demonstrates the concept's ability to hold its linguistic boundaries.

The concept of relief from anxiety using complementary therapies in the perioperative period is unable to *hold its boundaries* when positioned with other concepts within the logical principle.[6] The concept of relief from anxiety using complementary therapies becomes *blurred* when other concepts such as pain, vital sign changes, and BIS monitoring are considered.[6] Further research is needed to establish logical boundaries for this concept.

Research is also needed to address gaps identified in the literature. The current literature revealed no previous concept analysis or conceptual definition of relief from anxiety using complementary therapies in the perioperative period. Likewise, research aimed at anxiety relief in the perioperative period with complementary therapies has been

sparse in the last 15 years and beyond. Additionally, numerous complementary therapies (i.e. yoga, deep breathing exercises, meditation, etc.) have not been studied as ways to provide relief from anxiety for surgical patients in the perioperative period.

This analysis indicates that anesthesia, medicine, nursing, psychology, and society as a whole are beginning to embrace complementary therapies to relieve anxiety and more. This analysis also demonstrates how complementary therapies have provided "relief" from anxiety for surgical patients and how they are becoming more popular in the perioperative settings. Further research on complementary therapies aimed at relieving anxiety is needed, particularly methods in which therapies can be best integrated into practice in the perioperative period.

Limitations

Generalizability of findings from the review is limited as only research regarding anxiety in the perioperative setting was reviewed. Despite the scientific rigor of a principle-based concept analysis of 12 studies, the limited number of published studies over the last 15 years, the use of only two database searches and English language only could potentially limit the findings of this analysis.

Conclusion

The concept of relief from anxiety is critical in health care. Care guided by a well-defined concept of relief from anxiety using complementary therapies in the perioperative period, which provides the ability to assess anxiety as a unique entity, is appropriate for all surgical patients. According to the Agency for Healthcare Research and Quality[19], millions of surgeries are performed annually in the United States. The concept of relief as an action taken to ease, alleviate or remove the symptoms of distress, discomfort, pain and/or

anxiety during the perioperative period for surgical patients is an important concept for providers in multiple contexts. This analysis illuminated that relief from anxiety using complementary therapies along with conventional medical treatment can be effective in the perioperative period and produces substantial benefits for surgical patients. Further research to define and measure relief from anxiety using different complementary therapies is necessary. The use of complementary therapies for relief of anxiety appears to be an area of promising treatment for patients, families, and providers in the perioperative period.

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Figure 1. Data sources flow chart

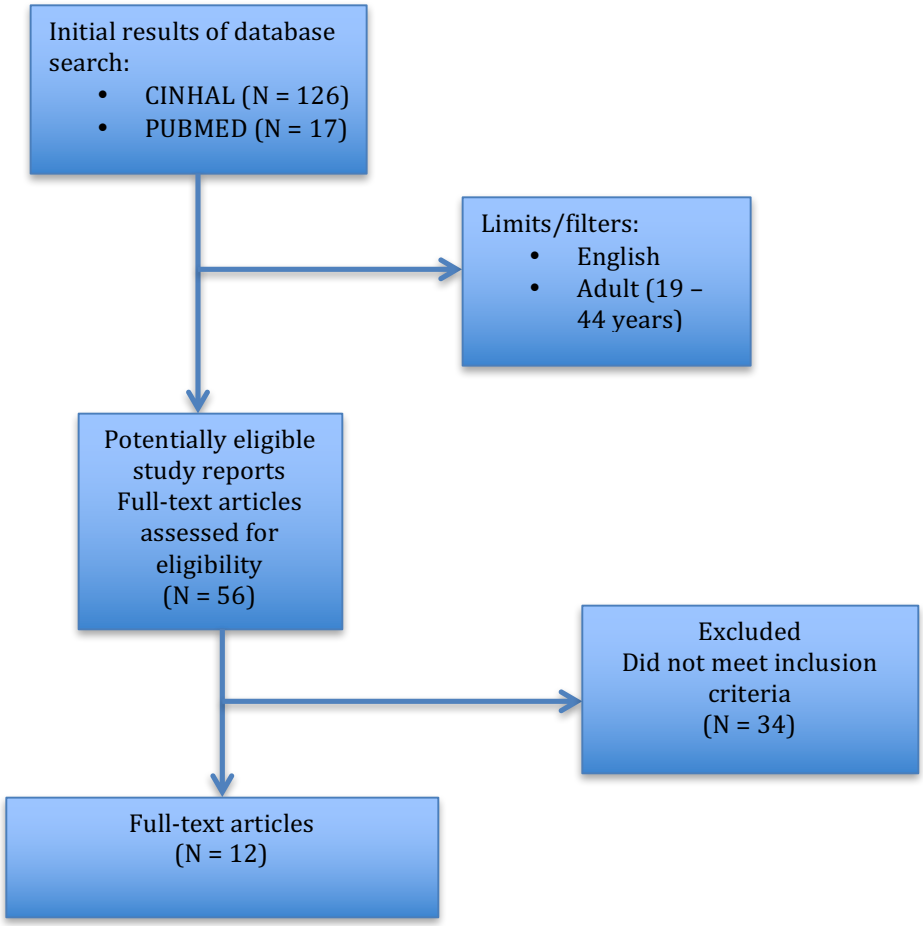

Table 1. Principle-based concept analysis

Author(s), Year, Study Design, Sample Size (n)	**Epistemiological**	**Pragmatic**	**Linguistic**	**Logical**
Acar, Cuvas, Ceyhan, & Dikmen, 2013 Randomized Control Trial (RCT) n= 52	Acupuncture to reduce anxiety Measurement Instruments: State-Trait Anxiety Inventory BIS	*Yintang* point acupuncture reduced preoperative anxiety ($p = 0.018$) and BIS values ($p < 0.0004$)	Reduced anxiety pre-operatively	Preoperative setting • Anxiety • BIS
Agarwal et al., 2005 RCT n=76	Acupressure to decrease anxiety Measurement Instruments: Visual Stress Scale BIS	*Extra 1* point acupressure decreased anxiety and BIS pre-operatively ($p < 0.001$)	Decreased anxiety preoperatively	Preoperative setting • Anxiety • BIS
Binns-Turner, Wilson, Pryor, Boyd, & Prickett, 2011 Quasi-experimental n=30	Music to decline anxiety levels Measurement Instrument: State Anxiety Scale	Perioperative music revealed a significant decline in anxiety levels ($p < 0.001$)	Perioperative decline in anxiety	Perioperative period - preoperative, intraoperative, and postoperative • Anxiety • Vital signs • Pain
Braden, Reichow, & Halm, 2009 Prospective experimental pretest/post-test n=150	Essential oil for lowered anxiety Measurement Instrument: Visual Analog scales	Essential oil, Lavandin, lowered anxiety on OR transfer preoperatively ($p = 0.01$)	Lowered anxiety preoperatively	Preoperative setting • Anxiety • Pain
Brunges & Avigne, 2003 Group assignment study n=44	Music to lower Epinephrine levels Measurement Instrument: Urine epinephrine level	Music therapy resulted in lower Epinephrine levels and shorter lengths of stay	Lower epinephrine (thereby anxiety) levels In the perioperative period through hospital discharge	Perioperative period through discharge from hospital. • Epinephrine levels • Anxiety • Length of hospital stay

Cooke, Chaboyer, Schluter, & Hiratos, 2005 RCT n=180	Music to reduce mean anxiety scores Measurement Instrument: State-Trait Anxiety Inventory	Preoperative music reduced mean anxiety scores ($p < 0.001$)	Reduced anxiety pre-operatively	Preoperative setting • Anxiety
Gonzales et al., 2010 RCT n=44	Guided imagery to decrease anxiety levels Measurement Instruments: Amsterdam Preoperative Anxiety & Information Scale Visual Analog Scale	Preoperative guided imagery resulted in decreased anxiety levels postoperatively ($p = 0.002$)	Decreased anxiety preoperatively and postoperatively	Preoperative and postoperative setting • Anxiety • Pain • Length of stay in PACU
Johnson, Raymond, & Goss, 2012 Experimental three-group design with pre- and post-measurement of anxiety n=119	Music and headsets to decrease anxiety scores Measurement Instrument: Rapid Assessment Anxiety tool	Perioperative music and noise-blocking headsets both resulted in decreased anxiety scores	Decreased anxiety in the perioperative period	Perioperative period - preoperative, intraoperative, and postoperative • Anxiety
Mitchell, 2011 Questionnaire n=674	Measurement Instrument: Questionnaire		Anxiety is experienced by the majority but was found to be more prevalent with general anesthesia and female patients	Surgery
Ni,Tsai, Lee, Kao, & Chen, 2012 RCT n=183	Music to lower anxiety Measurement Instrument: State-Trait Anxiety Inventory	Musical intervention preoperatively lowered anxiety ($p < 0.001$)	Lowered anxiety preoperatively	Preoperative setting • Anxiety • Vital signs

Seers, Chrichton, Tutton, Smith, & Saunders, 2008 RCT n=118	Relaxation techniques to decrease anxiety Measurement Instrument: State-Trait Anxiety Inventory	Relaxation techniques decreased anxiety ($p = 0.20$)	Decreased anxiety from pre-intervention to immediately post-intervention and 1, 2, 3, and 4 hours later	Pre-admission clinic, pre-intervention, immediately post-intervention and 1, 2, 3 and 4 hours later. • Anxiety • Pain
Valiee, Bassampour, Nasrabadi, Pouresmaeil, & Mehran, 2012 RCT n=70	Acupressure to reduce anxiety levels Measurement Instrument: Visual Analog Scale	Acupressure reduced anxiety levels preoperatively ($p < 0.001$)	Reduced anxiety pre-operatively	Preoperative setting • Anxiety • Vital signs

Manuscript II

Instruments to measure preoperative acute situational anxiety: An integrative review

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Instruments to measure preoperative acute situational anxiety: An integrative review

Abstract

Acute situational anxiety is a subjective fearful feeling of emotion that is influenced by an immediate situation and can vary in intensity and duration among patients in the preoperative period of hospitalization [1-4]. In adults, the incidence of preoperative acute situational anxiety ranges from 11% to 80% [2,5]. Untreated anxiety in the perioperative period can lead to multiple deleterious effects for patients. Previous reviews on instruments to measure anxiety have not focused on the preoperative period of hospitalization for surgical patients. The objective of this integrative review is to synthesize and describe the instruments used over the last decade to measure preoperative anxiety in the surgical setting. Methods: A systematic search strategy of the PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO databases was used to review the literature. Results: A total of 370 manuscripts were identified but only 5 met the inclusion criteria for this review. Within the 5 manuscripts, varying levels of reliability, validity, and feasibility, of the instruments were inconsistently reported as well as context considerations. Conclusions: Reliability and validity are not consistently reported among preoperational anxiety measurement instruments making it difficult for providers to measure preoperational anxiety and provide treatment based on the instrument results.

Keywords: Anxiety; anxiety index; preoperative period; complementary therapy; instrument.

Introduction

Acute situational anxiety is a subjective feeling of an unpleasant, fearful emotion or uneasiness that is influenced by the immediate situation [1-4]. The intensity and duration of

acute situational anxiety can vary widely among both patients and environmental settings, this is especially noticeable in the hospital environments during the preoperative period [2]. The estimated that the incidence of preoperative anxiety ranges from 11% to 80% in adult patients [2,5]. Preoperative anxiety can lead to multiple deleterious physiological effects including: tachycardia, arrhythmias, hypertension, increased levels of pain with difficulty to provide pain management, increased anesthetic requirements, increased incidence of postoperative nausea and vomiting, increased surgical risks, and longer hospitalization[1,5-8].

In order for practitioners to identify ways to effectively reduce the anxiety experienced by patients in the preoperative period, reliable and valid instruments to measure preoperative anxiety must first be identified. Specific focus on the preoperative period of hospitalization for surgical patients has not been provided in previous reviews of anxiety measurement instruments. The objective of this integrative review is to synthesize and describe the instruments and their psychometric properties used to measure preoperative anxiety in the past decade.

Theoretical framework

The Stress Response Theory was used as a guide to define acute situational anxiety in the preoperative period of hospitalization. The Stress Response Theory postulates the breakdown of acute situational anxiety as: the threat (i.e., stress); the individual reaction (i.e., fear, anxiety, elation); and physiological fight or flight response of health and survival that includes the central nervous system and hormonal responses [9,10]. The theoretical definition of acute situational anxiety guided by the Stress Response Theory that was utilized in this review is: a subjective fearful feeling of emotion influenced by an immediate situation which is variable in intensity and duration among patients in the preoperative

period of hospitalization [1-4,9,10]. Figure 1 (adapted from the work of Rice, 2012) represents the underlying principles of the Stress Response Theory principles[10].

Stress (psychological, physical, and perceived) leads to an individual reaction as well as a central nervous system response often commonly known as "fight or flight"[11]. When a stressful situation arises sympathetic activation occurs, which subsides once the stressful encounter ends. In addition to a subsiding sympathetic activation, parasympathetic activity also engages [12]. Collectively these two systems work together to achieve autonomic nervous system balance [12]. Unfortunately, perfect balance is often not achieved due to chronic bouts of acute stress as well as overarching chronic stress. This occurrence often allows sympathetic drive to remain increased and over time damages the vasculature and other regulatory systems [12,13]. In 1993, McEwen and Stellar labeled this imbalance "allostatic load" and demonstrated that if it is not properly assessed, managed, and, treated it can lead to poor health outcomes [14]. Physiological indictors for determining allostatic load and overall health include, but are not limited to, systolic and diastolic blood pressures, total cholesterol, serum dihydroepiandrosterone (DHEA-S), 24-hour urinary cortisol excretion, urinary noradrenaline and adrenaline[10].

Search strategy

A systematic approach was used to review the literature. Three databases were queried: PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO. In the first step of the search, key words *preoperative period* and *anxiety* were used to retrieve relevant articles as well as additional key words related to the concept of interest within each database. The terms *acute*, *situational anxiety,* and *surgery* did not yield additional results. In the second step of the search, the following key words were

added to the searches: *complementary therapy* and *anxiety index* in PubMed, and *instruments* in CINAHL and PsycINFO. In the third step of the search, the following filters or limiters were employed: English language, adults (18 years and older), and publication within the last 10 years.

During the literature search, many studies related to preoperational anxiety were designed to assess a specific complementary therapy. As a result, the key word *complementary therapy* was added to narrow the scope of this literature review. Additionally, there were three studies from this search that addressed the psychometric properties of instruments that measure preoperational anxiety for application in languages other than English. These studies were excluded due to the heterogeneity of preoperative clinical settings between countries.

Results

The five studies included in this review all used instruments to determine acute situational anxiety in the preoperative period of hospitalization: the State-Trait Anxiety Inventory (STAI) [1], State Anxiety Inventory (SAI) [7], Standard Visual Analog Scale for anxiety (VAS) [15], Visual Analog Scale (VAS) [16], and Anxiety Specific To Surgery Questionnaire (ASSQ) [8]. None of the studies reviewed reported a guiding theoretical framework however they all report psycho-physiological response data. The psycho-physiological responses included all of the following: Bispectral Index (BIS) monitoring [1]; Heart Rate (HR), Respiratory Rate (RR), Diastolic Blood Pressure (DBP), and Systolic Blood Pressure (SBP) [15]; Mean Arterial Pressure (MAP) and pain scores [7]; Heart Rate Variability (HRV) [16]; and the Multidimensional Scale of Perceived Social Support [8]. Four of the five studies were conducted outside of the United States. A total of 819 adult subjects were assessed within

the 5 studies. The description details of instruments varied widely across studies. Overall, the quality of the studies ranged from medium (3) to low (2) level evidence informing the results [17]. The instruments' psychometric properties of reliability and validity are reported in Table 1.

Levels of Evidence

The Oxforde Centre for Evidence-Based Medicine (2011) grade the quality of a study based on a hierarchy of questions to find the *likely best evidence*[17]*.* There are 5 levels of studies. The OCEBM Levels of Evidence aims to assist clinicians in conducting a rapid appraisal of research. Three of the five studies are randomized trials and thus are considered level 2 studies (Table 1). The remaining two studies are a quasi-experimental design and descriptive study, which are considered level 3 studies (Table 1).

Reliability

Four of the five studies reported some measure of reliability. Reliability describes the consistency of an instrument or method to assign scores to subjects [3]. As a subjective concept, acute situational anxiety can only be measured by asking the patient about his or her current level of anxiety. Thus stability is often not expected and the internal consistency of a tool to measure a transient fearful emotion such as anxiety is commonly reported as Cronbach's alpha coefficient versus split-half reliability [18]. Two of the five studies reported reliability in terms of internal consistency with Cronbach's alpha coefficient scores. However, there was significant variation in the Cronbach's alpha coefficient scores reported. Another two of the five studies reported that reliability of their instrument was based on its use in previous similar research. In an effort to quantitatively define reliability, the studies referenced regarding reliability were reviewed and additional

information, if available, was added to table 1. Finally, one of the five studies examined did not report reliability.

Validity

Validity describes if an instrument or method measures what it is intended to measure [3]. Of the five studies reviewed, three report some measure of validity. One of the five studies reported reference data for criterion validity of VAS as an instrument for measuring anxiety [16]. Two of the five studies report that the validity of their instrument is based on its use in previous similar research. In an effort to quantitatively define validity, the studies referenced regarding validity from the last 10 years were reviewed and additional information, if available, was added to table 1. The remaining two of the five studies do not discuss or report measures of validity. Though not reported as convergent or discriminant validity, all five studies use psycho-physiological responses among participants to corroborate the level of anxiety measured with the study's selected scale [18].

Discussion

Five instruments that measure acute situational anxiety in the preoperative period of hospitalization met criteria for inclusion in this integrative review. Previous reviews on instruments to measure anxiety have not focused on the preoperative period of hospitalization for surgical patients. Thus, the five studies included in this review represent the instruments used, within the last decade, to measure preoperative anxiety. Additionally, descriptions and implications of their psychometric properties are discussed.

According to this literature review, Spielberger's State-Trait Anxiety Inventory (STAI) and the Visual Analog Scale (VAS) for anxiety are the two most commonly used instruments to measure anxiety in the clinical setting [1,7,8,15]. The State-Trait Anxiety

Inventory measures both state anxiety, feelings when subjected to an anxiety-provoking stimulus, and trait anxiety, disposition of responses to stressful situations [6]. State and trait anxiety are each assessed by answering 20 items using a 4-point scale. Higher scores are indicative of greater anxiety [19]. Historically, the internal consistency coefficients have ranged from 0.86 to 0.95, with evidence to attest to the concurrent and context validity of the scale [19]. The Visual Analog Scale (VAS) for anxiety is a simple instrument to measure anxiety. Along an equally divided continuum (i.e., 0 to 10 or 0 to 100), the subject selects their level of anxiety.

Psychometric scoring for both reliability and validity is sparse among the included studies. Multiple studies report that both reliability and validity of the instrument was based on its use in previous research. In an effort to quantitatively define reliability and validity of the instrument, the references cited within the five studies were also reviewed. Unfortunately, the referenced studies offered additional references to other studies regarding reliability and validity or no information regarding psychometric information on reliability or validity of the instruments used in the preoperative period to assess anxiety. Therefore one must consider that previous results of these instruments may not generalize when used in the preoperative setting.

Acute situational anxiety is a subjective concept and can only be measured by asking the patient about his or her current level of anxiety. In order for providers to reduce measurement error and make appropriate clinical decisions from these subjective reports it is important to use an instrument with adequate reliability and validity. Researchers should not continue to perpetuate the use of anxiety indices without first acquiring new data on the reliability and validity of a tool for their patient population and setting.

Adequately identifying anxiety and treating anxiety are patient-centric concerns as reducing allostatic load is important to optimize patient health. Acute situational anxiety in the preoperative period of hospitalization is a complex concept. As a result a single score on a questionnaire or scale may not encapsulate all of the psycho-physiological clinical indicators of anxiety. Across the five studies reviewed the following indicators were captured: heart rate, heart rate variability, blood pressure, mean arterial pressure, pain, bispectral index (BIS), social support, and respiratory rate [1,7,15,16].

Further research aimed at establishing a reliable and valid instrument (and corroborative physiological metric) to measure acute situational anxiety in the preoperative period of hospitalization is warranted. Understanding the central nervous system response to stress and accurately assessing a patient's level of anxiety with a reliable and valid instrument in the preoperative period will enable providers to best tailor an anesthetic plan for each individual patient. Finally, research within the United States attempting to reduce acute situational anxiety through complementary therapies in the preoperative period of hospitalization are in their infancy making additional research warranted.

Conclusion

There are only a few instruments available to measure the concept of acute situational anxiety in the preoperative period of hospitalization. Of the five studies presented, reliability and validity are not consistently reported. This should raise concerns for providers who wish to use these instruments to measure preoperational anxiety and provide treatment based on the instruments' results. As a practicing CRNA, I can attest to the need for a deeper understanding of the concept of acute situational anxiety in the

preoperative period and the need for reliable and valid instruments to measure it. The physiological imbalance that occurs due to acute stress is important for practitioners since early detection and treatment of acute situational anxiety has the potential to reduce the deleterious effect of anxiety on the body and lead to improved patient outcomes.

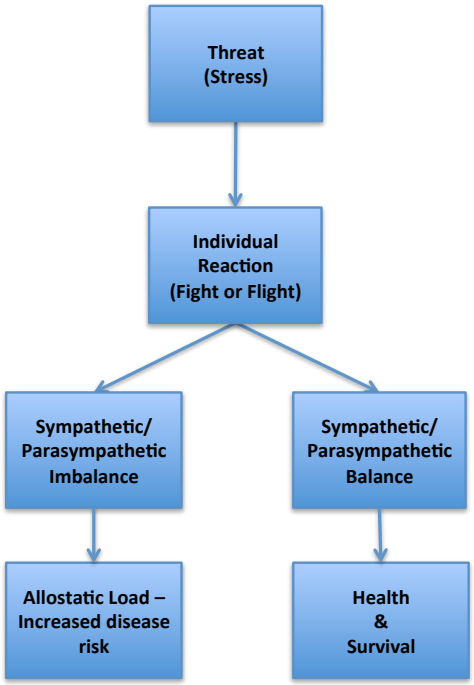

Figure 1. The Stress Response Theory. Diagram adapted from Rice, 2012 [9-14].

Instrument Reference	Framework/ Psycho-physiological response	Sample Subjects	Instrument Description and Scoring	Reliability	Validity	Feasibility	Level of Evidence[17]
State-Trait Anxiety Index (STAI): [1]	No framework reported; BIS monitoring	Adult surgical patients undergoing general or regional anesthesia, Ankara Training and Research Hospital of Ministry of Health, Ankara, Turkey, n=52	Consists of two 20-item sections for state anxiety (STAI-S) and trait anxiety (STAI-T)	Reported as: *supported by studies that demonstrated reductions in BIS and STAI correlated well with anxiolysis.* Correlations between dose propofol for BIS 65 and S-STAI was $r^2 = 0.033$ and T-STAI was $r^2=0.067$ from the original study[6]	Reported as "supported by studies"	20-30 minutes to complete on average, 40-item questionnaire potentially time consuming	2: prospective, randomized, single-blinded, controlled study.
Standard visual analog scale (VAS) to measure anxiety: [15]	No framework Reported; RR, HR, DBP, SBP	Adult surgical patients scheduled for abdominal surgery, Tehran, Iran, n=70	Visual analog scale from 0-10 to measure anxiety, mean anxiety scores were compared before and after intervention	Reported as proven reliable from its use in several different research studies[20-22]	Reported as proven valid from its use in several different research studies[20-22]; correlation coefficient (r) of 0.55-0.84 between VAS and STAI[21]	Simple tool, data is limited based on one scale rating, easier to use in difficult clinical settings[21]	2: randomized controlled clinical trial.
20-item Spielberger State Anxiety	No framework reported; MAP, Pain scores	Convenience sample of women with	20-item scale, anxiety level scores from T1 to	Internal consistency values for the	Not reported	10 minutes to complete; 20-item scale[21]	3: quasi-experimental design.

Scale (SAI): [7]		breast malignancy undergoing mastectomy at an urban hospital in western Tennessee, n=30	T2 were compared	SAI were reported as 0.958 at T1 and 0.973 at T2			
Visual Analog Scale (VAS): [16]	No framework reported; HRV	Adults waiting for surgery without premedication at a metropolitan teaching hospital in Taiwan, n=167	VAS is a 10-cm horizontal line marked by vertical lines at 1 cm intervals, scores range from "not anxious at all" (0) to "extremely anxious" (10)	Not reported	Report reference data for criterion validity of VAS for measuring anxiety, correlation with hospital anxiety (r=0.28) and STAI (r=0.5-0.6 or 0.78)	Simple tool, 5 seconds for patient to communicate their anxiety level and patient can remain lying flat	2: randomized controlled clinical study.
Anxiety Specific to Surgery Questionnaire (ASSQ); [8]	No framework Reported; Multidimensional Scale of Perceived Social Support	Adult patients having surgery at a university hospital in Central Anatolia region of Turkey, n=500	10 item questionnaire with a five-point scale for scoring (1 = strongly disagree and 5 = strongly agree) to assess patient specific concerns about what may happen during and after the surgery	Cronbach's alpha = 0.73 for this study.	Not reported	10-item questionnaire	3: descriptive study.

Table 1. Data extraction and psychometric properties

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Manuscript III

Aromatherapy for preoperative anxiety among female breast surgery patients: A feasibility study

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Abstract

Objective: Acute situational anxiety can affect a significant proportion of adult patients undergoing surgery. Failure to effectively manage anxiety in the perioperative period can lead to multiple adverse outcomes. The purpose of this study was to determine the feasibility of providing aromatherapy for anxiety during the preoperative period. **Methods:** Thirty female patients scheduled for breast surgery were recruited and enrolled in the study over a 6-week period. Feasibility was assessed through measuring participant and provider responses that were mapped to the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework and anxiety was measured with a 10-cm visual analog scale (VAS). **Results:** The majority of participants (81.8%, *n*=18) and providers (30%, *n*=3) reported being extremely likely to use or order an aromatherapy patch in the future. There was a statistically significant decrease from baseline anxiety to final anxiety measurements (M=5.7, SD=2.6 vs. M=4.2, SD=3.3; t[29]=2.3, p=0.03). **Conclusion:** Aromatherapy is a feasible and potentially efficacious intervention to reduce anxiety in the preoperative period of surgery for female patients undergoing breast surgery and may improve their preoperative experience. Future research warrants a randomized controlled clinical study.

Keywords: anxiety, preoperative, aromatherapy, complementary therapy, breast surgery

Introduction

Acute situational anxiety is a subjective feeling of an unpleasant, fearful emotion or uneasiness that is influenced by the immediate situation[1-4]. The intensity and duration of acute situational anxiety can vary among patients in the preoperative period before surgery[2]. Previous studies estimate that the incidence of preoperative anxiety ranges from 11% to 80% in adult patients[2,5]. In accordance with the Stress Response Theory[6,7], numerous deleterious effects of untreated anxiety during this period have been documented including tachycardia, arrhythmias, hypertension, increased levels of pain, difficulty with providing pain management, increased anesthetic requirements, higher incidence of postoperative nausea and vomiting, higher surgical risks, and longer hospitalization[1,5,8-10]. According to the Institute of Medicine[11], a major goal of patient-centered care is to assess negative bio-behavioral changes associated with stress and to implement strategies to alleviate those changes. Traditional anxiety treatment includes medications such as the anxiolytic, midazolam, which has been shown to produce negative physiological effects such as delayed awakening, nausea and vomiting, and other adverse side effects[9]. Non-pharmacological interventions such as music, acupuncture, relaxation techniques, and aromatherapy have been shown to reduce and/or alleviate anxiety without any sequelae[1,9,12,13].

Aromatherapy for Preoperative Anxiety

Aromatherapy is a low-risk complementary therapy that uses natural, plant essences (e.g. lavender, spearmint, peppermint, citrus) for therapeutic purposes[14,15]. Essential oils may provide a more gentle treatment option with significant psychological and physiologic benefits, without the use of artificially created anxiolytic chemicals[15,16].

Few studies to date have assessed the use of aromatherapy to reduce anxiety in the preoperative period of surgery. Aromatherapy offers multiple benefits over other complementary therapies (e.g. music, acupuncture, and relaxation techniques) as aromatherapy does not require active patient participation, supplemental equipment, new skills sets, or additional personnel for implementation. For this study, an aromatherapy skin patch was selected as a complementary modality to assess preliminary signals of efficacy on anxiety relief for female surgical patients undergoing breast procedures.

Prior Aromatherapy Research

Aromatherapy is gaining popularity as a complementary therapy strategy to manage anxiety. Over the last decade, a body of evidence has emerged suggesting that aromatherapy positively affects surgical patients in the preoperative setting. In 2009, Braden, Reichow, and Halm[17] used an experimental pretest/posttest design to investigate the effect of essential oils on preoperative anxiety in 150 adult patients (75 females and 75 females) undergoing gastrointestinal, genitourinary, and orthopedic procedures. They found that the topical use of the essential oil lavandin in comparison to the control and sham (jojoba oil) groups was statistically significant in lowering preoperative anxiety ($p = 0.01$) using a Visual Analog Scale (VAS) at the time of transfer to the Operating Room (Mean Scores = 29.96 lavandin group, 37.48 control group, 35.78 jojoba group)[18].

In 2011, Fayazi, Babashahi, and Rezaei[18] conducted a clinical study on the effect of inhalation aromatherapy on preoperative anxiety with 72 adult patients scheduled for heart and abdominal surgery. They reported a statistically significant difference in anxiety levels ($p = 0.001$) on the State-Trait Anxiety Index (STAI) between the case group and control group after twenty minutes of inhalation with a handkerchief containing lavandula

(Mean differences = 12.388 case group, 2.416 control group)[19]. In 2013, Ni et al.[13] conducted a randomized controlled trial on the anxiolytic effect of aromatherapy on 109 patients awaiting ambulatory surgery. The plant oil bergamot was diffused in the ward through an ultrasonic aroma diffuser device. The investigators reported a statistically significant decrease in STAI scores in the bergamot essential oil group compared to the control group in patients without previous surgical experience (-3.0 versus -2.0, $p = 0.021$) and in patients with previous surgical experience (-4.0 versus -1.0, $p = 0.005$). Additionally, heart rate (HR) (-6.0 beats/min, $p = 0.015$), systolic blood pressure (-11.0 mmHg, $p < 0.001$), and diastolic blood pressure (-5.0 mmHg, $p = 0.012$) significantly decreased in the bergamot group[13].

While these studies suggest that the use of aromatherapy as an anxiolytic agent has been beneficial for patients in the perioperative period, there is no standard delivery modality for aromatherapy. The inhalation technology and vapor delivery aromatherapy patch by Bioesse ® Technologies, LLC is a new and innovative modality used to consistently deliver aromatic essential oils to surgical patients in the preoperative period of hospitalization[16]. The patch contains 100% naturally pure lavender (*Lavandula Angustfolie*) essential oil[16]. The design of the patch includes an occlusive barrier to prevent oils from contacting or being absorbed through the skin but allows olfactory scent inhalation which activates receptor sites in the brain[16].

Female Surgical Patients

A number of studies report that female surgical patients experience more preoperative anxiety compared to their male counterparts[10,19-21]. Additionally, anxiety is increased when facing a procedure with a known cancer diagnosis or one that has the

potential for a cancer diagnosis[5,9]. Few studies to date have targeted preoperative anxiety in female patients undergoing lumpectomy, mastectomy, sentinel node biopsy or axillary node dissection procedures; thus methods that are best suited to reduce anxiety in this patient population remain poorly understood.

Prior research suggests that there is no standard assessment instrument for anxiety among female surgical patients. Despite the availability of instruments to measure anxiety, there is currently no routine assessment of anxiety using a reliable and valid instrument in the preoperative period at this medical center. This lack of standardized assessment has the potential to lead to inadequate and ineffective anxiety management in the preoperative period that could produce negative psycho-physiological outcomes for female surgical patients.

Purpose

This study evaluated the feasibility of providing lavender aromatherapy through a sustained-release patch applied to the chest and the use of a VAS to measure anxiety levels during the preoperative period for female patients scheduled for breast surgery. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework was selected to guide the feasibility assessment process[22,23]. The study aims were to 1) evaluate and determine the feasibility of using an aromatherapy patch in the preoperative period of surgery for anxiety using the RE-AIM framework by assessing recruitment, retention, adherence, and adoption; and 2) collect data on preliminary signals of efficacy on anxiety measured with a VAS and physiological signs of anxiety including HR and mean arterial blood pressure (MAP).

Theoretical Framework

The theoretical framework underlying this study is Hans Selye's General Adaptation Syndrome Theory of Stress[7]. Selye's model describes a three-stage bodily response to a stressor: 1) alarm, 2) resistance, and, 3) exhaustion[7]. During the alarm stage, the sympathetic nervous system is activated resulting in physiological changes that include but are not limited to increased respirations, heart rate, blood pressure, and perspiration[7]. During the resistance stage, the parasympathetic nervous system is activated in an attempt to restore homeostatic balance[7]. If a homeostatic balance cannot be restored, exhaustion occurs and the body is susceptible to disease and death[7]. The goal is adaptive coping in response to the stressor to balance the biological, psychological and social processes to resolve the stress response[7]. This study assessed the feasibility of providing an aromatherapy intervention to assist with adaptive coping for preoperative anxiety in female patients scheduled for breast surgery.

Methods

Study Overview

This study evaluated the feasibility of using an aromatherapy patch and measuring anxiety and its physiological indicators in the preoperative period of surgery for female patients scheduled for breast surgery. The study was conducted at the Ashley River Tower Hospital Operating Room at the Medical University of South Carolina (MUSC). The Ashley River Tower Operating Room performs approximately 3,500 cases per year. This study was conducted in January 2016 through March 2016. The study was approved by the MUSC Institutional Review Board and written informed consent was obtained.

Sample, Setting and Recruitment

Female patients scheduled for lumpectomy and/or mastectomy and/or sentinel node biopsy and/or axillary node dissection were invited to participate in the study until a convenience sample of 30 patients was reached. Approximately ten lumpectomy and/or mastectomy and/or sentinel node biopsy and/or axillary node dissection cases are scheduled per week. We anticipated that 50% of patients scheduled for these procedures would be eligible and would consent for enrollment resulting in approximately six weeks of recruitment to reach the target sample size of 30 participants. The sample size of 30 female participants was based on the pragmatics of recruitment and numbers needed to assess feasibility according to Leon et al[24].

Inclusion criteria included English-speaking, female patients, aged 18 years or older presenting for lumpectomy and/or mastectomy and/or sentinel node biopsy and/or axillary node dissection surgery. Exclusion criteria included known allergies to lavender and/or adhesive tape, acute serious medical conditions deeming the surgery an emergency at the time of enrollment, cognitive, mental, or visual impairment such as a diagnosis of blindness, anosmia or dementia in the medical record that would prevent participation in study components, and asthma or any reactive airway disease diagnosis that could be exacerbated by the aromatherapy patch. The preoperative Registered Nurse (RN) introduced female surgical patients scheduled for any of the appropriate procedures to the study during the standard phone call two days before surgery using the following script: "One of our nurse anesthetists is conducting a study on anxiety and aromatherapy during the preoperative period, would you be interested in participating in the study?" Those patients who indicated their interest in participating in the study were approached

regarding enrollment into the study upon arrival to their assigned preoperative bay on the day of surgery.

Enrolled participants received the aromatherapy patch protocol that included placement of a lavender Bioesse®[16] aromatherapy patch by the preoperative RN during routine monitor and accessory placement. Participants also received standard preoperative care which included, but was not limited to, patient identification with a hospital bracelet, changing into a hospital gown, preoperative vital sign measurement with a disposable blood pressure cuff and pulse oximetry probe, and the initiation of preoperative order sets.

Measures

Demographic data including age, race/ethnicity, marital status, and number of children and clinical characteristics such as diagnosis, surgery and surgical history, American Society of Anesthesiologists (ASA) physical status classification which is a grade of preoperative health for the surgical patient[25], body mass index in kg/m^2 (BMI), current anxiolytic, sedative and/or antidepressant medications, and smoking status were collected from the participant and/or the participant's medical record. Feasibility was assessed through the five dimensions (Reach, Effectiveness, Adoption, Implementation, Maintenance) of the RE-AIM framework. Study data and participant and provider responses to questions were mapped to the five dimensions. Participants received a follow up phone call from the PI within 24-hours of their discharge from the post-anesthesia care unit (PACU) and providers received a post-study survey via email within 48-hours of study completion to assess feasibility (Appendix 1 & 2).

RE-AIM for feasibility. Reach, defined as the number of individuals who were willing to participate in the study was measured through study recruitment and attrition.

Effectiveness measured the impact of the intervention. This dimension was assessed during the follow up phone call by asking participants to rate if they believed the patch was helpful on a scale from 0 (not helpful at all) to 5 (extremely helpful). Adoption was defined as the number of individuals, participants and providers, who were willing to initiate the protocol. This dimension was assessed during the follow up phone calls by asking participants to rate their likeliness to participate in an aromatherapy study in the future. Providers were asked to rate their likeliness to adopt a VAS for anxiety assessment and to use an aromatherapy patch for patients experiencing acute preoperative anxiety. Implementation examined the study protocol. This dimension was assessed during the follow up phone call with participants by asking if they had any recommendations for the study. During the post-study survey, providers were asked if they identified any problems with implementation of the study protocol, if they had any recommendations for the study, and if any problems were identified with patch placement or removal. Maintenance was defined as the extent to which the protocol may become a part of routine practice. This dimension was assessed during the post-study survey by asking providers to rate their likeliness to use an aromatherapy patch for patient's experiencing acute preoperative anxiety on a scale from 0 (not likely at all) to 5 (extremely likely). Additionally, participants and providers were asked to describe the scent of the patch as mild, moderate or strong.

Anxiety. Patients' anxiety levels were assessed by the principal investigator (PI) using a 10-cm VAS. The scale was anchored on each end with both numeric and verbal indicators (e.g., 0 = no anxiety and 10 = extreme anxiety) (Appendix 3). A standard ruler was used to measure marks between 0 and 10 in centimeters to one decimal place. The participant was asked to indicate their current level of anxiety by drawing a single vertical line directly on

the 10-cm VAS at baseline prior to the patch being placed on the chest by the preoperative RN and then every 15 minutes after patch placement until the time of anesthesia start. Anesthesia start was defined as arrival of the anesthesia provider (e.g., Certified Registered Nurse Anesthetist (CRNA), anesthesia resident, anesthesiologist) at the bedside for transfer to the operating room and/or administration of an anxiolytic or regional anesthetic.

Vital Signs. HR in beats per minute (bpm) and MAP measurements in millimeters of mercury (mmHg) were monitored and recorded by the PI from the preoperative monitors at the same 15-minute interval as the VAS. The PI removed the patch from the participants' chest at the time of anesthesia start.

Data Capture and Statistical Analysis

Study data were entered into Research Electronic Data Capture (REDCap) a secure, web-based application designed to support data capture for research studies that provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources[26].

Data were analyzed using statistical software SPSS[27] Version 23. The study sample was characterized using descriptive statistical analyses for demographic and clinical factors. Measures of feasibility including reach, effectiveness, adoption, implementation, and maintenance were reported as proportions for categorical measures; continuous measures were reported as means and standard deviations. Baseline and final measurements of VAS and VS measurements were reported as means and standard deviations with their 95% confidence intervals. Paired sample t-tests were conducted to

compare the differences between the means of baseline and final measurements of VAS and VS measurements. Comments from both participants and providers were summarized.

Results

Demographics

During the six-week recruitment period, 34 potentially eligible female patients scheduled for surgery were approached and asked to participate in the study. Thirty female participants (88%) were screened eligible and enrolled in the study. The mean age of the participants was 52.3 years ± 16.4 with a range of 18 years to 89 years (Table 1). The mean BMI was 29.1 kg/m^2 ± 6.9 (Table 1). The racial and ethnic enrollment profile was 66.7% White (*n*=20), 26.7% Black or African American (*n*=8), 6.7% Asian (*n*=2), and 96.7% not Hispanic or Latino (*n*=29). Diagnoses included 46.7% malignant neoplasm, breast (*n*=14), 3.3% benign neoplasm, breast (*n*=1), and 50% other (*n*=15; Table 1).

Marital status included 56.7% married (*n*=17), 26.7% not married (*n*=8), and 16.7% divorced (*n*=5). The number of children ranged from 69.9% (*n*=21) with 0-2 children, to 26.7% (*n*=8) with 3-4 children to 3.3% (*n*=1) with greater than 5 children. Participant ASA physical status classification for preoperative health ranged from I (healthy patient) to III (severe systemic disease)[25] (I = 6.7% (n=2), II = 70% (n=21), III = 23.3% (n=7)). Smoking status included 66.7% never smoked (*n*=20), 20% quit smoking > 1 year ago (*n*=6), and 13.3% current smoker (*n*=4; Table 1). Thirteen participants (43%) had active prescriptions for an anxiolytic, sedative and/or antidepressant.

Feasibility Assessment

Participants waited in the preoperative area an average of 78.7 ± 31.9 minutes. The preoperative time for participants, which is defined as arrival in the preoperative bay to

anesthesia start, ranged from 30 to 168 minutes. The average amount of time that the lavender aromatherapy patch was worn by participants was 58.1 ± 31.4 minutes. The total patch time for participants, which is defined as patch placement to patch removal, ranged from 9 to 152 minutes.

The RE-AIM dimensions, definitions, assessment measures and results are presented in Table 2. For reach, 29 participants (97%) completed the entire preoperative period. One participant (3%) requested that the patch placement be removed prior to the first 15-minute assessment due to the patch scent being "too strong" after chemotherapy. All 30 participants agreed to a follow up phone call but 8 participants (26.7%) could not be reached via phone within 24-hours of PACU discharge. Twenty-two participants (73.3%) completed the follow up phone call portion of the study. Twelve providers, 8 RNs and 4 surgeons, participated in the study; of those, ten providers (83%), 8 RNs and 2 surgeons, completed the post-study survey. No adverse events were reported in the preoperative period, follow up phone call, or post-study survey portions of the study.

The effectiveness ratings ranged from 0 (not helpful at all) to 5 (extremely helpful). The majority (81.7%) of effectiveness ratings reported by participants were 3 (13.6%; *n*=3), 4 (13.6%; *n*=3), and 5 (54.5%; *n*=12). The adoption ratings ranged from 0 (not likely at all) to 5 (extremely likely). The majority of adoption ratings reported by participants were 5 (81.8%; *n*=18). The majority (90%) of ratings reported by providers for the adoption of a VAS instrument were 0 (40%; *n*=4), 1 (10%; *n*=1), 2 (20%; *n*=2), and 3 (20%; *n*=2). For adopting the use of an aromatherapy patch, the majority (70%) of ratings reported by providers were 3 (20%; *n*=2),4 (20%; *n*=2), and 5 (30%; *n*=3; Table 3).

For implementation, 41% of participants and 10% of providers reported recommendations for the study. The recommendations included "*a longer aromatherapy patch time"; "not enough preoperative time to get the full benefit of the therapy"; "addition of other aesthetics (i.e., lighting, music, additional aromas, etc.) in the preoperative setting"; "participants enjoyed having the option"; "choice of site other than the chest for patch placement";* and *"after surgery would be a nice time for it too"* (Table 2). The maintenance ratings of the scent for participants were 22.7% (*n*=5) mild, 54.5% (*n*=12) moderate, and 22.7% (*n*=5) strong whereas the providers' ratings of the scent were 50% (*n*=4) mild, 25% moderate (*n*=2), and 25% (*n*=2) strong.

Impact measures

Mean baseline, final and change in VAS, HR and MAP measurements with their means, standard deviations, and 95% confidence intervals are presented in Table 3. There was a significant decrease in the anxiety VAS measurements from baseline to final scores (M=5.7cm, SD=2.6cm vs. M=4.2cm, SD=3.3cm, p=0.03; Table 3). No significant change in HR or MAP from baseline to final measurement was observed for this sample (M=76.1bpm, SD=12.9bpm vs. M=75.9bpm, SD=12.0bpm, p=0.922) and (M=87.1mmHg, SD=13.7mmHg vs. M=84.5mmHg, SD=12.3mmHg, p=0.134; Table 3) respectively.

Discussion

The aims of this study were to assess the feasibility of using an aromatherapy patch in the preoperative period and to examine preliminary signals of efficacy on reducing anxiety with a VAS and physiological signs of anxiety including HR and MAP in a sample of female patients undergoing breast surgery procedures. Demographic data demonstrated

that a wide range of females, from teens to octogenarians, were interested in using aromatherapy to augment preoperative anxiety.

The mean BMI of 29.1 kg/m^2 for this study sample indicated an overweight patient population[28]. The Centers for Disease Control and Prevention report that obese people are at an increased risk for a number of diseases and health conditions which include, but are not limited to, breast cancer and mental illness such as depression and anxiety[28-31]. Previous research on perioperative and postoperative anxiety suggests that a known cancer diagnosis or the potential for a diagnosis of cancer will increase anxiety[5,9]. To better understand the association between a cancer diagnosis and acute preoperative anxiety further research is needed.

Social support systems are a part of the adaptive coping process to a stressor[7]. In an effort to determine available support systems of participants, information on marital status and number of children was collected. However, all participants had visitors, either family members or friends, with them for support on the day of surgery in the preoperative area. This demonstrates that the participants understood the importance of having their support system with them during the preoperative period of surgery. Additionally, the health care team encourages preoperative visitors. The surgeon speaks with the patient and their family member(s) and/or friend(s) prior to surgery and then again to the pre-determined support system after surgery. A future study should address to what extent support systems in the preoperative period influence anxiety.

Feasibility was evaluated and determined through the five dimensions of the RE-AIM framework. Data from this study demonstrated that the approaches to recruitment, retention, adherence and adoption were feasible and acceptable to participants and

providers. In particular, the recruitment approach in which the RNs introduced the study to patients during the preoperative call was found to be a successful strategy. This method of recruitment is promising for complementary therapy studies in the preoperative period of surgery. Additionally, enrolling participants on the day of surgery in their preoperative bay was a successful strategy. However, enrolling them prior to them changing into their hospital gown may have delayed patch placement. In an effort to maximize the total aromatherapy patch time for each participant, the preoperative RNs were diligent in placing the patch as soon as reasonably possible. The providers truly "bought in" to the study procedures and were instrumental to the success of this study.

After receiving an in-service on the study protocol, all of the preoperative RNs were able to follow the aromatherapy patch protocol. The patch was placed with the top of the patch sitting at the suprasternal notch using the manufacture recommendation for best patch adhesion[16]. This mode of delivery is consistent and holds better promise compared to past delivery modalities of diffusers, handkerchief doused with an essential oil, or topical application[13,17,18]. In observing each patch placement, the PI noted that some participants would comment to the RN (i.e., "*That smells good*; *I can smell it*, *That's nice"*) on the scent of the patch during placement. Total preoperative time and total patch time varied considerable for each participant which may have contributed to a less than optimal reduction in anxiety for participants.

The effectiveness of the patch was self-reported by participants and the majority of participants rated the impact of the aromatherapy patch as extremely helpful. Some of the participants' comments included "*a welcomed distraction"; "very impressed"; "I liked having the option"; "very relaxing"; "enjoyed the scent"; "soothing"; "I believe in lavender";* and *"the*

doctor loved it as well". One of the providers commented that they would be happy to offer this to all of their patients. Consistent with the previous aromatherapy research findings in the preoperative period, there was a significant decrease in anxiety VAS scores from baseline to final measurement. While not statistically significant, the physiological signs of anxiety including HR and MAP measurements indicated a trend toward decreases in mean HR and MAP from baseline to final measurement. Detecting statistically significant differences in these outcomes necessitates a larger sample size with adequate power and more sensitive physiological indicators such as heart rate variability.

All participants completed the 10-cm VAS without difficulty. The scale allowed them to indicate their current level of anxiety instead of stating a random number. One participant commented, "*it* [the VAS] *did let me know that the closer time* [to surgery], *I was getting anxious and I was able to tell somebody. I usually keep that to myself*." Taking the recommendations from both the participants and providers, this feasibility study has set the stage for the adoption of a sustained-release aromatherapy patch and utilization of a VAS for anxiety measurement into routine preoperative practice.

Limitations. A limitation to this study is the small convenience sample and the use of only one preoperative location. Additional limitations include the inability to standardize preoperative times and patch time application, the inability to control for the schedule timing of surgery, the differences in preoperative bay assignment, the number of attempts necessary for IV placement, and the number of providers that visit the patient in the preoperative period. The PI's field notes indicated that certain preoperative bays are predisposed to more traffic and noise and that multiple providers (i.e., Preoperative RN, operating room RN, surgical residents, medical students, CRNA, Student Registered Nurse

Anesthetist, anesthesiologist, and surgeons) visited the participants. The aromatherapy patch scent is another consideration. The scent of lavender may not appeal to all participants or providers. Having additional aromatherapy patch scents available should be a consideration for future research. Despite these limitations, this study supports that a sustained-release aromatherapy patch is a feasible, and potentially efficacious, intervention to reduce preoperative anxiety in female patient undergoing breast surgery and may improve their preoperative experience.

Conclusion

This feasibility study provides the first step toward understanding the role and impact of aromatherapy on preoperative anxiety reduction. Further research is needed to address the experience of preoperative anxiety and the challenges of managing preoperative anxiety. Our interdisciplinary team of nurses, anesthesia providers, and surgeons is well positioned to continue work in this area including a future randomized controlled trial to determine the effect of a sustained-release aromatherapy patch on preoperative anxiety.

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Table 1. Demographics of female breast surgery participants

Participant Characteristics (N = 30)	
	Mean ± SD
Age (years)	52.3 ± 16.4
BMI (kg/m^2)*	29.1 ± 6.9
	Percent (%)
Race	
White (*n* = 20)	66.7
Black or African American (*n* = 8)	26.7
Asian (*n* = 2)	6.7
Ethnicity	
Not Hispanic or Latino (*n* = 29)	96.7
Hispanic or Latino (*n* = 1)	3.3
Diagnosis	
Malignant neoplasm, breast (*n* = 14)	46.7
Benign neoplasm, breast (*n* = 1)	3.3
Other (*n* = 15)	50
Marital Status	
Married (*n* = 17)	56.7
Not married (*n* = 8)	26.7
Divorced (*n* = 5)	16.7
Number of Children	
0 – 2 (*n* = 21)	69.9
3 – 4 (*n* = 8)	26.7
>5 (*n* = 1)	3.3
ASA Physical Status Classification[25]	
I (*n* = 2)	6.7
II (*n* = 21)	70
III (*n* = 7)	23.3
Smoking Status	
Never Smoked (*n* = 20)	66.7
Current Smoker (*n* = 4)	13.3
Quit Smoking > 1 year (*n* = 6)	20

*BMI = Body Mass Index

[25] = American Society of Anesthesiologist physical status classification. I = healthy patient; II = mild, well-controlled systemic disease; III = severe systemic disease.

Table 2. RE-AIM dimensions for evaluating feasibility

RE-AIM Dimension	Definition	Assessment Measures	Results	Comments
Reach	The number of individuals who are willing to participate in the study.	Recruitment – the number of participants that enrolled divided by the number that were asked to participate. Attrition – the number of participants retained in the study.	Recruitment: 30 participants enrolled/34 approached = 88.2% Attrition: 1 participant withdrew in the preoperative period (3%) and 8 participants did not complete the post-study phone call (26.7%).	
Effectiveness	The impact of the intervention.	During the follow up phone call, participants were asked to rate if they believed the patch was helpful using a scale from 0 to 5 (0 = not helpful at all and 5 = extremely helpful).	Ratings (N=22): 0 = 9.1% (*n*=2) 1 = 0% 2 = 9.1% (*n*=2) 3 = 13.6% (*n*=3) 4 = 13.6% (*n*=3) 5 = 54.5% (*n*=12)	*A welcomed distraction, very impressed, I liked having the option, very relaxing, enjoyed the scent, soothing, I believe in lavender,* and *the doctor loved it as well*.
Adoption	The number of individuals who are willing to initiate the protocol.	During the follow up phone call, participants were asked to rate their likeliness to participate in an aromatherapy study in the future using a scale from 0 to 5 (0 = not likely at all and 5 = extremely likely).	Ratings (N=22): 0 = 9.1% (*n*=2) 1 = 0% 2 = 0% 3 = 9.1% (*n*=2) 4 = 0% 5 = 81.8% (*n*=18)	*I think it should be an option, love too, positive experience, most definitely, I feel great.*
		During the post-study survey, providers were asked to rate how likely they would be to adopt the use of a VAS for anxiety assessment in the preoperative period and how likely they would be to use an aromatherapy patch for patient's experiencing acute preoperative	Ratings (N=10): VAS 0 = 40% (*n*=4) 1 = 10% (*n*=1) 2 = 20% (*n*=2) 3 = 20% (*n*=2) 4 = 0% 5 = 10% (*n*=1) Patch 0 = 0% 1 = 10% (*n*=1)	*I would rather verbalize the 1-10 scale; I would likely often forget this tool. Participant stated: it (the VAS) did let me know that the closer time (to surgery), I*

		anxiety on a scale from 0 to 5 (0 = not likely at all and 5 = extremely likely)	2 = 20% (*n*=2) 3 = 20% (*n*=2) 4 = 20% (*n*=2) 5 = 30% (*n*=3)	*was getting anxious and I was able to tell somebody. I usually keep that to myself.*
Implementation	The assessment and use of the protocol.	During the follow up phone call, participants were asked if they had any recommendation for the study. During the post-study survey providers, were asked if the identified any problems with implementation of the study protocol, if they had any recommendation for the study, and if there were any problems with patch placement or removal.	Answers (N=22): Yes = 40.9 (*n*=9) No = 59.1% (*n*=13) Protocol (N=10): Yes = 20% (*n*=2) No = 80% (*n*=8) Recommendations: Yes: 10% (*n*=1) No: 90% (*n*=9) Patch Placement/Removal: Yes: 0% No: 100% (*n*=10)	*A longer aromatherapy patch time, not enough preoperative time to get the full benefit of the therapy, addition of other aesthetics (i.e., lighting, music, additional aromas, etc.) in the preoperative setting, participants enjoyed having the option, choice of site, other than the chest, for patch placement,* and *after surgery would be a nice time for it too.*
Maintenance	The extent to which the protocol may become a part of routine practice.	During the follow up phone call, participants were asked to rate how helpful they found the patch on a 0 to 5 scale (0 = not helpful at all and 5 = extremely helpful) and to describe the scent of the patch as mild, moderate or strong. During the post-study	Ratings (N=22): 0 = 9.1% (*n*=2) 1 = 0% 2 = 9.1% (*n*=2) 3 = 13.6% (*n*=3) 4 = 13.6% (*n*=3) 5 = 54.5% (*n*=12) Scent: Mild = 22.7% (*n*=5) Moderate = 54.5% (*n*=12) Strong = 22.7% (*n*=5) Ratings (N=10):	Scent: *Smells good, it was perfect, I liked the lavender – commonly used in spas so our brain makes that connections, strong for the first couple of minute but after that it was perfect, not a fan of lavender,*

		survey, providers were asked to rate how likely they would be to use an aromatherapy patch for patient's experiencing acute preoperative anxiety on a scale from 0 to 5 (0 = not likely at all and 5 = extremely likely) and to describe the scent of the patch as mild, moderate or strong.	0 = 0% 1 = 10% (*n*=1) 2 = 20% (*n*=2) 3 = 20% (*n*=2) 4 = 20% (*n*=2) 5 = 30% (*n*=3) Scent: Mild = 50% (*n*=5) Moderate = 30% (*n*=3) Strong = 20% (*n*=2)	*found it to be truly relaxing, overpowering, it didn't just blend in – I could focus on it.*

Table 3. Comparison using paired samples test for baseline and final VAS, HR, and MAP measurements

	Baseline	**Final**	**Change**	
Measurements	**Mean ± StD (95% CI)**	**Mean ± StD (95% CI)**	**Mean ± StD (95% CI)**	**p-value (t[df])**
VAS (cm)	5.7 ± 2.6 (4.7; 6.6)	4.2 ± 3.3 (3.0; 5.5)	1.4 ± 3.4 (0.15; 2.7)	0.030 (2.3[29])
HR (bpm)	76.1 ± 12.9 (71.3; 80.9)	76.0 ± 12.0 (71.4; 80.4)	0.17 ± 9.2 (-3.3; 3.6)	0.922 (0.1[29])
MAP (mmHg)	87.1 ±13.7 (82.0; 92.2)	84.5 ± 12.3 (79.9; 89.1)	2.6 ± 9.2 (-0.85; 6.0)	0.134 (1.5[29])

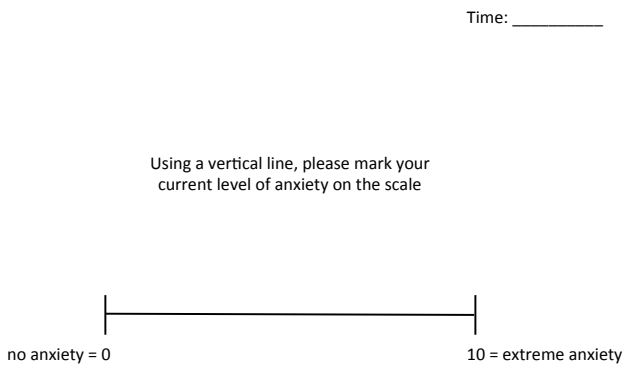
APPENDIX 1. Participant Follow Up Phone Call Questionnaire

1. On a scale from 0 to 5 (0 = not helpful at all and 5 = extremely helpful), how helpful did you find the patch? Comments:
2. Would you describe the scent of the patch as mild, moderate, or strong? a. Mild b. Moderate c. Strong Comments:
3. Do you have any recommendations for the study? a. Yes b. No Comments:
4. On a scale from 0 to 5 (0 = not likely at all and 5 = extremely likely), how likely would you be to participate in an aromatherapy study in the future? Comments:

APPENDIX 2. Provider REDCap Post-Study Survey

1. On a scale from 0 to 5 (0 = not likely at all) and 5 = extremely likely), how likely would you be to adopt the use of a Visual Analog Scale (VAS) for anxiety assessment in the preoperative period? Comments:
2. On a scale from 0 to 5 (0 = not likely at all) and 5 = extremely likely), how likely would you be to use an aromatherapy patch for patient's experiencing acute preoperative anxiety? Comments:
3. Did you identify any problems with implementation of the study protocol? a. Yes b. No Comments:
4. Do you have any recommendations to improve the process or protocol implementation? a. Yes b. No Comments:
5. Were there any problems with patch placement and/or patch removal? a. Yes b. No Comments:
6. Would you describe the scent of the patch as mild, moderate, or strong? a. Mild b. Moderate c. Strong Comments:

Appendix 3. 10-cm Visual Analog Scale for Anxiety Level Assessment (not to scale)



Conclusion

This dissertation explored the concept of relief from anxiety using complementary therapies in manuscript one. Relief was found to be a dynamic concept and relief from anxiety is critical in health care. Care guided by an ability to assess anxiety as a unique entity is essential for surgical patients to ensure their health, healing and wellbeing. Thus, further research to accurately define relief as well as measure relief from anxiety is a future goal.

In the second manuscript of this dissertation, instruments used to measure anxiety levels and their psychometric properties were explored. Unfortunately, only a few instruments exist that specifically measure acute preoperative anxiety for surgical patients. The VAS appeared to provide the easiest to use and most efficient measure in the preoperative period; however, reliability and validity were not consistently reported for all the instruments reviewed. This should raise concerns for providers who wish to use a VAS, the STAI, the SAI, or the ASSQ to measure preoperational anxiety and provide treatment based on the instruments' results. Further research is needed to design and implement a practical instrument with high sensitivity and specificity to measure anxiety in the perioperative period.

Building on the conclusions of manuscripts one and two, a study was designed and conducted to evaluate the feasibility of recruitment, retention, adherence, and adoption of a sustained-release lavender aromatherapy patch applied to the chest and the use of a VAS to measure anxiety levels during the preoperative period among female patients scheduled for breast surgery. The results of the study indicate that aromatherapy is a feasible and potentially efficacious intervention to reduce anxiety as measured by a VAS in the

preoperative period. The recruitment approach was highly feasible and acceptable to patients and adherence and adoption of the protocol was feasible and incorporated with ease by the preoperative providers. As a logical next step, an adequately powered randomized controlled trial is needed to determine the efficacy of a sustained-release aromatherapy patch on preoperative anxiety and the best approach to measure bio-behavioral outcomes.

Lessons Learned and Next Steps

Several limitations were substantiated by this dissertation. First, little is known about the "best" methods to assess, measure and treat acute situational anxiety in the preoperative period. This limitation led to a feasibility study rather than a randomized controlled study to first determine whether the approach was sound and acceptable to patients and providers, thus assessing implementation processes was the first step. Second, a convenience sample of female patients, from one preoperative location in a large quaternary medical center, scheduled for breast surgery was recruited for this study. These restrictions on sampling, location and surgical procedure will limit the generalizability of findings. Third, the use of biomarkers of stress such as cortisol, epinephrine, and norepinephrine levels or additional physiological signs such as respiratory rate, perspiration and heart rate variability could have provided more sensitive indicators of anxiety. Lastly, only one scent, lavender, was available to patients. This scent may not appeal to everyone; a choice of scents may have provided more positive outcomes on preliminary signals of efficacy, for example, on heart rate and blood pressure reductions. Despite these limitations, this dissertation contributes to the current body of knowledge on the concept of relief, instruments to measure acute situational anxiety, and the feasibility of

recruitment, adoption, and implementation of an aromatherapy intervention for anxiety in the preoperative period. The potential health implications for the field of symptom science are numerous.

A number of valuable lessons were learned about the research process from my interactions with members of the Protocol Review Committee and the Institutional Review Board and their processes to creating and utilizing an electronic database and opportunities to work with writing experts. Additionally, the time I spent in the preoperative area recruiting and monitoring participants allowed me to better understand the preoperative environment, have a better relationship with the preoperative nurses, and see first hand what the preoperative experience overall is like for patients. As for the next steps, our interprofessional team of preoperative nurses, anesthesia providers and surgeons is well positioned to continue work in this area including a future randomized controlled trial. The plan is to build on findings from this feasibility study toward a grant application through the National Institute of Nursing Research to determine the efficacy of an aromatherapy patch compared to a placebo patch on preoperative anxiety among patients undergoing a variety of surgical procedures. The study will explicate a measurement model that includes bio-behavioral outcomes for a more definitive study of the symptoms of anxiety. The long-term objective would be to offer patients undergoing operative and non-operative procedures the opportunity to self-manage anxiety through the use of aromatherapy.

Appendices

Protocol Review & Monitoring System
86 Jonathan Lucas St.
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Charleston, SC 29425
Phone: (843) 792-9409
Fax: (843) 876-1962
E-mail: hccprms@musc.edu

December 11, 2015

Candace Jaruzel, MSN, CRNA
Instructor
Department of College of Health Professions/ Anesthesia for Nurses Medical University of South Carolina
Charleston, SC, 29425

Dear Ms. Jaruzel:

At the December 11, 2015 meeting of the Protocol Review Committee (PRC), your research protocol entitled "Aromatherapy for Preoperative Anxiety for Female Patients Undergoing Breast Surgery: A Feasibility Study" (CTO #: 102425/Sponsor: MUSC; protocol version December 10, 2015) was **approved** as written for use at Hollings Cancer Center.

As required by the NCI for all Designated Cancer Centers awarded a Cancer Center Support Grant (CCSG), MUSC-HCC must report all oncology clinical trial activity occurring at MUSC. Because the abovementioned study has qualified for PRC review and approval, this study is subject to ongoing reporting requirements to the PRC to ensure compliance to CCSG standards. **As Principal Investigator, it is your responsibility to ensure the following information is submitted to the HCC PRC at hccprms@musc.edu. Please make sure that CTO#102425 is listed in any email correspondence.**

1) MUSC IRB Initial Approval Letter and Date of Study Activation
Please note that consideration for approval of this study by the MUSC IRB is pending. The MUSC IRB will require the provision of a PRC approval letter within your IRB application. Once a study is IRB approved, please submit the IRB approval letter to the PRC. If the study does not receive IRB approval and the study is withdrawn, please contact the PRC of this status. Study Activation is defined as the time when the study is eligible to begin enrollment to the trial. When the study is activated, please provide the PRC this activation date.

2) All Significant Protocol Amendments require PRC approval
Significant Protocol changes are defined as changes in any of the following: a) Study objectives, b) Research plan or study design, c) Eligibility, d) Statistical Consideration, e) Patient population and/or accrual figures. Any significant change requires PRC approval prior to IRB submission. It is required that a marked document and/or detailed summary of changes and the *PRC Amendment Form* be provided to the PRC. The PRC form is located at http://hcc.musc.edu/intranet/prms/protocolcommittee.htm The PRC Chair will initially review the documents and may approve under expedited review. Should there be additional concerns, the PRC chair has the authority to request full board review of the amendment.

2) Monthly Accrual Updates and Biannual Accrual Review

On a monthly basis, it is required that updated accrual information is provided. A copy of the accrual log form is located on the HCC PRC website at
http://hcc.musc.edu/intranet/prms/protocolcommittee.htm
In addition, PRC conducts a biannual trial performance review in which the level of accrual is reviewed. Should your predicted accrual period or accrual estimate change from your initial form submission, please contact the PRC.
3) Changes in Study Status
When the study is closed to accrual or terminated, it is required that the PRC be notified of the status change. Any applicable IRB letter regarding this change in status should be provided.

Conducting research is a critical component of our University's mission. Thank you for your efforts and should you have any questions regarding PRC, please feel free to contact the PRC chairs or administrator.

Sincerely,

James Ravenel, MD
Co-Chair, Protocol Review Committee

cc: CTO Binder #102425

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00049642** entitled:
Aromatherapy for preoperative anxiety for female patients undergoing breast surgery: A feasibility study

submitted by: **Candace Jaruzel, CRNA, MSN**
Department: **HEALTH PROFESSIONS RESEARCH DIVISION - MUSC**
Protocol Version: **6**
Dated: **12/10/2015**

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **1/5/2016**
Approval Expiration: **1/4/2017**

Type: **Full IRB Review**

Vice Chair, **IRB-I - Medical University of South Carolina**
Susan Newman∗

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

∗***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Aromatherapy for preoperative anxiety for female patients undergoing breast surgery: A feasibility study

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the primary investigator of this study discusses this consent form with you, please ask her to explain any words or information that you do not clearly understand. The purpose of this study is to determine the feasibility of using an aromatherapy patch in the preoperative holding room for acute situational anxiety for female, surgical patients undergoing a lumpectomy and/or mastectomy and/or sentinel node biopsy and/or axillary node dissection procedure in addition to standard preoperative care. Aromatherapy is the use of natural, plant essences (e.g. lavender, spearmint, peppermint, citrus) for therapeutic purposes. You are being asked to participate in this study because you are female, and a surgical patient scheduled for a lumpectomy and/or mastectomy and/or sentinel node biopsy and/or axillary node dissection. The lavender patch for this research has been donated in kind by Bioesse Technologies, LLC. The investigator in charge of this study is Candace Jaruzel, MSN, CRNA, PhD candidate. The study is being done at 1 site, Ashley River Tower Operating Room. Approximately 42 people will take part study-wide at MUSC including patients, nurses and surgeons.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will be asked questions about your medical history, demographic information (race/ethnicity, marital status, number of children), and your medial chart will be reviewed.
2. You will be asked to complete a Visual Analog Scale rating (0 – 10) to rate your anxiety.
3. A lavender aromatherapy patch will be applied to your chest at the same time the electrocardiogram leads that monitor heart rate.
4. Your vital signs (heart rate and blood pressure) will be continuously monitored during your preoperative time.
5. You will be asked to rate your anxiety on the Visual Analog Scale every 15 minutes until your anesthesia time starts.
6. The lavender aromatherapy patch will be removed when your anesthesia time starts.

7. The Primary Investigator will review your medical records to gather additional information about your age, body mass index, physical status classification, smoking status, diagnosis, surgical history, and surgical procedure.
8. If you agree, you will receive a follow-up phone call on the first day after your surgery to complete a brief survey.

____ Yes, I agree to receive a follow-up phone call.

____ No, I do not agree to receive a follow-up phone call.

C. DURATION

Participation in the study will take place during your time in the preoperative holding area. An additional 10 minutes of your time will be requested for a follow-up phone call on the first day after your surgery.

D. RISKS AND DISCOMFORTS

There are no known physical, psychological, social, financial, or legal risks associated with this study.

The lavender aromatherapy patch is applied to your skin and affixed by a hypo-allergenic adhesive. There are no known side effects. Minor reactions may include, but are not limited to, sneezing, coughing, and/or watery eyes. The experimental treatment may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Coding of all identifying data will minimize this risk. Whenever data are reported, no individual subject will be identified.

E. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours and will help the researcher learn more about preoperative anxiety and aromatherapy for surgical patients.

F. COSTS

There will be no cost to you as a result of participation in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company.

G. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

H. ALTERNATIVES

Your alternative is to not participate in this study.

____SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

___STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

___EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

___FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Candace Jaruzel, MSN, CRNA, PhD candidate (843) 792-3787. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148.This includes any questions about my rights as a research subject in this study. I agree to participate in this study. I have been given a copy of this form for my own records. If you wish to participate, you should sign below.

Signature of Person Obtaining Consent	Date
Signature of Participant	Date

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to the Medical University of South Carolina (MUSC) to use or disclose (release) your health information that identifies you for the research study described here:

Aromatherapy for preoperative anxiety for female patients undergoing breast surgery: A feasibility study. This study will assess the feasibility of providing aromatherapy through a sustained-release patch applied to the chest during the preoperative period for acute situational anxiety in female patients scheduled for lumpectomy and/or mastectomy procedures.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment;
- Parents of minor children is less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Food and Drug Administration;
    - National Institutes of Health; or
    - Other governmental offices, such as a public health agency or as required by law.

MUSC is required by law to protect your health information. By signing this document, you authorize MUSC to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not

be allowed to be a participant in this research study.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, MUSC may still use or disclose (release) health information already obtained about you as necessary to maintain the integrity or reliability of the research study. If you revoke this Authorization, you may no longer be allowed to participate in this research study. To revoke this Authorization, you must write to:

Candace Jaruzel, MSN, CRNA
151-B Rutledge Avenue, MSC 962
Charleston, SC 29425-9620

You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization will expire at the end of the research study. If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at 843-792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

Signature of Research Participant ages 16 & above* Date

Signature of Research Participant's Legally Authorized Representative (if applicable) Date

Printed Name of Research Participant

Printed Name of Research Participant's Legally Authorized Representative (if applicable)

Representative's Relationship to Research Subject

*If the research participant is 16 to 18 years of age, signatures of both the research participant and the Legally Authorized Representative are required.

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. **For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. **To obtain payment**. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. **For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. **For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. **Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. **Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. **Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.

8. **Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.

9. **Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. **For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. **Research.** We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in

certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.