Abstract

PAIN MANAGEMENT AFTER CARDIAC SURGERY

by

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Postoperative pain relief is one of the most important concerns for patients undergoing cardiac surgery and is one of the most clinically challenging problems for nurses. It is widely recognized that postoperative pain can negatively impact cardiac surgery outcomes, yet recent surveys report only modest success in pain management as patients continue to describe poorly controlled pain and studies report pain as underestimated, undermedicated, and underrelieved. Research in basic and clinical science has advanced the knowledge of pain management following cardiac surgery. However, the emergence of fast-track cardiac surgery programs, which includes tracheal extubation within 6 hours of surgery, early ambulation, a shortened intensive care length of stay and hospital discharge within 3 to 5 days presents a challenge to conventional methods of pain management.

The problem of pain management after cardiac surgery was examined from three perspectives 1) the relationships of patients' preoperative health-related quality of life, pain management, and postoperative outcomes, 2) nurses' clinical decision-making

regarding pain management during weaning from mechanical ventilation, and 3) the evaluation of a new pain management modality. The studies presented in this dissertation used a variety of theoretical models and research methodologies to allow for synthesis and a broader contribution to nursing science. Each study is presented as an individual manuscript to be prepared and submitted for publication. Collectively, the manuscripts represent a cohesive body of research, with each topic informing the other.

This body of research extends the understanding of the relationships of patients' perceptions of health-related quality of life and postoperative pain management and early recovery clinical outcomes. It also illuminates nurses' clinical decision-making processes in a unique clinical setting that require nurses to effectively manage pain while simultaneously facilitating early extubation in fast track programs. Finally the evaluation of a new pain management modality, the use of a continuous local anesthetic infusion at the sternotomy did not reduce patients' postoperative pain intensity or improve other clinical outcomes.

PAIN MANAGEMENT AFTER CARDIAC SURGERY

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by

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DEDICATION

To my husband, Luke, for his love, encouragement, and sacrifice. To my son, Bryce, and my grandchildren, for their limitless potentials. To my parents James F. and Alma Rae Best Pauley, who taught me the value of hard work and perseverance.

Each of you has inspired me throughout my educational endeavors. I love you and dedicate this dissertation to you and your life's dreams.

Go confidently in the direction of your dreams. Live the life you have imagined.

(Henry David Thoreau)

He who began a good work in you…will be faithful to complete it.

(Philippians 1:6)

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I have been amazingly blessed to have a dissertation committee that gave me the opportunity to explore my ideas from a variety of theoretical perspectives and methodologies, and at the same time provided the guidance to recover when my steps faltered. Dr. Martha Engelke has been there to listen and give great advice. Her insightful comments and constructive criticisms at different stages of preparation for the dissertation were thought-provoking and they helped me focus my ideas. I am grateful to her and her colleagues, for handling the administrative challenges that made the 'Manuscript Option' Dissertation a reality at the College of Nursing and enabled me to pull together my course work and directed research projects in pain management after cardiac surgery. It is my hope that other doctoral students will benefit from this precedent.

Dr. Melvin Swanson and I created the database that formed the core of the work presented in this dissertation. I am grateful to him for holding me to a high research standard and enforcing strict validations for each research result, thus teaching me how to do research. His supportive interest and intrigue with the clinical research we were conducting was encouraging and motivated me to see the project through to completion, even during the most difficult of times.

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Many friends have helped me stay grounded through these challenging years. Their prayerful support and care helped me overcome setbacks and stay focused on my doctoral studies. I greatly value their friendship and I deeply appreciate their belief in me.

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CHAPTER 1: INTRODUCTION

Pain and critical care were separate fields of research until the late 1980s when Bryan-Brown (1986) and colleagues drew attention to the issue of pain in the critically ill and critical care nurses identified pain research as a high priority (Lewandowski & Kositsky, 1983; Lindquist et al., 1993). Since then, significant scientific advancements have been made in assessment and management of pain in critically ill patients. Basic science has provided a more detailed understanding of pain mechanisms and clinical science has provided important knowledge about pain measurement and management. Pain is now recognized as an important physiological and psychological stressor in critical care patients (Cochran & Ganong, 1989; Novaes et al., 1999). Numerous sources of pain have been identified, such as surgical trauma, invasive lines and tubes, nursing interventions and medical procedures (Puntillo et al., 2004; Stanik-Hutt, Soeken, Belcher, Fontaine, & Gift, 2001). Multidimensional methods of pain assessment and analgesic pharmacology have aided the improvement of pain management practices.

Several organizations have published clinical practice guidelines to assist clinicians who provide care for patients in pain. The Agency for Health Care Policy and Quality suggested measures to ensure all patients have access to the best level of pain relief that can be safely provided (Department of Health and Human Services, Public Health Services, 1992). The Joint Commission on the Accreditation of Healthcare Organizations (2001) established organizational standards regarding patients' rights to pain management. The American Pain Society recommended pain assessment as "the 5th vital sign" (Berry et al., 2001) and in a joint effort with other organizations and the

United States (U.S.) Congress, passed a resolution that designated the years 2000 to 2010 as the "Decade of Pain Control and Research" (American Pain Society, 2003). Although these research and regulatory initiatives address the widespread problem of pain management in the general population, pain in the critically ill remains problematic.

Critically ill patients present unique challenges in pain management. For example, critically ill patients may be hemodynamically unstable, unable to communicate verbally due to the presence of an endotracheal tube, and restrained. To address these issues, the American College of Critical Care Medicine developed multidisciplinary clinical practice guidelines for the use of analgesics and sedatives for critically ill patients (Jacobi et al., 2002). The American Society for Pain Management Nursing drafted a position paper and clinical recommendations regarding pain assessment for nonverbal patients, including intubated and/or unconscious patients (Herr et al., 2006).

Background and Significance

One particular group of critically ill patients, those undergoing cardiac surgery, warrant special consideration with regards to pain management because the majority of these patients are transferred from the operating suite to the ICU intubated and ventilated with varying degrees of hemodynamic instability and pulmonary impairment.

Traditionally, patients who underwent cardiac surgery received high dose-narcotic based anesthesia intraoperatively and were mechanically ventilated and sedated for 18-24 hours postoperatively. They remained in the ICU an average of 2-3 days, with a postoperative hospital length of stay (LOS) of 8 to 13 days (Dunstan & Riddle, 1997).

However, over the last decade, economic and societal expectations for rapid recovery following cardiac surgery have spawned the emergence of 'fast track' programs.

The term 'fast track' describes a multidisciplinary approach to patient care designed to improve organizational efficiency and reduce costs. Fast track programs include strategies to facilitate early tracheal extubation within 6 hours after surgery (Cheng, 1998), a shortened ICU stay, and hospital discharge within 3 to 5 days (McKee, Sidebotham, & Gladding, 2007). These programs are now considered the standard of care for all but the most critical patients, and have been shown to be a safe practice (Hawkes, Dhileepan, & Foxcroft, 2003). However, fast track programs fuel the intraoperative use of short-acting anesthetic agents and administration of fewer narcotics to restore patients' consciousness and spontaneous breathing within hours of surgery (Gerhardt, 2008). Unfortunately, these strategies may render patients at higher risk for postoperative pain and its detrimental consequences (Schwann & Chaney, 2003). For example, severe pain limits deep breathing and forceful coughing, which contributes to sputum retention and atelectasis and increases the risk for pneumonia (Miller, McKee, & Mazer, 2007).

Pain following cardiac surgery arises from the sternotomy, pleural irritation caused by chest drains, osteoarticular trauma caused by retraction of the thoracic cage, and sites from which bypass conduits have been obtained (saphenous vein, radial artery). Pain has been reported to be maximal on the first and second postoperative days, with the greatest intensity in the sternal, substernal, and parasternal regions (Mueller et al., 2000; McDonald et al., 2005). Although research in basic and clinical science have advanced the knowledge of pain following cardiac surgery, these strides may be hindered by the

rapid recovery expectations of fast track programs, as management of acute postoperative pain remains problematic. Patients continue to describe poorly controlled pain (Watt-Watson, Stevens, Garfinkel, Streiner, & Gallop, 2001; Milgrom et al., 2004) and studies report pain as underestimated, undermedicated, and underrelieved (Ferguson, Gilroy, & Puntillo, 1997; Gust et al., 1999; Gelinas, 2007).

This dissertation explores three areas of research regarding pain management following cardiac surgery. Each area is presented as an individual manuscript to be formatted and submitted for publication. Collectively, the manuscripts represent a cohesive body of research, with each topic informing the other. The three areas to be addressed include:

1. The relationships among patient's preoperative health-related quality of life, pain management, and select postoperative outcomes after coronary artery bypass graft surgery.
2. Nurses' clinical decision-making regarding pain management during weaning patients from short-term mechanical ventilation after cardiac surgery.
3. The effects of a continuous local anesthetic infusion at the sternotomy on postoperative pain management outcomes after coronary artery bypass graft surgery.

Manuscript #1: Health-Related Quality of Life, Pain Management and Postoperative Outcomes in Cardiac Surgery Patients

Background and Significance

According to the Society of Thoracic Surgeons, the profile of patients referred for CABG surgery has significantly changed during the last decade. The mean age of coronary artery bypass graft (CABG) candidates increased from 63.7 years in 1990 to 65.1 in 1999 as did the percentage of women (25.7% versus 28.7%) (Ferguson, Hammill, Peterson, Delong, & Grover, 2002). Women who presented for (CABG) were older than men with more concomitant diseases preoperatively. Medical therapy and interventional cardiology procedures delay the need for CABG, increasing the age at which patients present for CABG, thus changing risk factors, such as age, gender, and preoperative health-related quality of life (HRQL).

As the characteristics of CABG candidates change, it is likely that patients' preoperative HRQL have also changed. Previous research on HRQL has primarily focused on outcomes during the posthospitalization phase of recovery (Barnason, Zimmerman, Anderson, Mohr-Burt, & Nieveen, 2000; Hunt, Hendrata, & Myles, 2000; Mathisen et al., 2005). Therefore HRQL may be associated with postoperative pain intensity and management as well as early recovery outcomes during hospitalization. Because it is impossible to draw conclusions about postoperative pain management outcomes without first appreciating the age, gender, and HRQL perceptions of patients presenting for surgery, exploration is needed to determine if there are relationships

among these characteristics regarding pain management and other early recovery outcomes.

Purpose and Aims of the Study

It is possible that HRQL may also be associated with postoperative pain management after CABG as well as other indicators of recovery during hospitalization and this relationship has not been studied. Therefore, the specific aims of this study were to examine:

- The SF-36 normed scores for patients stratified by age (< 65 and ≥ 65 years) and gender.
- The relationship of HRQL to postoperative pain management measures (location, intensity, and opioid analgesic consumption).
- The relationship of HRQL to postoperative outcomes (duration of mechanical ventilator hours and hospital length of stay).

Institutional Review Board Status

This study was initially reviewed and approved using expedited review by the University and Medical Center Institutional Review Board on February 14, 2009 (see Appendix A). The study was a secondary analysis of existing data from a larger randomized clinical trial regarding pain management after cardiac surgery, was unfunded with no more than minimal risk to participants.

Journal to Which Manuscript will be Submitted

The manuscript is well suited for publication in the *American Journal of Critical Care (AJCC)*, a peer-reviewed, official publication of the American Association of

Critical Care Nurses. The mission of the AJCC is to provide clinically relevant, evidence-based practice content to critical care nurses.

Abstract

Background. The profile of patients referred for CABG has changed significantly during the last decade. Patients are older, more women are having surgery, and patients have more co-morbidities. Few investigators have examined the relationship of pre-operative HRQL with cardiac surgery clinical indicators in patients stratified by age and sex. This study used the acute form, version 1, of the SF-36 to assess the HRQL in the study patients.

Objective: To examine the relationships of preoperative HRQL and postoperative pain management, duration of mechanical ventilation and hospital length of stay.

Methods. A descriptive correlational design was used for this secondary analysis with patients in a larger parent study who completed a preoperative Medical Outcome Short Form - 36. The sample (n = 90) was dichotomized into groups of patients < 65 and ≥ 65 years of age.

Results. Fifty-nine percent of the patients were under age 65. Sixty-six percent of the total group was male, and the average age of the men (M = 62.6 years) and women (M = 62.3) was almost identical. Patients < 65 years had lower scores on several SF-36 measures than patients ≥ 65 years. Patients < 65 years had higher pain intensity and opiate consumption than patients ≥ 65 (P = .001). Patients ≥ 65 with low perceptions of general health had a longer duration of mechanical ventilation (P = .03). Patients < 65 years with lower vitality had longer hospital length of stay (P = .01). All of the mean

scale scores for men and women < 65 were below the national norm average. For women ≥ 65, their mental health, general health, role emotional, and mental health summary score means were above the national average. For men ≥ 65, only the mental health scale score and mental health component score were above the national average.

Conclusions. Preoperative HRQL could be utilized as a component of preoperative patient screening and has potential to contribute to risk stratification in the cardiac surgery population.

Manuscript #2: Clinical Decision-Making during Weaning from Mechanical Ventilation after Cardiac Surgery

Background and Significance

The evolution of fast-track cardiac surgery programs, in which patients are rapidly weaned and extubated within 6 hours of surgery (Cheng, 1998) have created a unique clinical setting that require nurses to use dynamic, complex decision-making skills regarding pain management. In these clinical settings, nurses must decide how to effectively manage postoperative pain during weaning from mechanical ventilation (MV) while simultaneously facilitating early extubation. Pain is not easily managed in postoperative ventilated patients who are restrained and unable to verbalize; and is usually treated by opioids that are administered as an intravenous (IV) bolus by nurses on the basis of patients' physiologic and behavioral pain cues. Relief of postoperative pain is one of the most important concerns for CV surgery patients, yet to facilitate tracheal extubation, nurses often withhold or administer low intermittent IV boluses of opioid analgesia during weaning from MV (Renaud, 2002).

The reasons for under-treatment are not clear, although they have been attributed to insufficient knowledge about pain management (Watt-Watson et al., 2001; Brown, Bowman, & Eason, 1999), nurses' beliefs, attitudes toward pain management (Hurlock-Chorostecki, 2002), and inadequate pain assessment tools (Puntillo, Stannard, Miaskowski, Kehrle, & Gleeson, 2002). Although barriers to assessment and management of pain in critically ill patients have been identified, little is known about the process of nurses' clinical decision-making (CDM) to administer or withhold analgesia

while they are involved in the rapid weaning and extubation phase of patient recovery from cardiac surgery.

Purpose and Aims of the Study

The purpose of this grounded theory study was to explore the CDM processes of nurses regarding pain management while weaning patients from short term MV after cardiac surgery. The secondary purpose of this study was to examine decision-making with respect to nurses' skill level.

Institutional Review Board Status

This study was reviewed and approved by the University Medical Center Institutional Review Board using expedited review on October 11, 2006 (Appendix B) and received continuing review on October 10, 2007 (Appendix C). The research was conducted with staff nurses at Cape Fear Valley Health System and a letter of support from the patient care manager of the cardiac surgery intensive care unit can be found in Appendix D. The study was closed on July 21, 2008 (Appendix E)

Journal to Which Manuscript will be Submitted

This manuscript will be submitted to The *Journal of Nursing Scholarship (JNS).* The *JNS* is published quarterly on behalf of Sigma Theta Tau International, the Honor Society of Nursing. It is one of the most widely read and respected health care journals. The *JNS* is interested in receiving manuscripts that provide new knowledge designed to improve nursing practice. This grounded theory study contributes to new knowledge in a unique, complex clinical setting as a first step toward developing a middle-range theory

of CDM regarding pain management during weaning patients from short-term MV after cardiac surgery.

Abstract

Purpose. To explore the process of nurses' CDM regarding pain management when they are weaning postoperative cardiac surgery patients from short term MV.

Methods. A grounded theory approach was utilized in this qualitative study.

Findings. A core problem of "balancing goals of tolerable pain levels and early extubation" was identified with three distinct categories: monitoring physiological parameters, establishing communication, and fine-tuning medications. The core category was identified as "goal-directed pain management decisions during weaning". Differences were noted in the CDM processes of less experienced and more experienced nurses.

Conclusions. This research was a first step toward the development of a middle range theory of nurses' CDM processes regarding pain management while weaning cardiac surgery patients from short-term MV. Additional research should replicate this study in other fast-track cardiac surgery programs so that the results can be validated.

Manuscript # 3: Effects of a Continuous Local Anesthetic Infusion at the Sternotomy on Postoperative Pain Management Outcomes

Background and Significance

Wound perfusion using a local anesthetic was first recorded in 1935 by Capelle (1935) through thin, curved, hollow needles. In the 1950's, early studies by Blades & Ford, (1950) and Gerwig, Thompson, & Blades, (1951) reported decreases in narcotic consumption with the use of a postoperative anesthetic infusion into thoracotomy and abdominal wounds. Recently, technological advances have produced portable elastomeric infusion pumps that provide continuous flow of local anesthesia to incision sites. The pumps are connected to slim catheters that are inserted at the surgical incision prior to skin closure.

There is an increasing body of literature on the efficacy of a continuous local anesthetic infusion (LAI) at incision sites for postoperative pain management in obstetric, plastic, and general surgery (Lu & Fine, 2005; Sanchez, Waxman, Tatevossain, Famberdella, & Read, 2004; Givens, Lipscomb, & Meyer, 2002). However, only 4 studies have explored patient outcomes of continuous LAIs at the sternotomy incision after cardiac surgery.

In a randomized, double-blind clinical trial of 36 patients (White et al., 2003) reported lower patient-controlled analgesia (PCA) morphine requirements and pain scores in a group receiving 0.5% bupivacaine for 48 hours via catheters placed above the sternum. Time to tracheal extubation was not significantly reduced, however, patients ambulated earlier and had reduced hospital LOS. In another randomized, double-blind

clinical trial of 35 patients, it was reported that a group receiving 0.2% ropivacaine for 48 hours via catheters placed anterior to the sternum, had lower PCA opiate analgesic usage and pain scores (Dowling et al., 2003). There was no significant difference in extubation time or ambulation, however, a shorter length of stay was observed.

In a randomized study of 47 patients, Magnano et al., (2005) reported no improvement in morphine consumption or pain control in a group receiving 0.5% bupivacaine over 36 hours. In this particular study, the catheters were of the type generally used for epidural analgesia (small diameter with a few holes at the tip) and were placed anterior to the sternum. The control group was extubated earlier than the treatment group. Another study of 76 patients reported reductions in postoperative pain and opioid analgesic use in a group receiving a ropivacaine mixture for 96 hours via catheters placed on the sternum. Information regarding randomization or blinding was not reported. In addition, the authors reported that patients were informed that they could use intravenous drugs only for "severe or disturbing pain" (Koukis et al., 2008).

In these studies, the types of catheters and placement varied, with mixed results regarding patients' pain scores, opioid analgesic requirements, and time to extubation. More recently, a 10 inch soaker catheter has been developed that that may be more beneficial to patients with longer surgical incisions such as sternotomies. It is inserted 3-5 cm lateral to the incision edges using tunneling technique. A prospective, randomized, placebo-controlled, double-blind clinical trial randomized was designed to study the effectiveness of this new modality on pain management outcomes.

Purpose and Hypotheses

The purpose of this study was to determine the effect of a continuous LAI at the median sternotomy following CABG on postoperative pain management measures and select clinical outcomes. A prospective, dual-armed (with and without cardiopulmonary bypass), randomized, placebo-controlled, double-blind clinical trial was conducted to examine the following hypotheses:

The primary hypotheses:

1. Patients receiving a continuous LAI at the sternotomy will report less postoperative pain intensity after CABG when compared to patients receiving a placebo.
2. Patients receiving a continuous LAI at the sternotomy will require less opioid analgesia after CABG when compared to patients receiving a placebo.

Secondary Outcome Measures:

1. To examine the impact of a continuous LAI at the sternotomy on duration of MV, initial ambulation from bed to chair, ICU hours, and hospital LOS when compared to a placebo.

Institutional Review Board Status

This study was subject to a full review and was approved on December 29, 2006 by the Institutional Review Board (IRB) at Cape Fear Valley Health System (Appendix F). Enrollment began in January 2007. All documentation was forwarded to the University Medical Center Institutional Review Board (Appendix G).

Journal to Which Manuscript will be Submitted

This manuscript will be submitted to *Heart & Lung–The Journal of Acute and Critical Care* for consideration for publication. *Heart & Lung* publishes original, peer-reviewed articles on investigations that are conducted in acute and critical care. *Heart & Lung* is an appropriate selection for this manuscript because the mission of the journal is to provide nurses with a framework for applying research results in clinical practice.

Abstract

Objective. Postoperative pain control is one of the most important concerns for CABG patients and is one of the most clinically challenging problems for health care providers. The authors investigated the effectiveness of a continuous LAI of bupivacaine at the sternotomy incision after CABG with regards to pain intensity, opioid analgesic requirements, and select clinical outcomes.

Design. This was a prospective, dual armed, randomized, placebo-controlled, double-blind clinical trial.

Methods. Patients (n = 108) undergoing CABG had continuous LAI catheters placed at the sternotomy. Pain intensity scores and opioid analgesic requirements were recorded from postoperative day (POD) 1 – POD 3. Secondary outcome measures were duration of MV, initial ambulation, ICU and hospital LOS.

Results. Participants in all 4 groups were similar in demographic and clinical parameters. Patients in the treatment and control groups of both arms of the study reported comparable pain intensity scores on POD 1 – POD 3. The total amount of opioid analgesia required during weaning from MV did not vary significantly between treatment

and control groups in either arm of the study. No statistically significant differences were found in the average time to first ambulation from bed to chair. Most patients in both arms of the study met step-down criteria within 24 hours of surgery. The average postoperative hospital LOS was 4-5 days and did not vary statistically between groups.

Conclusion. The use of a continuous LAI at the sternotomy did not reduce postoperative pain intensity or opioid analgesic consumption in this study. It also did not have an effect on secondary clinical outcomes.

CHAPTER 2: HEALTH-RELATED QUALITY OF LIFE, PAIN MANAGEMENT, AND POSTOPERATIVE OUTCOMES IN CARDIAC SURGERY PATIENTS.

Background

Cardiovascular disease is our society's number one health problem, affecting 80.7 million Americans, or 37.1% of our population. CABG is one of the most commonly performed operations in the U.S. with approximately 469,000 performed in the United States in 2005 (American Heart Association, 2008), accounting for more expenditure of resources than any other single procedure in cardiovascular medicine (Eagle et al., 2004).

According to the Society of Thoracic Surgeons, the profile of patients referred for CABG surgery has significantly changed during the last decade. The mean age of CABG candidates increased from 63.7 years in 1990 to 65.1 in 1999. The percentage of women increased from 25.7% to 28.7% (Ferguson et al., 2002) with more concomitant diseases preoperatively. Medical therapy and interventional cardiology procedures delay the need for surgery, increasing the age at which patients present for CABG, thus changing risk factors, such as age, gender and preoperative HRQL.

Previous research on HRQL in CABG patients has primarily focused on outcomes 3 – 12 months after hospital discharge(Barnason et al., 2000;Hunt et al., 2000; Elliott et al., 2005). Differences in HROL have also been examined in patients undergoing CABG using off-pump versus conventional on-pump techniques (Mathisen et al., 2005; Puskas et al., 2004). Sjoland and colleagues (1999) studied quality of life between men and women up to 2 years after CABG. Rumsfeld et al., (1999) examined HRQL as a predictor

of mortality and Barnason, et al., (2008) investigated the relationships of fatigue and recovery outcomes at 6 weeks and 3 months among adults ≥ 65 years after CABG.

However, it is possible that HRQL may also be associated with postoperative pain management after CABG as well as other indicators of recovery during hospitalization and this relationship has not been studied. Therefore, the specific aims of this study were to examine:

- The SF-36 normed scores for patients stratified by age (<65 and ≥ 65 years) and gender.
- The relationship of HRQL to postoperative pain management measures (location, intensity, and opioid analgesic consumption).
- The relationship of HRQL to postoperative outcomes (MV hours and hospital length of stay).

Methods

Design

This study was a descriptive correlational secondary analysis of data collected during a larger randomized control trial (RCT) to evaluate the use of a pain management modality after CABG. Because there were no statistically significant differences in patient demographics, clinical parameters, MV hours, total opioid analgesic usage, or hospital LOS in the treatment and control groups of the larger study, all subjects were combined into one group for this secondary analysis.

Sample and Setting

The participants in the original study were male and female adult patients who underwent initial, elective CABG in a 760-bed, acute care, non-academic hospital in the southeastern U.S. None of the patients had cognitive impairment by clinical impression, and all were fluent in English. Exclusion criteria included renal failure requiring dialysis, concurrent (cardiac or noncardiac) procedures, body weight less than 45 kg, prolonged intubation (>24 hrs), reintubation, reoperation, and postoperative invasive procedures.

Measures

Health-related quality of life. The instrument used to measure HRQL was the Medical Outcomes Study Short Form (SF-36) (Ware, Kosinski & Keller, 1994). The SF-36 is a generic, self report health status instrument that consists of 36 items, which measures 8 health constructs; using 8 scales with 2 to 10 items per scale. In addition, a physical component score (PCS) and mental health component score (MCS) are derived from the eight SF-36 scales. Dempster & Donnelly (2000) compared the validity, reliability, and sensitivity of the SF-36 with other generic questionnaires and concluded that the SF-36 is one of the most appropriate and currently available generic instruments to assess HRQL of cardiac patient populations. The acute (1-week) recall version was utilized in this study because Keller et al. (1997) found it to be more responsive to recent changes in disease state than the standard (4-week) form.

Pain intensity and location. Because the assessment of pain in the first 24 hours after surgery might be influenced by residual intraoperative anesthetics, data were recorded from POD 1 - POD 3 regarding pain intensity, location, and opioid analgesic consumption. Patients were approached every 4 hours for pain assessment, and if they were awake, nurses asked the patients if they were experiencing pain and used a numeric rating scale to ask, "What number would you give your pain right now?" The numeric rating was interpreted as 0 = no pain, 1–3 = mild pain, 4–6 = moderate pain, 7–10 = severe pain (McCaffery & Beebe, 2003).

Because the purpose of the larger RCT was to examine the effectiveness of a pain management modality at the sternotomy, patients were asked to identify the location of their pain. Pain location was recorded as none, sternum, chest tubes, general body, head, back, other, and patient asleep. Since the most frequently reported pain location was the sternum, a sternum frequency variable was created. Patients who did not report any sternum pain or only reported sternum pain once on any of the three PODs, were categorized as 'infrequent' and patients that reported sternum pain on at least 2 of the 3 PODs were categorized as 'frequent'.

Opioid analgesic consumption. Postoperative pain was managed via a PCA pump on an as needed basis. If patients required rescue pain medications beyond their PCA lockout, nurses administered boluses of opioid analgesics. PCA pumps were discontinued 48 hours postoperatively. Pain was then managed with oral oxycodone administered every 4 hours on an as needed basis. For comparison, opioid analgesics were

standardized to IV morphine equivalents (ME) (McAuley, 2007). Anti-inflammatory medications and sedatives were not included in the equianalgesic calculations.

Mechanical ventilator hours. Following surgery, patients were transferred to the cardiac surgery ICU intubated and mechanically ventilated until hemodynamically stable with minimal chest tube bleeding. Ventilator weaning was guided by standardized fast-track protocol to facilitate patient extubation within 6 hours of surgery. The interval between patients' arrival in the ICU to tracheal extubation was calculated in hours.

Hospital length of stay. Postoperative care was performed per standard-of-care guidelines for all patients undergoing CABG. The interval between patients arrival in the ICU to the point at which patients left the hospital was recorded in number of days.

Data Collection

Following approval by the appropriate ethics committee (Appendix A), consenting patients were introduced to the SF-36 by trained research assistants and instructed on how to complete the instrument prior to surgery. If a patient was unable to complete it independently, the research assistant conducted a personal interview for administration of the SF-36. Patient demographics, SF-36 raw scores, and select outcome measures were retrieved from the existing database.

Data Analysis

Analyses were performed using SPSS version 15 (SPSS Inc., Chicago, IL). Descriptive statistics, including frequencies, means, and standard deviations where appropriate, were produced for the total study sample, and for the age subgroups. Comparison of means between groups was performed with a one-way analysis of

variance, while contingency table analysis with chi-square was used to compare the proportions between groups. Statistical significance was defined as a p value less than 0.05.

Scoring of the SF-36 for the 8 scales and 2 component scores followed the methods described by Ware et al., (1994). All of the 8 scales and two component scores were standardized to the general U.S. population such that all the scores have a mean of 50 and a standard deviation of 10. The advantage of the norm-based scoring is that all scores in the study sample above or below 50 are above or below the national average. To investigate the relationship of SF-36 measures to clinical outcomes, each SF-36 measure was categorized into 2 categories, low scores ($\leq 25^{th}$ percentile) and high scores ($> 25^{th}$ percentile). This categorization was done because of the varying skewness of the measures and the expectation that lower scores would have the strongest potential relationship to the clinical outcomes.

In an earlier version of the SF-36, a one-item measure (perception of health) was used as a separate item and demonstrated some strong validity. In this study, the single-item measure, perception of health (PH), was used as an independent variable.

Results

Characteristics of the Sample

Of the 108 patients who were enrolled in the larger RCT, 90 (83%) completed the SF-36. The primary reasons for not completing the instrument were a lack of time due to interruptions for preoperative diagnostic procedures or patient refusal to complete the survey. The mean age of the total group was 62.6 years, ranging from 43-84. Fifty-nine

percent of the patients were under age 65. Sixty-six percent of the total group was male, and the average age of the men (M = 62.6 years) and women (M = 62.3) was almost identical. Approximately one half of the sample had a history of smoking and diabetes, while a third of the sample claimed to have a chronic pain condition. Harvesting of the internal mammary artery was done in 94% of the surgeries. Off-pump (i.e. beating heart) surgeries occurred in 56% of the total sample, with 61% of women and 53% of men having off-pump surgery. Off-pump surgeries occurred in 63% of patients ≥ 65 and in 51% of patients < 65 years.

The single-item PH score asked participants to rate their perception of their general health on a 5 point Likert scale ranging from excellent/very good/good/fair/poor and does not have any national norms for comparison. The total group mean score of 59.1 indicates that the average score is near the midpoint of the 5 point response scale. Women < 65 and men ≥ 65 rated their PH lower than women ≥ 65 or males < 65.

Table 1 presents the SF-36 scores normed for the U.S. population. All of the mean scale scores for men and women < 65 were below the national norm average. For women ≥ 65, their mental health, general health, role - emotional, and mental health component score means were above the national average. For men ≥ 65, only the mental health scale score and mental health component score were above the national average.

Table 1

Mean Scores on SF-36 Measures Standardized and Norm-Based to the U.S. Population

SF-36 Scale	< 65 Years		≥ 65 Years		
	Women	**Men**	**Women**	**Men**	**Total**
	n = 17	**n = 36**	**n = 14**	**n = 23**	**Sample**
Physical Functioning	33.8 (11.2)	41.5 (11.0)	33.8 (11.2)	40.4 (10.8)	39.9 (11.3)
Role-Physical (RP)	36.1 (11.3)	35.2 (10.9)	40.9 (13.9)	39.3 (11.2)	37.3 (11.7)
Bodily Pain (BP)	33.8 (9.4)	40.9 (14.2)	47.3 (12.4)	48.2 (13.6)	42.4 (13.6)
General Health (GH)	43.3 (11.5)	47.5 (10.4)	50.3 (7.5)	44.9 (10.1)	46.4 (10.1)
Vitality (VT)	40.9 (10.9)	46.9 (14.1)	49.4 (10.5)	49.6 (11.2)	46.6 (12.5)
Social Functioning (SF)	35.1 (17.3)	40.2 (15.5)	42.2 (16.6)	44.2 (12.8)	40.6 (15.4)
Role-Emotional (RE)	36.1 (14.4)	42.3 (12.9)	50.3 (11.2)	44.7 (13.9)	43.0 (13.7)
Mental Health (MH)	43.1 (13.6)	48.8 (14.0)	53.8 (8.6)	55.1 (7.5)	50.1 (12.4)
Physical Component Score (PCS)	35.5 (8.3)	39.6 (11.3)	41.2 (9.2)	40.4 (12.1)	39.2 (10.7)
Mental Component Score (MCS)	41.6 (14.1)	47.1 (13.6)	52.5 (9.2)	51.9 (11.0)	48.0 (12.9)

Table 2 presents the clinical indicators for the age and sex groups. The number of ventilator hours was higher in women than men, regardless of age; however this trend did not reach statistical significance. Mean pain intensity scores were significantly higher in patients < 65 years ($p < .004$) as well as mean opioid consumption ($p < .001$) regardless of gender. There were no statistically significant differences in length of stay between

gender and age groups. The lowest mean length of stay (4.4 days) was observed in males < 65, compared to an average of 5.1 days in the other patients.

Table 2

Mean SF-36 Scores and Clinical Outcomes for Age and Sex Groups

	< 65 Years		**≥ 65 Years**		
Clinical Outcomes	**Women**	**Men**	**Women**	**Men**	**Total**
	n = 17	**n = 36**	**n = 14**	**n = 23**	**Sample**
Ventilator Hours	6.8 (5.8)	5.1 (3.3)	7.8 (5.2)	5.4 (2.3)	5.9 (4.1)
Pain Intensity POD 1-3	2.8 (1.5)	1.8 (1.2)	1.3 (1.2)	0.9 (1.0)	1.8 (1.3)
ME POD 1-3	74.4 (55.2)	66.5 (41.1)	29.0 (20.0)	40.1 (27.9)	55.4 (41.9)
Hospital LOS	5.0 (1.2)	4.4 (0.9)	5.2 (1.9)	5.1 (1.2)	4.8 (1.3)

Values expressed as M (SD)

Pain Management Outcomes

The next aim was to examine the relationship between the SF-36 scales and pain measures. First, we examined the relationships among the pain variables (location, intensity, and opioid consumption). Twenty patients did not report any sternum pain during PODs 1 - 3, twenty-two patients reported sternum pain on only 1 of those days, while 48 reported sternum pain on all three days. There was a strong relationship between those patients who frequently experienced sternum pain, pain intensity,and opiate consumption. Those patients with frequent sternum pain had higher mean pain scores of (M = 2.26, SD = 1.26) than those with infrequent sternum pain [$F(1, 88) = 45.0$, $p < .001$]. Similarly, those who experienced frequent sternum pain used more opiates (M = 74.4, SD = 45.28) as compared to those with infrequent sternum pain (M = 33.7, SD =

23.3); [F (1, 88 = 27.62, p < .001]. To examine the relationship between the SF-36 and pain, scores on the scales were re-coded into those with low scores (≤ 25th percentile) and those with high scores (≥ 25th percentile). The only significant relationship between any of the SF-36 scales and pain measures was a relationship between vitality (VT) and opiate consumption for those patients who experienced frequent sternum pain. Patients who reported low VT used more opiates (M = 104.0, SD = 62.65) when compared to patients reporting high VT (M = 64.6, SD = 33.47, p = .01).

Clinical Outcomes

The final aim focused on examining the relationship between HRQL, MV hours, and LOS. The single item measure of PH had the strongest relationship with MV hours. Patients with lower PH scores had statistically longer MV hours (M = 5.4, SD = 3.61); [F (1, 88) = 4.18, p = .04] than those with higher PH scores. For patients < 65 years, there was no statistically significant difference between those with high or low PH scores. However, patients ≥ 65 years who had a low PH scores had statistically significant higher mean MV hours (M = 8.8, SD = 6.02) when compared to those with higher PH scores (M = 5.6, SD = 2.71; [F (1, 35) = 5.16, p = .03].

The single item measure of PH demonstrated interesting differences between genders. For example, women who rated their PH as excellent/very good had fewer MV hours, used less opioid analgesia, and had a hospital LOS over a day less than those with lower PH ratings. However, these differences were not as evident for males. The only SF-36 measure that was strongly associated with hospital LOS was preoperative VT for

those patients experiencing infrequent sternum pain. For patients reporting low VT, their LOS was significantly higher (M = 5.2 days, SD = 1.3) than those with higher VT (M = 4.3 days, SD = 1.1); [F (1, 40) = 5.10, p = .03]. For patients aged < 65 years, those with lower VT had a significantly higher LOS (M = 5.0 days, SD = 1.2) than those with higher VT (M = 3.8 days, SD 0.5); [F (1, 17) = 7.75, p = .01].

Discussion

The patients in this study were undergoing initial, elective CABG, and there was no difference in the groups in terms of the severity of their disease, preoperative ejection fraction, and comorbidities. However, in all SF-36 measures, younger patients presenting for CABG reported HRQL below the national norms. Mental health measures were higher than the national norms in older patients. This finding is counterintuitive to traditional thinking that older people have lower HRQL.

There was little difference in duration of MV between men and women; however that may be explained by the use of standardized weaning protocols that were designed to achieve tracheal extubation within 6 hours of surgery. The only SF-36 measure related to MV hours was patients' PH. Older patients who had a lower PH had higher ventilator hours when compared to those with a higher PH. Women with higher PH had a shorter duration of MV.

With regards to pain management measures, younger patients reported higher pain intensity than older patients. Younger women had the highest levels of pain intensity and older men had the lowest levels. Consumption of opioid analgesics was significantly higher among younger men and women. Thus, patients < 65 years reported higher

postoperative pain and consumed more opiates than their ≥ 65 elders. Patients with frequent sternal pain and low VT used more opiate analgesia than patients with high VT. Hospital LOS did not demonstrate statistical significance, although younger men were discharged sooner than all the other groups and women with higher PH were also discharged early. Lower scores on VT were associated with longer hospital LOS for younger patients when compared to those with higher VT.

Some limitations of our study should be acknowledged. This study of initial, elective CABG patients was not designed to map outcomes beyond hospital discharge and is not generalizable to other types of cardiac surgeries. More research is needed with larger sample sizes in multiple centers to examine the relationship of HRQL with postoperative pain management and other clinical outcomes.

Conclusions

It is interesting younger patients report a poorer HRQL prior to surgery. Vitality also seems to play an important role in pain management and LOS. Therefore, asking patients how they feel about their health before surgery might be important. Patients perceptions of their HRQL may have a role in helping the cardiac surgery team anticipate which patients might require a longer duration of MV or higher dosages of opioid analgesics to manage their postoperative pain. This study is an initial attempt to understand the relationships of preoperative HRQL, pain management, and other clinical outcomes after CABG, however additional research required explore how these findings can be applied in the clinical setting to improve postoperative pain management and early recovery outcomes.

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CHAPTER 3: CLINICAL DECISION-MAKING DURING WEANING FROM MECHANICAL VENTILATION AFTER CARDIAC SURGERY

Background

The evolution of fast-track cardiac surgery programs, in which patients are rapidly weaned and extubated within 6 hours of surgery (Cheng, 1998) have created unique clinical settings that require nurses to use dynamic, complex decision-making skills regarding pain management. In these clinical settings, nurses must decide how to effectively manage postoperative pain during weaning from MV while simultaneously facilitating early extubation. Pain is not easily managed in postoperative ventilated patients who are restrained and unable to verbalize; and is usually treated by opioids that are administered as an IV bolus by nurses on the basis of patients' physiologic and behavioral pain cues. Relief of postoperative pain is one of the most important concerns for cardiac surgery patients, yet to facilitate tracheal extubation; nurses often withhold or administer low intermittent IV boluses of opioid analgesia during weaning from MV (Renaud, 2002).

The reasons for under-treatment are not clear, although they have been attributed to insufficient knowledge about pain management (Watt-Watson et al., 2001; Brown et al. 1999) , nurses' beliefs, attitudes toward pain management (Hurlock-Chorostecki, 2002), and inadequate pain assessment tools (Puntillo et al., 2002). Although barriers to assess and manage pain in critically ill patients have been identified, little is known about the process of nurses' CDM to administer or withhold analgesia while they are involved in the rapid weaning and extubation phase of patient recovery from cardiac surgery.

Therefore, the primary purpose of this grounded theory study is focused on exploring the process of nurses' CDM when they are weaning postoperative cardiac surgery patients from MV in a fast-track setting. Because nurses are often the gatekeepers of analgesia to mechanically ventilated patients, this issue is important to the nursing profession. A preliminary review of the literature was conducted to gain a broad grasp of the theoretical and empirical knowledge of the topic (Strauss & Corbin, 1998). The 3 relevant bodies of literature that were reviewed included 1) pain management during weaning, 2) CDM theories, and 3) nurses' skill levels as they relate to CDM. Both the researchers' personal experience as a cardiac surgery critical care nurse and the information gained from the literature were bracketed to enable a thorough, open, investigation of the phenomenon.

Pain Management during Weaning

In the immediate postoperative period, nurses must deal with competing demands, such as stabilizing cardiovascular function, controlling bleeding, promoting thermoregulation, and assessing neurological status. These life-threatening issues take priority over pain management. Assessment of pain while transitioning patients from total ventilatory support to spontaneous breathing can be confounded by the lingering effects of intraoperative anesthesia and sedation. In addition, physiologic responses to pain such as changes in heart rate and blood pressure may be masked by the effects of certain medications such as beta blockers and vasoactive drugs used to promote postoperative hemodynamic stability.

Patients' verbal reports of pain and behavioral cues are impeded by the presence of endotracheal tubes that prevent verbal communication and the use of restraints that restrict movement. Unfortunately, the lack of patient pain indicators may be interpreted as an absence of postoperative pain and thus, nurses may withhold or administer inadequate analgesia (Passaro & McCaffery, 2005). Uncontrolled pain may prolong the need for MV by interfering with respiratory mechanics and causing ventilatory asynchrony. On the contrary, administration of opioid analgesics can result in respiratory depression, hypoxemia, and hypoventilation, which can also delay extubation. This challenging clinical dilemma presents unique opportunities for nurses to exercise CDM skills to provide adequate pain management while facilitating rapid weaning and extubation.

Clinical Decision-Making Theories

A long history of research regarding nurses' CDM has yielded knowledge about the models which guide decision making. Much of the early research was framed within analytical models of cognition. For example, early studies addressing CDM were primarily based on analytical approaches produced by statistical models, decision analysis theory, and the information processing theory (Hammond, Kelly, Schneider, & Vancini, 1967; Aspinall, 1979). These theories assumed that CDM was a linear process involving hypothesis generation, rational assessment of alternatives, and the selection of actions to reach desired goals (Thompson, 1999; Hancock & Durham, 2007). However, the assumption that nurses think in a linear fashion has been questioned because it does

not capture the reality of clinical practice (Thompson, 1999), nor is it suitable for the type of prompt decisions that are characteristic of nursing.

The recognition of intuition as a component of CDM gained interest over the last 20 years. For example, Tanner (1987) found that nurses use patterns and relationships in CDM, knowledge was derived from similar and dissimilar situations, and action preceded rational analytic thought. In other studies, intuition was described as the deliberate application of knowledge or understanding gained immediately as a whole, beyond what is discernable to the senses, and distinct from linear and analytical reasoning processes (Benner & Tanner, 1987; Rew, 1986; Gerrity, 1987).

Studies have also described decision-making as a cognitive continuum with analytical and intuitive cognition occupying opposite anchoring positions (Hamm, 1988; Hammond et al., 1967; Lauri & Salanterä, 1998). Lauri et al. (1998) described CDM of nurses that practiced in intensive care units. She reported that nurses' decision-making involved various models of decision-making represented by analytical, intuitive, and quasirational modes of cognition based on the complexity of the task. In a study examining the CDM processes of expert critical care nurses in relation to hemodynamic monitoring, Aitken (2003) found that participants used a range of decision-making strategies. In a study of decision-making of critical care nurses when extubating patients following cardiac surgery, Hancock & Easen (2006) reported that CDM emerged as a complex and dynamic process, reflecting both analytical and intuitive characteristics.

Nurses' Skill Level

Studies that examined the role of clinical experience in CDM suggest that experience gained from time spent in the clinical setting facilitated CDM. Benner, Tanner, & Chesla (1992) described the nature of skill acquisition with a sample of nurses who practiced in ICUs. She reported that advanced beginners use learned procedures to infer what action needed to be taken for patients. Proficient nurses experience a shift in perceptual grasp and developed the ability to look at patients' clinical situation and notice changes sufficiently enough to warrant a change in perspective and action. Expert nurses grasp situations immediately and directly, and allowed patients' nuances and subtleties provide direction for care. Benner et al. (1992) suggested that experience was the foundation of expert nurses' ability to recognize a situation holistically, identify salient aspects, and quickly and accurately identify and act on a problem. In a grounded theory study regarding pain management during weaning from MV in a trauma ICU, Hurlock-Chorostecki (2002) described CDM as a continuous dynamic process, highlighting Benner's (1984) theory that clinical experience influences the means by which nurses gather and interpret knowledge about patients. Therefore, a secondary purpose of this qualitative study was to explore decision-making with respect to nurses' skill level.

Methods

Grounded theory (GT) methodology was developed to explore patterns of behavior in a particular group of people in a certain context (Strauss & Corbin, 1998). Institutional Review Board approval was granted (Appendix B) and the principle investigator obtained permission from the nurse manager of the cardiac surgery ICU

(Appendix D) to conduct the interviews in a non-academic hospital in the southeastern U.S. New employees in the orientation phase of employment were excluded from the sample because they do not routinely admit patients from the operating suite. Weaning and extubation were protocol driven in the cardiac surgery ICU, which included criteria for physiological parameters, neurological status, and hemogasanalysis.

Recruitment and Data Collection Procedures

A convenience sample of registered nurses (RNs) working in the ICU were invited to participate in the study. Prior to the interview, each participant signed a consent form, completed demographic information, and rated their professional skill level using a short instrument created by Hurlock-Chorostecki (2002) that was based on Benner's (1984) levels of skill acquisition (see Table 3). To validate the participating nurses' self perception of professional skill while maintaining confidentiality, the researcher asked the manager of the ICU to provide a rating of the entire ICU nursing staff. The ratings of the study participants were compared to the ratings of the nurse manager and found to be the same.

Table 3

Levels of Skill Acquisition

Level of Skill	Characteristics
Novice	Limited experience with patients who are being weaned from mechanical ventilation. Goals and tools of patient care are unfamiliar.
Advanced Beginner	Limited experience with patients who are being weaned from mechanical ventilation. Overall characteristics, such as weaning success indicators, can be identified from previous experiences.
Competent	Has worked with mechanically ventilated patients 2 or 3 years. Able to cope with and manage changes in the patient. Conscious, deliberate planning of the weaning process takes place.
Proficient	Has worked with mechanically ventilated patients more than 3 years and has the ability to recognize whole situations. Knows typical events that can be expected during weaning from mechanical ventilation and recognizes deterioration or patient problems and modifies plans prior to explicit changes (such as vital signs)
Expert	Has an intuitive understanding of weaning each patient from mechanical ventilation. Has a deep understanding of the whole situation and can zero in on a problem quickly and accurately.

Source: Adapted from: Benner, P. (1984). *From Novice to Expert.* Menlo Park, Ca: Addison-Wesley.

After interviewing the first 3-4 participants and analyzing and comparing the data, it was recognized that nurses' skill level and the type of shift worked (days or nights) in the cardiac surgery ICU might have a bearing on the CDM process. Theoretical sampling

was then used to recruit additional volunteers who varied in skill level and who worked day and night shifts. Theoretical sampling is a process whereby participants are selected with the aim being to explore varied conditions along which the properties of the concepts vary and to obtain a reasonably balanced sample relative to participant knowledge of the topic (Strauss and Corbin, 1998).

The final sample was comprised of 11 RNs with a range of experice levels in weaning patients from MV in fast-track cardiac surgery programs. All participants were females between 25 and 55 years of age with 1 to 15 years of experience in cardiac surgery ICU practice. Two African American and one Hispanic nurse were included in the sample. Five participants were baccalaureate-educated nurses, and 6 had associate degrees. Only 2 of the participants held professional certification in adult critical care. Seven nurses worked day shifts and 4 worked nights. The self-reported skill level of the participants included: 3 advanced beginners, 2 competent, 1 proficient, and 5 expert nurses. For simplification of analysis, Benner's five skill levels were collapsed into two broad levels: the less experienced (novice, advanced beginner, and competent) and the more experienced (proficient and expert), yielding 5 less experienced nurses and 6 more experienced nurses in the sample.

The principle of constant comparison process was utilized during data collection. Data were gathered through face-to-face semi-structured interviews lasting 45-75 minutes. The leading question for each interview was "how do you make decisions about pain management while weaning patients from mechanical ventilation after cardiac surgery?" The interviews were audio taped at private locations selected by the

participants. Tapes and field notes were transcribed by the researcher within 24 hours of each interview and secured separately from the transcripts. Pseudonyms were used to ensure participant confidentiality. Constant comparative data analysis continued until data saturation was reached and no new information was reported.

Data Analysis

At the beginning of the study, consideration was given to whether the transcribed data would be analyzed by hand or by computer. The researcher, in consultation with an advisor, decided to code by hand to enable greater visualization of the data than using qualitative software. The analysis of the data was coded in a multiple stage process of open coding, axial coding, and selective coding. Open coding began with identification of approximately 80 codes using line-by-line *in-vivo* coding. Caution was used to select the most descriptive and explicit codes that were reported by the majority of the nurses.

During axial coding, the codes were linked to subcategories by noting their properties, dimensions, and interrelationships. Some codes and subcategories were combined with others according to how they were conceptually related. For example, 'monitoring physiological parameters', 'observing behavioral cues', and 'obtaining medical history' were linked to the subcategory of 'knowing the patient'. The categories were further refined to ensure they were interpretive of the events and actions described in the interviews.

Selective coding was then used to integrate and organize categories around a core category (Strauss and Corbin, 1998). The researcher established linkages in the data that represented the challenges nurses' encounter when making decisions about managing

pain while weaning patients from short term MV. A core category that represented nurses' CDM process was then conceptualized.

Findings

Nurses consistently expressed beliefs that patients "had to endure some pain" during weaning to reach the 6-hour goal of tracheal extubation after surgery. Three domains of the CDM process were identified: knowing the patient, becoming a team, and promoting the patients' best interest. The categories and phases of decision-making were clustered around phases of caring: assessment, coaching, and advocating.

Knowing the Patient

Assessment

The ability to internally and externally monitor patients is a distinguishing feature of critical care and influences CDM of nurses working in cardiac surgery ICUs. The technological data sources demand competent decision-making from nurses working with critically ill, unstable patients with complex goals (Bucknall, 2003). The availability of technology enabled nurses to obtain initial knowledge of patients from several sources in the immediate postoperative period, including physiological signs and the medical history. This knowledge, which was usually obtained in rapid succession while multi-tasking to stabilize patients, was considered vital in that it established a baseline to guide decision-making through the next several hours.

Monitoring physiological parameters. Nurses monitored patients' physiological responses to pain via hemodynamic status and vital signs such as blood pressure, heart rate, and respiratory rate. Particular emphasis was placed on these parameters after arrival

to the ICU from the surgical suite when patients were possibly under the residual effects of neuromuscular blockade medications that were administered intraoperatively. The more experienced nurses related a stronger clinical knowledge base regarding this barrier to pain assessment as reflected by this expert nurse's statement: "I go by hypertension and tachycardia because they (the patients) are probably waking up underneath that neuromuscular blocker and they can't move (to communicate that they are experiencing pain)".

Observing behavioral cues. In addition to monitoring physiological parameters, when the effects of anesthesia begin to wear off and patients became more awake, nurses observed patients' for behavioral cues that would indicate the presence of postoperative pain. Regarding observing behavioral cues, one experienced nurse put it in these words " you just have to read the patient the best you can". Some nurses stated that there was a lot to take into consideration, and "you really don't think about it, you just do it". Behavioral cues were described by a less experienced nurse as "making any type of grimacing or other body gestures that would indicate nonverbal pain cues" and by a more experienced nurse as "being able to verbalize (pain) through motion". Another experienced nurse described her approach to pain assessment in the non verbal mechanically ventilated patient in this statement:

I also look at their eyes. You can tell a lot by looking in a person's eyes, and they can tell you (if they are in pain) just by looking at them…whether it's a tear in their eye, whether it's a look of fear, whether it's a calmness…

Nurses at both experience levels made clear distinctions between behavioral cues associated with postoperative pain and those linked with patients' difficulty emerging from anesthesia. Comments regarding patients who "wake up hard" (from anesthesia) were described as being "agitated" and "combative". They exhibited behaviors such as "kicking", "pulling up", and "banging" (their head and arms) and looking "freaked out", "startled", and like a "dear in the headlight". Nurses considered these behaviors "detrimental to the patient", because they could possibly "rip their chest open", jeopardizing the sternal incision and risking dislodgement of invasive lines. Pharmacological management of these patients included sedation to allow them to "calm back down, regroup, and wake up easy".

Obtaining the medical history. This category included comments that described nurses' belief about the importance of patients' medical history in decision-making regarding pain management during weaning. One nurse stated: "History is a big thing". Sources for obtaining the medical history included the 'history and physical' located in patients' charts, medication administration records, and handoff communication from surgical staff. Family members were recruited by nurses to obtain information regarding patients' history and pain tolerance. Family members offered insights into patient's pain-related behaviors such as "he (the patient) is very stoic" and "she (the patient) won't ask for pain medicine when she needs it".

Nurses across both experience levels indicated that patients with medical histories such as chronic pain or previous back surgeries might require adjustments in their pain medications and were prepared to negotiate with physicians for stronger analgesics or

non-steroidal anti-inflammatory medication. This was illustrated by the following comment: “patients with chronic pain require more pain meds”…“a lot of these people are on morphine and fentanyl at home….they live with pain…and we have give those people something….that’s really going to help them”.

Becoming a Team

Coaching

Later in the weaning process, as patients became fully conscious, nurses attempted to establish a meaningful form of communication, which involved explaining and reinforcing information, and proposing a partnership to prepare for extubation.

Establishing communication. Nurses established functional communication patterns with patients by asking them to “nod” their head “yes or no” to questions. One nurse stated “I’ll untie their hands and say ‘point to what is bothering you’…is it the (endotracheal) tube, the (urinary drainage) catheter, the chest tubes?” The use of eye contact, having patience, and speaking in a calm voice were also important aspects of establishing effective communication patterns with patients.

Explaining and reinforcing. Explanatory approaches included showing patients equipment, explaining noises from the cardiac monitor and ventilator, and describing the pressure changes that patients experience in different ventilator modes during weaning. One nurse stated “I explain…you’re going to start doing some of the work of breathing now…and you’re going to feel some pressure changes…you’re going to feel like your suffocating…but I promise, you’re not”. Reinforcement strategies included comments such as “have patience, you know, work with them…”, “teach and re-teach over and

over… in a calm and reassuring manner …because they fall back asleep and forget what you tell them".

Proposing a partnership. Successful weaning from MV required active participation and cooperation between patients and nurses. Nurses tried to instill confidence and courage in patients by explaining that they were "unable to take *all* the pain away", yet promised to "take the edge off" with medication so patients could stay awake, and work with them to facilitate extubation. This type of collaboration was illustrated by the following example: "you're (the patient) gonna have to help me, you're gonna have to endure some pain, and if you can tolerate it, we'll get that (endotracheal) tube out". Another nurse described collaboration with patients regarding the use of the restraints: "Work with us so we can get those restraints off as soon as we get that breathing tube out". Partnership with family members was handled on an individual basis, as some members were capable of "calming the patient down" and others "agitating the patient".

Promoting the Patients' Best Interest

Advocating

Nurses collaborated with patients, fine-tuned medication regimens and negotiated modifications in the weaning protocol as needed with the physician and other members of the health care team.

Fine-tuning the medication regimen. Although nurses had general parameters for medication administration, they exerted considerable judgment on the dose and timing of administering medications. Nurses' dosing decisions for opioid analgesics appeared to be

related to the length of time since arrival in the ICU and the estimated time to extubation. One nurse described it this way: “I may give them the full 5 mg if it’s real soon after they have come out (from the operating suite). If it’s closer to the extubation time …then I’ll just give a couple of mgs”. When nurses determined that analgesics or dosages were not effectively alleviating pain, they demonstrated patient advocacy by contacting the surgeon to recommend adjusting dosage ranges, obtaining orders for stronger analgesics, or requesting nonsteroidal anti-inflammatory agents.

Negotiating modifications to the weaning plan. Although the nurses had considerable leeway in administering medication; sometimes it was necessary to negotiate a new plan for weaning and extubation. This could include contacting the surgeon to request more time for weaning as expressed by an expert nurse: “give them a little extra (morphine) and if they go to sleep, what’s an extra hour or two on the clock if they’re (patients) going to wake up with their pain a little more controlled?” Less experienced nurses tended to consult with more experienced nurses prior to contacting the surgeons. An expert nurse described her approach in contacting the surgeon to modifying the weaning plan in this way: “I know you want to extubate this patient, but, sir, this person is 70 years old and just had open heart surgery…please let him rest, let him recuperate, he needs a little more time’. She emphasized the importance of being “tactful” in negotiating because “we (nurses) are professionals”, yet she also admitted, “I’ve had to come to words with them (the surgeons) and be more aggressive” to advocate for patients’ needs.

A few participants stated that they believed nurses did not medicate patients "enough" because the surgeons try to get patients extubated within 6 hours following surgery. One nurse stated that due to the pressure of the rapid weaning and early extubation protocol, she felt nurses do a disservice to patients by not effectively controlling their pain during weaning and described her sentiments on a personal level: "Knock me out…I don't care how long I sleep. Don't leave me on the vent for 24 hours, but don't be afraid to give me pain medication either!" Another nurse echoed the same sentiments: "I'd rather give the medication and leave them on the vent a little bit longer versus …not making them suffer to extubate".

Identifying the Core Problem and Core Category

After coding and categorizing the data, the next step was to identify a core problem that was experienced by the nurse participants, but was not always clearly articulated in the data. The concept of *balance* as it related to pain management during weaning was mentioned frequently in terms such as "weigh," "a grey area," "a fine line," and "a slippery slope". Less clear, however, was exactly *what* the nurses were balancing. After constant comparative analysis, persistent questioning, and analytical thinking, it was realized that the nurses were balancing *goals* such as 1) the goal of achieving a "tolerable" level of pain control for patients during weaning and 2) the goal of extubating patients within the "6 hour window". Therefore, the core problem was identified as 'balancing goals'.

Analysis then focused on identifying a core category and attempting to establish links between this and other categories. It was a cyclical process, shifting from open to

axial and then selective coding. A core category began to emerge and was conceptualized as *Goal-Directed Pain Management during Weaning*, which represented the way nurses made clinical decisions about pain management while rapidly weaning patient from MV after cardiac surgery. The relationships between the categories, phases, domains, the core problem, and core category as they relate to pain management and weaning is demonstrated in Table 4.

Table 4

Overview of the Findings

Core Category	Goal-Directed Pain Management Decisions during Weaning		
Core Problem	Balancing Goals of Tolerable Pain Levels and Early Extubation		
Domains	Getting to Know the Patient	Becoming a Team	Promoting the Patients Best Interest
Phases	Assessment	Coaching	Advocating
Categories	Monitoring Physiological Parameters	Establishing Communication	Fine-tuning Medications
	Observing Behavioral Cues Obtaining Medical History	Explaining and Reinforcing Proposing a Partnership	Negotiating Modifications

Discussion

Previous research by Aitken (2003) suggested that nurses use various decision-making strategies such as the highly structured analytical approach to the ill structured intuitive approach in hemodynamic monitoring. She also asserted that nurses used a wide

range of data in the decision-making process and that the decision-maker must have a good grasp of the topic under consideration. The current study supports her findings in that cardiac surgery nurses utilized information processing approaches to monitor physiological parameters and make decisions on dosing analgesics. While physiological data were always used in nurses' CDM, it formed only part of the basis for decisions. For example, the use of intuitive decision-making approaches was also evident in the current study as nurses learned to 'read' their patients and 'just doing it" without thinking about it. Our results support Lauri & Salanterä, (1998) findings that CDM involves both analytic and intuitive reasoning. Skill level was noted to play a part of decision-making by nurses in our study. More experienced nurses supported the less experienced when they were hesitant in fine-tuning the medication regimen or negotiating modifications to the weaning plan. This finding supports the conclusions reached by (Hurlock-Chorostecki, 2002) in her study of weaning patients in a trauma ICU.

Participants indicated that weaning can be associated with pain from multiple sources such as the endotracheal tube, the sternal incision, chest tubes, and invasive monitoring lines. However, they were conservative in the administration of analgesics in that they "start with low doses" and "give small increments" to "take the edge off (the pain) in order to "wean with as little narcotics as possible…because the ultimate goal is to get them extubated". Previous research reported pain as poorly controlled pain (Watt-Watson et al.,2001; Milgrom et al., 2004), underestimated, undermedicated, and underrelieved (Ferguson et al., 1997; Gust et al., 1999; Gelinas, 2007). In this study, nurses are not underestimating patients' pain and they are attempting to control it,

however, they are balancing administrating of opioid analgesia with trying to rapidly wean patients from MV to meet early extubation goals. The findings in this study indicate that in this unique clinical setting, nurses see pain as something that is at least partly necessary and through "promoting partnership" they try to help patients understand the weaning process and they also advocate for patients when needed. Previous studies portray nurses as unsympathetic and harsh, while it is clear in this study that nurses were not intentionally ignoring patients' pain.

Understanding clinical decision-making of cardiac surgery ICU nurses is important from both a clinical and health systems perspective. Nurses, particularly new nurses, need to understand concept of "balance" in caring for posterative cardiac surgery patients. Too often orientation programs focus on what to do (i.e. policies and procedures) without adequate attention to the "how". Helping new nurses accurately read cues, both physiologic and behavioral, and then encouraging them to act on that knowledge is important. Mentoring new nurses on how to establish communication with the patient, the family, and the physician is important because the novice nurse is more likely to focus on following the rules and will miss opportunities to fully engage the patient as a partner or to advocate with physicians when there needs to be a modification in the plan. Using role play or simulation to help new nurses understand and practice these skills might lead to a better safer work environment in which new nurses thrive rather than feel overwhelmed. Nurse managers need to adjust staff workloads to be sure that experienced nurses are available on units when cardiac surgery patients are arriving from the operating suite to be available as a resource to less experienced nurses. In

addition, this knowledge has the potential to establish broader guidelines and protocols for administration of analgesia during weaning.

Conclusion

This study was a first step toward developing a middle-range theory of CDM regarding pain management during weaning patients from short-term MV after cardiac surgery; however it should be replicated in other fast-track cardiac surgery programs so that the results can be validated.

(This manuscript will be submitted to the *Journal of Nursing Science* after final revisions and formatting. 1st Author: Malinda Langley, RN, PhD(c), 2nd Author: Martha Engelke, RN, PhD, 3rd Author: Sylvia Brown, RN, EdD-CNE)

CHAPTER 4: EFFECTS OF A CONTINUOUS LOCAL ANESTHETIC INFUSION AT THE MEDIAN STERNOTOMY ON CARDIAC SURGERY OUTCOMES

Background

Pain relief is one of the most important concerns for CABG patients and is one of the most clinically challenging problems for nurses. Recent surveys report only modest success in pain management as patients continue to describe poorly controlled pain (Watt-Watson et al., 2001); Milgrom et al., 2004) and studies report pain following CABG as underestimated, undermedicated, and underrelieved (Ferguson et al., 1997; Gust et al., 1999; Gelinas, 2007). Pain following CABG surgery arises from the sternotomy, pleural irritation caused by chest drains, osteoarticular trauma caused by retraction of the thoracic cage, and sites from which bypass conduits have been obtained (saphenous vein, radial artery) (Mueller et al., 2000; Miller et al., 2007; McDonald et al., 2005).

It is widely recognized that postoperative pain can negatively impact cardiac surgery outcomes (Swope, 2002). For example, uncontrolled pain during weaning from MV can delay tracheal extubation due to hypoxemia, hypoventilation, and ventilator asynchrony (Renaud, 2002). After extubation, pain limits deep breathing and forceful coughing, which contributes to sputum retention and atelectasis and increases the risk for pneumonia (Miller et al., 2007). Postoperative pain contributes to patients' reluctance to participate in daily activities that promote early mobilization and prevent the development of deep vein thrombosis (Margereson & Riley, 2003). The consequences of

uncontrolled postoperative pain impede the recovery process, thereby prolonging ICU hours, and hospital LOS.

In addition, over the last decade, economic and societal expectations for rapid recovery following CABG have spawned the emergence of fast-track programs. Key components of fast-track cardiac surgery programs are interventions that facilitate early extubation and accelerate activity without compromising patient care (Dunstan & Riddle, 1997). Therefore, optimizing postoperative pain control is essential for patients who are on fast track extubation (e.g., 1-6 hours after surgery) (Cheng, 1998) and discharge protocols (e.g., discharge 3-5 days after surgery) (McKee et al., 2007). Approximately 469,000 CABG surgeries were performed in 2005 U.S. (American Heart Association, 2008), and fast track programs are now considered the standard of care for all but the most critical patients (Hawkes et al., 2003).

Traditional pain management after sternotomy consists of IV and oral administration of opioid analgesics via patient or nurse controlled delivery systems. However, opioid effects, such as respiratory depression can delay tracheal extubation. Opioid induced drowsiness can hamper participation in daily activities including ambulation and produce unwanted gastrointestinal effects (e.g., nausea and vomiting). To reduce the adverse systemic effects of opioid analgesics, adjunctive use of nonsteroidal anti-inflammatory drugs (NSAIDS) have been introduced into some pain management regimens. Although NSAIDS can produce opioid-sparing effects after CABG, they must be used sparingly to prevent untoward side effects on gastric, renal, and coagulation parameters (Hynninen et al., 2000). Another adjunctive modality that might help improve

postoperative pain and reduce the need for opioid analgesics is surgical placement of a catheter to continuously infuse local anesthetic into the surgical wound.

There is an increasing body of literature on the use of a continuous LAI at surgical wounds as a component of a multimodal postoperative pain management approach in specialties such as obstetric, plastic, and general surgery (Lu & Fine, 2005; Givens et al. 2002; Sanchez et al., 2004). In the cardiothoracic literature, most RCTs examined use of continuous LAIs for pain management at thoracotomy incisions after lung resection. Only 4 published studies investigated the use of this adjunctive modality at the median sternotomy (White et al., 2003; Dowling et al., 2003; Magnano et al., 2005; Koukis et al., 2008).

The sample sizes in these studies were small and included a variety of major cardiac surgeries such as initial and reoperative CABG with and without transmyocardial revascularization; valve replacements/repairs, septal defect repairs, and reconstruction of left ventricular aneurysms. Overall, some improvement in pain control was demonstrated, a decreased requirement for opioid analgesics was noted, and a shorter hospital LOS was recorded. However, diverse types of catheters were utilized with varying placement techniques and the selection of local anesthetic agents differed as well as the duration of infusion.

Recently, 10-inch soaker catheters have been developed for longer surgical incisions that may be beneficial for patients with sternotomies. In addition, to date, there have been no published reports have examined the effectiveness of a continuous LAI as an adjunct to pain control with and without the use of cardiopulmonary (CPB) surgical

techniques. Therefore, we designed a prospective, dual-armed (with and without CPB), randomized, placebo-controlled, double-blind clinical trial to examine the following hypotheses:

Primary Hypotheses:

- Patients receiving a continuous LAI at the sternotomy will report less postoperative pain intensity after CABG when compared to patients receiving a placebo.
- Patients receiving a continuous LAI at the sternotomy will require less opioid analgesia after CABG when compared to patients receiving a placebo.

Secondary Outcome Measures:

- To examine the impact of a continuous LAI at the sternotomy on duration of mechanical ventilation, initial ambulation from bed to chair, ICU hours, and hospital LOS when compared to a placebo.

Materials and Methods

Setting and Procedures

The setting for the study was the cardiac surgery ICU and step-down unit of a 760-bed, acute care, non-academic hospital in the southeastern U.S. After obtaining approval from the Institutional Review Board (Appendix F, G), research assistants began screening and enrollment in January 2007 and continued until January 2008. The study population included adult patients who underwent initial, elective CABG via standard median sternotomy. The exclusion criteria included a known allergy to local anesthetics, renal failure requiring dialysis, concurrent (cardiac or noncardiac) procedures, body

weight less than 45 kg, non-fluent in English, or the inability to understand the consent form.

Using the results from a preliminary study, we determined an effect size, Cohen's d of .78, which was used to estimate sample sizes for both arms of the study. Assuming a power of 80%, a two-sided significance level of .05, and a Cohen's d of .78, we estimated a sample size of 26 in each group.

Off-pump (without CPB) or on-pump (with CPB) surgery was based on the surgeons' routine practice. Assignment of the participants to the treatment or control groups was determined by the study pharmacist on the basis of a random table created in advance of patient enrollment using the Research Randomizer © Program (Urbaniak, 2007), resulting in 4 groups for analysis. Designated pharmacy personnel prepared the study solutions, filled, and labeled the pumps. Thus, all participants, surgeons, surgical staff, and RNs were blinded to the contents of the pump. The assignment sequence remained concealed until enrollment was closed and data analysis was complete.

Preoperative Procedures

Patients were introduced to the numeric rating scale (NRS) used to rate their pain from 0 (no pain) to 10 (worst pain imaginable). Patients were informed that they would receive IV hydromorphone by means of a PCA pump, instructed on its use, and were advised to use it as needed for pain control. This study did not incur any additional cost to patients. Patients received standardized isoflurane-based anesthesia with minimal amounts of midazolam and fentanyl, which allowed for early extubation and lessened residual intraoperative anesthetics as a confounding variable.

Intraoperative Procedures

CABG was performed either with or without CPB using standard techniques. Although 2 surgeons participated in the study, one surgeon performed most of the off-pump cases, and the other performed most of the on-pump cases. After re-approximation of the sternum, two 10-inch soaker catheters with multiple openings along the infusion segment were inserted percutaneously at the lower end of the sternum. The catheters were guided into the subfascial plane, 3–5 cm lateral to each side of the sternal incision using a subpectoral tunneling technique and attached via a Y-connector to a pressurized elastomeric infusion pump filled with 500 ml of 0.5% bupivacaine (treatment) or saline (control). The infusion pump, a single use, disposable unit with a flow restrictor, continuously delivered 4 ml/hr (2 ml/catheter) along the lateral borders of the sternum for 96 hours. The catheters were sutured into place and the extension tubing was coiled and secured with an occlusive dressing to deter accidental removal. On POD 4, when the infusions were completed, RNs discontinued the catheters.

Postoperative Procedures

Following surgery, patients were transferred to the cardiac surgery ICU intubated and mechanically ventilated until hemodynamically stable with minimal chest tube bleeding. Ventilator weaning was guided by standardized fast-track protocol, and postoperative care was performed per standard-of-care guidelines for all patients undergoing CABG. Within 1 hour of arrival to the ICU, a PCA pump, programmed with weight-based (0.003mg/kg) IV hydromorphone was initiated for use on an as needed basis. If patients required rescue pain medications beyond their PCA lockout, RNs

administered weight-based hydromorphone boluses. If pain continued to be uncontrolled, the surgeons were notified and based on renal function, coagulation studies, and postoperative bleeding; IV ketorolac was ordered as an initial 30 mg IV dose, followed by 15 mg IV every 6 hours for 3 additional doses. PCA pumps were discontinued 48 hours postoperatively. Pain was then managed with oral oxycodone administered every 4 hours on an as needed basis.

Because the assessment of pain in the first 24 hours after surgery might be influenced by residual intraoperative anesthetics, data were recorded from POD 1 - POD 3 regarding pain intensity, location, and opioid analgesic consumption. Patients were approached every 4 hours for pain assessment, and if they were awake, RNs asked the patients to identify the location of their pain and used the NRS to ask, "What number would you give your pain right now?" The numeric rating was interpreted as 0 = no pain, 1–3 = mild pain, 4–6 = moderate pain, 7–10 = severe pain (McCaffery & Beebe, 2003).

The interval between arrivals in the ICU to extubation was noted. Because unit routines and hospital processes sometimes delay patient progression, criteria were established for 1) patient readiness to initially ambulate a few steps from bed to chair, and 2) patient readiness for the step-down unit. The actual time patients initially ambulated from bed to chair and the time of transfer out of the ICU were also recorded. Criteria were not established for patient readiness for hospital discharge, therefore the point at which patients left the hospital was recorded. For comparison, opioid analgesics were standardized to MEs (McAuley, 2007). Anti-inflammatory medications and sedatives

were not included in the equianalgesic calculations. The incidence of nausea and vomiting was also noted.

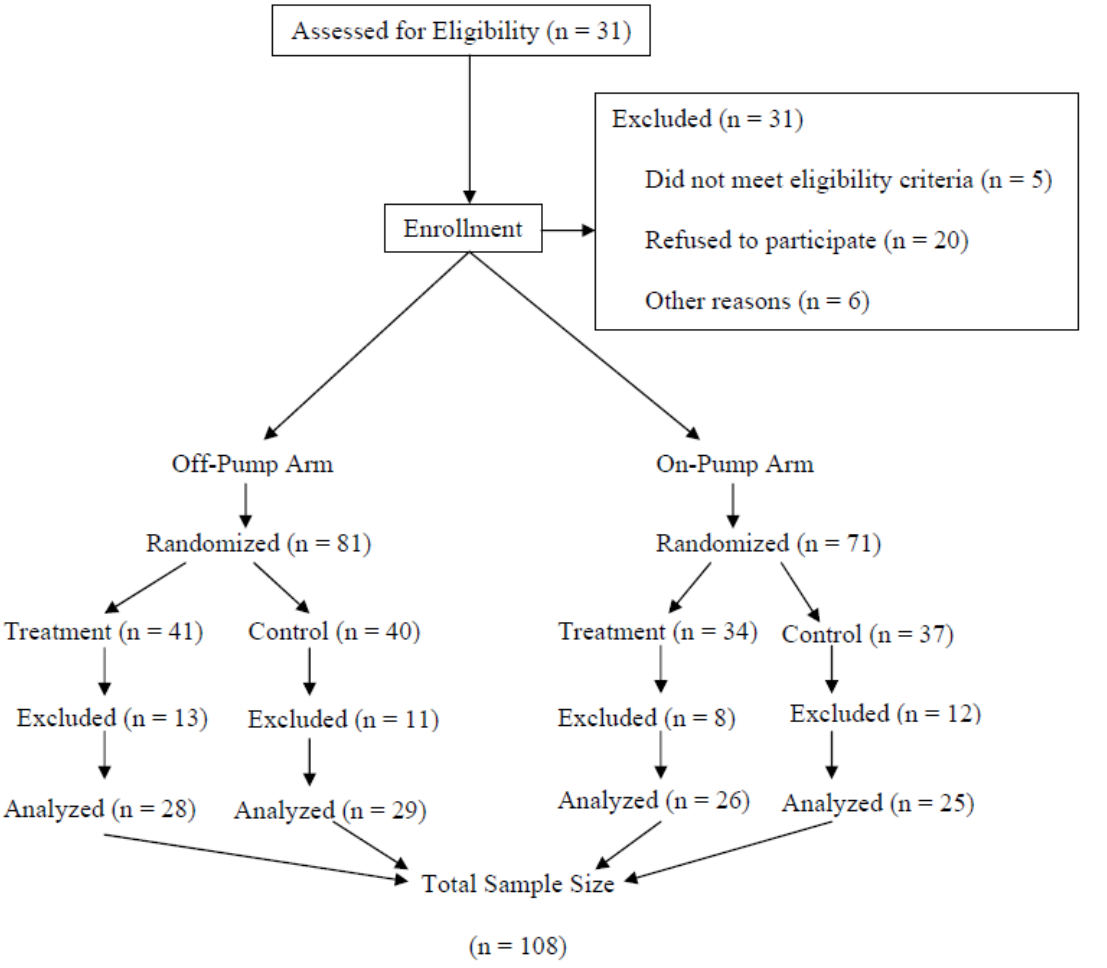
Demographic and baseline characteristics between study groups were analyzed with the Pearson χ^2 test or the Fisher's exact test for categorical variables and a one-way between groups analysis of variance (ANOVA) for continuous variables. A one-way ANOVA was conducted to explore the effect of a LAI on pain intensity, opioid analgesic consumption, time to extubation, time to initial ambulation to chair, ICU hours, and hospital LOS. All parameters had descriptive statistics calculated. Inferential and descriptive analyses were performed at the 0.5 significance level. The Statistical Package for the Social Sciences version 15.0 was used for statistical analysis.

Results

A total of 152 patients were enrolled in the study. However, 44 patients were excluded from data analysis because of failure to initiate therapy (e.g., surgery cancellation, intraoperative complications) or protocol violations (e.g., prolonged intubation (>24 hrs), reintubation, reoperation, and postoperative invasive procedures). No local anesthetic drug toxicity was identified in any patient. Figure 1 demonstrates the flow of participants through each stage of the study. The final sample (n = 108) included 2 arms (off and on CPB), each containing a treatment and control group. Therefore, 4 groups were analyzed: off-pump/treatment (n = 28), off-pump/control (n = 29), on-pump/treatment (n = 26), on-pump/control (n = 25).

Figure 1

Flow of Participants



Participants in all 4 groups were similar in demographic and clinical parameters. There were no differences with respect to age, height, and weight. The majority of participants were Caucasian males in their 60's. Approximately one half of the sample had a history of smoking and diabetes, while a third of the sample claimed to have a chronic pain condition. The groups did not differ significantly with respect to the preoperative Society of Thoracic Surgeons (2008) Morbidity and Mortality Risk

Calculations, preoperative ejection fraction, anesthesia protocol, or harvesting of an internal mammary artery (IMA). Treatment and control groups that were performed off-CPB had similar operative minutes. Although the surgeries performed with CPB were slightly longer cases, the treatment and control groups were similar in length, as well as CPB bypass and aortic cross clamp times. See Table 5 for demographic and clinical details.

Table 5

Baseline Characteristics and Operative Data

	Off –Pump (Without CPB)		On-Pump (With CPB)	
	Treatment	Control	Treatment	Control
Patients (n)	28	29	26	25
Male†	19 (68%)	18 (62%)	18 (69%)	18 (72%)
Age (yrs)*	63 ± 10.3	63 ± 10.7	62 ± 10.1	61 ± 11.4
Height (cm)*	171 ± 10.4	170 ± 11.9	173 ± 10.2	172 ± 8.1
Weight (kg)*	91 ± 22.1	85 ± 19.2	96 ± 21.3	87 ± 17.0
Caucasian†	25 (89%)	18 (62%)	20 (77%)	20 (80%)
Smoker†	23 (82%)	18 (64%)	12 (46%)	15 (60%)
Diabetes†	13 (46%)	12 (41%)	14 (54%)	9 (36%)
Chronic Pain Condition†	9 (32%)	6 (21%)	9 (35%)	6 (24%)
Ejection Fraction*	62 ± 12.7	57 ± 10.9	61 ± 6.7	58 ± 13.2
STS Mort Risk*	1.9 ± 1.9	2.2 ± 1.9	1.8 ± 2.0	1.7 ± 1.3
STS Morb/Mort Risk*	13.5 ± 9.9	14.4 ± 8.6	13.2 ± 8.6	11.9 ± 6.2
IMA†	26 (93%)	26 (90%)	26 (100%)	24 (96%)
OR (min)*	201 ± 46	193 ± 42	250 ± 35	235 ± 35
CPB Time (min)*	-	-	99 ± 25	93 ± 26
Cross-Clamp (min)*	-	-	62 ± 17	57 ± 17

*Values expressed as mean ± standard deviation; n = sample size; † Values expressed as n and % within study group. STS = Society of Thoracic Surgeons; Mort = Mortality; Morb = Morbidity; IMA = Internal Mammary Artery; OR = length of operation; CPB = cardiopulmonary bypass; min = minutes; yrs = years; cm = centimeters; kg = kilograms. All values are statistically nonsignificant.

Approximately half of the patients in all 4 groups identified the sternal area as a location of pain on POD 1 – POD 3. Patients in the treatment and control groups of both arms of the study reported comparable pain intensity scores. Pain intensity appeared to peak at a moderate level with NRS scores at 4–5 on POD 2 and 3 (Table 6), with a limited number of patients experiencing severe postoperative pain in the sternal region.

Table 6

Pain Intensity Scores

	Off –Pump (Without CPB)		On-Pump (With CPB)	
	Treatment	Control	Treatment	Control
POD 1				
M ± SD	3.0 ± 0.8	3.0 ± 1.2	3.7 ± 2.6	3.9 ± 1.2
Range	2 – 4	1 – 5	1 – 10	2 – 5
n	n = 13	n = 14	n = 12	n = 13
(% group)	(46%)	(48%)	(46%)	(52%)
POD 2				
M ± SD	5.2 ± 1.6	4.4 ± 2.2	4.1 ± 1.8	4.5 ± 1.6
Range	2 – 8	1 – 9	1 – 7	2 – 8
n	n = 15	n = 18	n = 12	n = 16
(% group)	(54%)	(62%)	(46%)	(64%)
POD 3				
M ± SD	4.7 ± 1.4	5.1 ± 1.4	4.4 ± 1.0	5.0 ± 1.5
Range	3 – 8	3 – 8	3 – 6	2 – 7
n	n = 13	n = 15	n = 16	n = 15
(% group)	(46%)	(52%)	(62%)	(60%)

Pain Intensity measured using the Numeric Rating Scale: 0 = no pain, 10 = worse pain imaginable.

Values are mean (SD); range, number (n); (% of group reporting sternal area as a location of pain).

POD = Postoperative day. All values are statistically nonsignificant.

The total amount of MEs required during weaning from MV did not vary significantly between treatment and control groups in either arm of the study. Limited patient dosing via PCA was expected until they were awake enough to use the PCA. Rescue opioid analgesics were administered for 18 patients in the on and off CPB treatment groups and for 15 patients in the on and off CPB control groups respectively. Nine patients in the entire sample required midazolam IV during weaning due to agitation. The total ME requirements were similar and patients in all 4 groups were extubated within an average of 5–6 hours (Table 7).

A secondary analysis was conducted with the entire sample (n = 108) with regards to extubation hours as they related to time of arrival from the operating suite to the ICU. Patients arriving in the ICU prior to 1 pm were considered morning cases n = 3 (68%), and cases arriving after 1 pm were considered afternoon cases n = 34 (32%). The average extubation hours were 6.0 ± 4.2 and 5.6 ± 3.8 for morning and afternoon cases, respectively.

Table 7

Morphine Equivalent Requirements during Weaning and Ventilator Hours

	Off –Pump (Without CPB)		On-Pump (With CPB)	
	Treatment	Control	Treatment	Control
	n = 28	n = 29	n = 26	n = 25
PT dose via PCA	6.7 ± 8.0	5.9 ± 11.3	4.8 ± 9.3	5.2 ± 7.9
RN Rescue ME	0.9 ± 1.7	0.7 ± 1.3	1.0 ± 1.8	1.0 ± 1.8
Total ME	7.6 ± 8.2	6.6 ± 11.2	5.8 ± 9.2	6.1 ± 8.8
Total ME Range	0 – 34.6	0 – 58.0	0 – 46	0 – 34
Extubation (hrs)				
M ± SD	5.6 ± 4.0	5.5 ± 3.9	5.8 ± 3.2	6.7 ± 5.0
Range	1.6 – 20.4	1.3 – 21.2	1.4 – 14.6	2.1 – 23.3

Values expressed as Mean ± SD; Sample Size (n). PT = Patient; PCA = patient controlled analgesic pump; RN = Registered Nurse; ME = Morphine Equivalents; hrs = hours.

Opioid analgesic requirements were highest on POD 1, and within the off-pump arm, the treatment group opioid usage was greater than that of the control group, although the difference did not reach statistical significance. Opioid requirements within the on-pump arm were similar between groups. Table 8 shows ME requirements for all 4 groups. No significant differences were detected, and no trend toward reduced analgesic usage was observed. Ketorolac was administered in 36 patients in the on-pump arm of the study and 15 in the off-pump arm. The differences in frequency of ketorolac orders may be related to physician preference.

Table 8

Morphine Equivalent Requirements POD 1 – POD 3

	Off –Pump (Without CPB)		On-Pump (With CPB)	
	Treatment	Control	Treatment	Control
POD 1				
M ± SD	53.5 ± 34.7	33.5 ± 23.6	42.5 ± 22.8	46.1 ± 32.1
Range	16.0 – 149.3	8.0 - 84.4	22.0 – 96.0	5.3 – 126.0
n	13	14	12	13
POD 2				
M ± SD	15.2 ± 9.8	16.5 ± 12.2	24.1 ± 26.7	25.9 ± 15.7
Range	0 – 34.7	2.0 – 48.7	5.0 – 106.0	5.0 – 56.0
n	15	18	12	16
POD 3				
M ± SD	12.1 ±4.7	10.3 ± 6.7	12.3 ±6.1	15.6 ±8.6
Range	5.0 – 20.0	2.5 – 25	5.0 – 20.0	5.0 – 30.0
n	13	15	16	15

Morphine equivalent conversions. Values are mean (SD); range, number (n).POD = Postoperative day.

All values are statistically nonsignificant.

No statistically significant differences were found in the average time to first ambulation from bed to chair (e.g., 6-8 hrs after extubation). The control group for the on-pump arm took a few additional hours to reach readiness, but most importantly, most patients were ready to sit up in a chair and ambulate with assistance on the day of surgery or POD 1. Values for secondary outcomes are located in Table 9.

Most patients in both arms of the study were ready for step-down criteria within 24 hours of surgery. This finding was consistent between treatment and control groups in both arms. However, the actual transfer of patients out of the ICU took approximately 36 hours longer.

The average postoperative hospital LOS was 4-5 days and did not vary between groups. The overall incidence of postoperative nausea and vomiting during the 96 hour observation period was 54% and 43% in the treatment and control groups, respectively. Data regarding time to first bowel movement could not be analyzed due to missing data.

Table 9

Secondary Outcomes

	Off–Pump (Without CPB)		On-Pump (With CPB)	
	Treatment	Control	Treatment	Control
	n = 28	n = 29	n = 26	n = 25
Amb to Chair Criteria (hrs)				
M ± SD	8.0 ± 9.3	9.3 ± 7.7	9.8 ± 6.4	13.8 ± 7.8
Range	105 – 44.1	2.0 – 28.3	1.3 – 23.1	2.0 – 27.5
Amb to Chair Actual (hrs)				
M ± SD	16.8 ± 7.0	18.2 ± 5.4	18.7 ±5.5	20.4 ± 7.7
Range	8.1 – 44.1	8.2 – 29.4	11.3 – 39.0	10.0 – 48.2
ICU Criteria (hrs)				
M ± SD	23.0 ± 23.0	22.9 ± 20.2	20.6 ± 18.8	20.0 ± 7.7
Range	2.5 – 98.2	2.1 – 84.1	2.5 – 73.1	10.0 – 48.2
ICU Actual (hrs)				
M ± SD	60.0 ± 28.8	61.9 ± 28.5	59.9 ± 22.4	62.5 ± 24.9
Range	17.3 – 104.0	24.4 – 123.1	25.1 – 122.5	25.3 – 119.1
Hosp LOS (days)				
M ± SD	4.7 ± 1.4	4.6 ± 1.0	5.2 ± 1.4	4.8 ± 1.2
Range	2.8 – 9.9	3.0 – 8.0	3.8 – 8.1	3.2 – 9.0

Amb = Ambulation; ICU = Intensive Care Unit; LOS = Postoperative Length of Stay; n = sample size hrs = hours; All values are statistically nonsignificant.

Discussion

Effective management of postoperative pain after cardiac surgery is a major concern for patients and health care providers. There is increasing evidence that improved postoperative pain control has significant physiological benefits that can improve cardiac surgery outcomes. The primary purpose of this RCT was to investigate the effect of a continuous LAI at the median sternotomy as part of a multimodal analgesic strategy with regards to postoperative pain intensity and opioid analgesic consumption after CABG.

It was not unexpected that during the 48 hours of PCA use that the reported NRS scores would be similar. Patients titrate PCA medication to bring their pain to tolerable levels. Although approximately half of the sample identified pain in the sternal area, the LAI did not seem to reduce the pain intensity. These findings contrasted with those of several previous studies (White et al., 2003; Dowling et al., 2003; Koukis et al., 2008) that reported significant decreases in pain rating scores with use of a continuous LAI. However, Magnano (2005) reported similar postoperative pain levels in both treatment and control groups. One explanation may be that pain in the area of the sternum is more related to spreading of the thorax, dissection of the IMA and the presence of mediastinal chest tubes than the incision itself. Therefore, the LAI may be only partially effective in patients with sternotomy incisions. Although statistical significance regarding pain intensity was not reached, the results may be a further indication that the LAI provided better analgesia than conventional opioid analgesic therapy alone.

It was interesting that the ME usage was comparable between all groups during weaning from MV and from POD 1 - POD 3. This finding is in contrast with other studies that reported decreases in pain with use of a continuous LAI (Dowling et al., 2003; White et al., 2003). On the contrary Magnano (2005) reported total morphine consumption to be higher in their treatment group. In our study, the PCA appeared to be adequate supplementation for most patients, although almost half of the patients in the treatment groups of both arms required opioid rescue. This result is in contrast with findings by Koukis (2008) who reported that only 25% of their sample needed supplemental opioid infusions and the rest of the sample needed only small infrequent doses. It should be noted however, that patients in their study were instructed they could use opioid analgesic medications to alleviate postoperative pain only "when the pain was really disturbing and severe".

As with any regional anesthetic, effectiveness relies on placement of the catheters and duration of infusion. This study is the first to report patient outcomes with the use of two 10-inch soaker catheters placed in the subfascial plane adjacent to the sternum using a tunneling technique. The ineffectiveness of the anesthetic may be attributed to variations of absorption in the subfascial tissues, including body temperature (gradual re-warming with increased blood flow to the periphery), and the need for vasoactive drugs which might decrease peripheral blood flow. The pharmacokinetics of continuous regional infusion of anesthesia into subfascial tissues has not been well studied. Furthermore, it is uncertain what effect the harvesting of the IMA has on absorption of the local anesthetic. In addition, the previously published studies utilized diverse types of

catheters (e.g., 5-inch soaker catheters, epidural catheters) with assorted anesthetic solutions (0.5% bupivacaine, 0.25 % bupivacaine, 0.2% ropivacaine, and a mixture of ropivacaine), differing placement techniques (anterior to the sternum, subfascial and subcutaneous) for varying lengths of continuous infusion (e.g., 72 hrs, 36, hrs, 48 hrs, 96 hrs). The studies also differed in the use of PCA pumps verses nurse administered IV analgesics.

Although our study was powered to detect differences for the primary endpoints of pain intensity and opioid consumption, statistical significance may have been lost for some of the secondary clinical outcomes. Our findings that demonstrated no differences in extubation times were consistent with findings by Dowling et al., (2003) and White et al. (2003), while Magnano (2005) reported that their control group was extubated earlier than the treatment group. Patients in all groups of our study were able to ambulate from bed to chair by POD 1, a finding that was consistent with the treatment group in the study by White et al., (2003). Ambulation was not reported in other published studies. Our study did not demonstrate that a continuous LAI improved ICU hours as measured by predetermined criteria, findings which were comparable to (White et al., 2003) and (Dowling et al., 2003). Finally, most of the other studies reported a shorter hospital LOS; a finding we failed to demonstrate possibly because we did not establish discharge criteria.

The infusion catheters proved easy to use and did not cause discomfort to patients in any way. Nurses reported that they did not have any difficulty dealing with the elastomeric pump or the device as a whole. However, in 2 cases, the catheters were

inadvertently cut during removal, which required re-exploration of the insertion site under local anesthetic. There were no sternal wound infections in the study sample.

Even though this study was prospective, randomized, double-blind, and placebo controlled, there were limitations. The strict exclusion criteria made recruitment and retention difficult. Because a relatively healthy group of CABG patients were enrolled, the results may not be generalizable to patients undergoing other types of cardiac surgery.

Conclusion

In this study, use of a continuous LAI at the sternotomy did not reduce postoperative pain intensity or opioid analgesic consumption. It may have the potential to improve other cardiac surgery outcomes in fast-track programs, such as early extubation, early ambulation, reduced ICU hours and hospital LOS. However, hospital service delivery barriers need to be addressed to maximize this potential. Clinical trials with larger sample sizes will be needed to examine these and other clinical outcomes. More outcomes data is needed with cardiac surgery patients, particularly those undergoing median sternotomy. Ongoing research by the investigator is examining other factors which contribute to postoperative pain management of cardiac surgery patients.

(This manuscript will be submitted to *Heart & Lung* after final revisions and formatting. 1st Author: Malinda Langley, RN, PhD(c), 2nd Author: Ali Husain, MD, 3rd Author: Melvin Swanson, PhD)

CHAPTER 5: SYNTHESIS OF FINDINGS

This dissertation explored postoperative pain management after cardiac surgery from a variety of theoretical approaches and methodologies. Pain management was examined from patients' perceptions of HRQL using a descriptive correlational design, nurses' CDM processes were explored using a qualitative grounded theory approach, and a RCT was conducted to evaluate the effectiveness of a new pain management modality.

Because pain relief is one of the most important concerns for patients and one of the most challenging problems for the health care team, interdisciplinary clinical research is essential to evaluate new pain management modalities. Although RCT that was conducted to evaluate the effectiveness of a continuous LAI at the sternotomy did not improve pain management measures or clinical outcomes in our study, it was the first to utilize the longer soaker catheters that are inserted in the subfascial plane using a tunneling technique. While the lack of effectiveness of the LAI was disappointing, the findings illuminated other factors that may influence management of postoperative pain after cardiac surgery.

For example, HRQL was examined for relationships to pain management measures and clinical outcomes such as pain intensity, opioid analgesic consumption, duration of MV, and hospital LOS. While only a few of the HRQL measures were related to the variables of interest, it supports the findings of the grounded theory study in which nurses described the importance of getting to know the patient in order to fine-tune analgesic medications, and negotiate modifications in weaning protocols that are in the patient's best interest.

Further research can explore linkages between HRQL measures and the importance of establishing a nurse/patient partnership to balance tolerable levels of pain and meet complex clinical goals in specialized fast-track cardiac surgery programs. Ongoing research by the investigator is examining other factors which contribute to postoperative pain management of cardiac surgery patients.

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APPENDIX A: HRQL IRB APPROVAL

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Boulevard • LSB 104 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Malinda Langley, RN, 1726 Swann Street, Fayetteville, NC 28303

FROM: UMCIRB

DATE: February 23, 2009

RE: Expedited Category Research Study

TITLE: "Patient Characteristics and Health-Related Quality of Life as Predictors of Postoperative Pain Intensity Following Coronary Artery Bypass Graft Surgery"

UMCIRB #09-0172

This research study has undergone review and approval using expedited review on 2.14.09. This research study is eligible for review under an expedited category because it is a research on individual or group characteristics or behav (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultu beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category ma be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listin refers only to research that is not exempt.)
The Chairperson (or designee) deemed this **unfunded** study **no more than minimal risk** requiring a continuing revie in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessar to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participant and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **2.14.09** to **2.13.10**. The approval includes the following items:

- Internal Processing Form (dated 2.3.09)
- Cape Fear Valley, IRB Approval Letter
- Summary of Proposal

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX B: NURSES' CDM IRB APPROVAL

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Boulevard • LSB 104 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: Charles W. Daeschner, III, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Malinda Langley, RN, 1726 Swann Street, Fayetteville, NC 28303

FROM: UMCIRB

DATE: October 16, 2006

RE: Expedited Category Research Study

TITLE: "Management of Pain During Weaning from Mechanical Ventilation After Cardiac Surgery"

UMCIRB # 06-0636

This research study has undergone review and approval using expedited review on **10.11.06**. This research study is eligible for review under an expedited category because it is on collection of data from voice, video, digital, or image recordings made for research purposes.
Dr. C. Daeschner deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months**.

The above referenced research study has been given approval for the period of 10.11.06 to 10.10.07. The approval includes the following items:

- Internal Processing Form (dated 10.5.06)
- Protocol Summary
- Informed Consent Document
- Participant Demographic Form
- Letter of Support: Cape Fear Valley Health System

Dr. C. Daeschner does not have a potential for conflict of interest on this study.

The UMCIRB complies with 45 CFR 46, 21 CFR 50, 21 CFR 56, ICH Guidelines, UMCIRB operating policies and procedures, institutional policies and other applicable federal regulations.

APPENDIX C: NURSES' CDM IRB CONTINUING REVIEW

FILE COPY

Biomedical IRB
ECU
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Blvd., LSB 104 • Greenville, NC 27834 • 252-744-2914 • Fax: 252-744-2284

CONTINUING REVIEW SUBMISSION FORM

MAILED

Date: July 2, 2007
Investigator: **Malinda Langley, RN, MSN**
Protocol: Management of Pain During Weaning from Mechanical Ventilation After Cardiac Surgery
ID: 60636 Protocol#: 06-0636

Initial BIO Approval Date: 10/11/2006
Previous Continuing Reviews: N/A
Approval Expiration: 10/10/2007

The UMCIRB continuing review of human subject research is a requirement under the federal regulations according to OHRP at 45 CFR 46.109. Research studies must undergo review regardless of what activity occurred during that approval period. For instance, investigators must still submit a continuing review application for their study even if no participants were enrolled, or their study never started for any reason. Investigators must also submit a continuing review form to close the study if all research-related activity has been completed. If you have received this notice then the UMCIRB office has determined that your research study meets the federal requirements for continuing review and you must submit a continuing review application.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.109

The UMCIRB processes provide for sending two notices of continuing review approximately 90 and 60 days prior to expiration. Additionally, the office will send an e-mail approximately 30 days prior to expiration. The UMCIRB processes also provide that expired research studies will be reported to relevant institutional offices and administration. Any research study that has not been renewed will automatically expire. Research participants may not be enrolled into a study outside the period of UMCIRB approval dates. The UMCIRB is not permitted to grant approval to cover any period of lapse or to provide any type of retrospective approval. If you have a special circumstance, please contact the UMCIRB office immediately.

A research study's expiration date can be found on the approval letter and on the continuing review notices. Additionally, you may call the office at any time to request your study's expiration date.

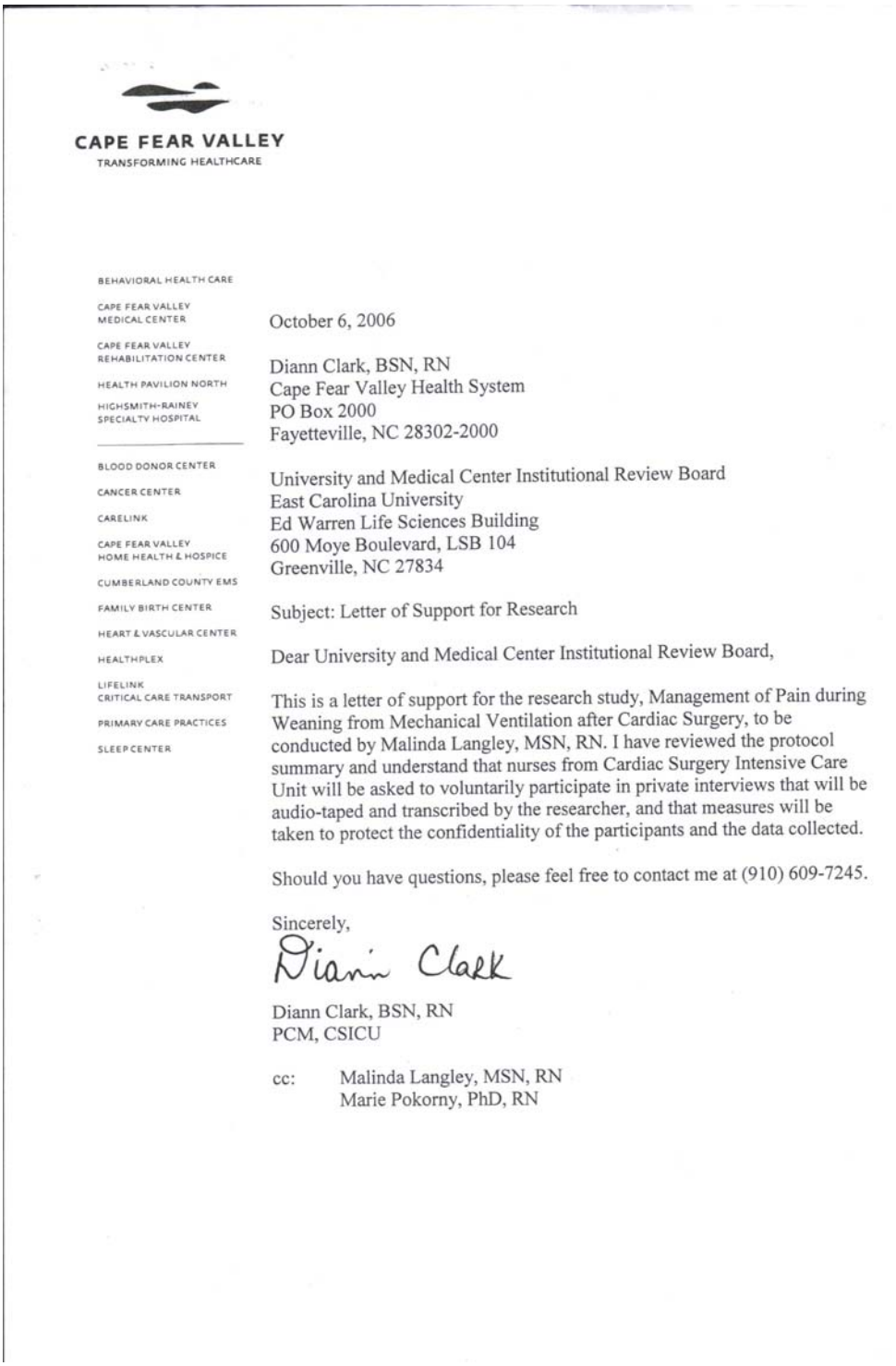
The continuing review/closure form is located on the UMCIRB web site at www.ecu.edu/irb under "forms and documents". You must then follow the link to either the Behavioral/Social Sciences or Biomedical forms. The continuing review/closure forms are located beneath the application form for new studies. Please read the instructions for completing these forms for detailed information, or contact the UMCIRB office at 744-2914.

If your research study must undergo full committee review, please ensure that it is submitted in time to meet the full committee deadlines prior to expiration. The UMCIRB meeting deadlines may be found on our website at www.ecu.edu/irb under "meeting information". If your research study is eligible for expedited review, please ensure that the continuing review form is submitted at least 10 business days prior to expiration. The UMCIRB will reset the approval date and period when review and approval are conducted prior to the expiration date.

Please contact the UMCIRB office at 744-2914 or via our e-mail address at umcirb@ecu.edu for assistance.

Page 1 of 1

APPENDIX D: LETTER OF SUPPORT FROM UNIT MANAGER



CAPE FEAR VALLEY
TRANSFORMING HEALTHCARE

BEHAVIORAL HEALTH CARE
CAPE FEAR VALLEY MEDICAL CENTER
CAPE FEAR VALLEY REHABILITATION CENTER
HEALTH PAVILION NORTH
HIGHSMITH-RAINEY SPECIALTY HOSPITAL

BLOOD DONOR CENTER
CANCER CENTER
CARELINK
CAPE FEAR VALLEY HOME HEALTH & HOSPICE
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
PRIMARY CARE PRACTICES
SLEEP CENTER

October 6, 2006

Diann Clark, BSN, RN
Cape Fear Valley Health System
PO Box 2000
Fayetteville, NC 28302-2000

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building
600 Moye Boulevard, LSB 104
Greenville, NC 27834

Subject: Letter of Support for Research

Dear University and Medical Center Institutional Review Board,

This is a letter of support for the research study, Management of Pain during Weaning from Mechanical Ventilation after Cardiac Surgery, to be conducted by Malinda Langley, MSN, RN. I have reviewed the protocol summary and understand that nurses from Cardiac Surgery Intensive Care Unit will be asked to voluntarily participate in private interviews that will be audio-taped and transcribed by the researcher, and that measures will be taken to protect the confidentiality of the participants and the data collected.

Should you have questions, please feel free to contact me at (910) 609-7245.

Sincerely,

Diann Clark

Diann Clark, BSN, RN
PCM, CSICU

cc: Malinda Langley, MSN, RN
Marie Pokorny, PhD, RN

APPENDIX E: NURSES'CDM IRB CLOSURE

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Boulevard • LSB 104 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Malinda Langley, 1726 Swann St. Fayetteville, NC 28303

FROM: UMCIRB

DATE: July 21, 2008

RE: Closure of a Research Study

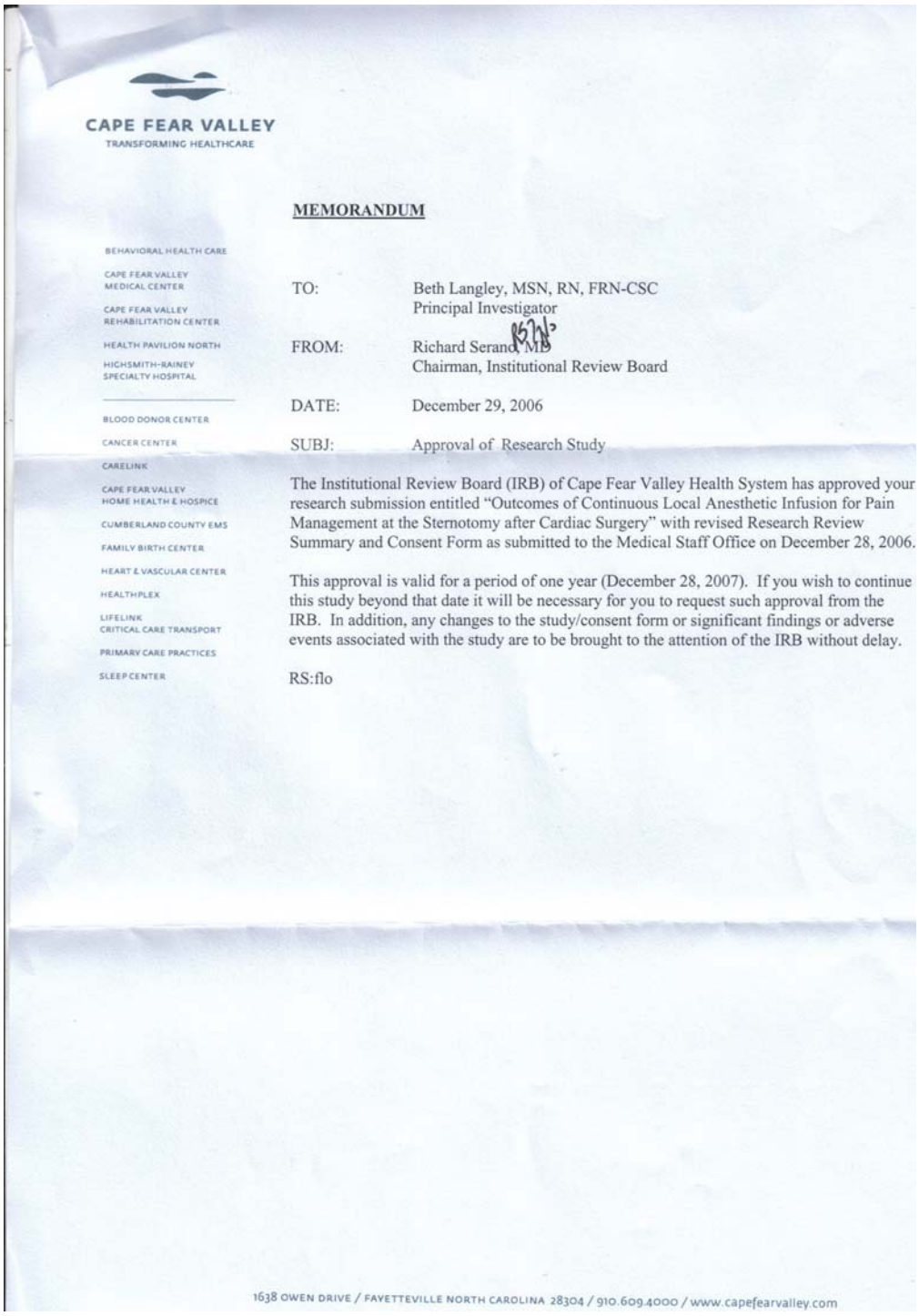
TITLE: "Management of Pain During Weaning from Mechanical Ventilation After Cardiac Surgery"

UMCIRB #06-0636

The closure submission was submitted by the investigator on **7/9/08.** This research study has undergone expedited review for closure on **7/20/08**. This above referenced research study has been closed by the principal investigator secondary to study completion.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX F: RCT IRB APPROVAL



CAPE FEAR VALLEY
TRANSFORMING HEALTHCARE

BEHAVIORAL HEALTH CARE
CAPE FEAR VALLEY MEDICAL CENTER
CAPE FEAR VALLEY REHABILITATION CENTER
HEALTH PAVILION NORTH
HIGHSMITH-RAINEY SPECIALTY HOSPITAL
BLOOD DONOR CENTER
CANCER CENTER
CARELINK
CAPE FEAR VALLEY HOME HEALTH & HOSPICE
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
PRIMARY CARE PRACTICES
SLEEP CENTER

MEMORANDUM

TO: Beth Langley, MSN, RN, FRN-CSC
Principal Investigator

FROM: Richard Serand, MD
Chairman, Institutional Review Board

DATE: December 29, 2006

SUBJ: Approval of Research Study

The Institutional Review Board (IRB) of Cape Fear Valley Health System has approved your research submission entitled "Outcomes of Continuous Local Anesthetic Infusion for Pain Management at the Sternotomy after Cardiac Surgery" with revised Research Review Summary and Consent Form as submitted to the Medical Staff Office on December 28, 2006.

This approval is valid for a period of one year (December 28, 2007). If you wish to continue this study beyond that date it will be necessary for you to request such approval from the IRB. In addition, any changes to the study/consent form or significant findings or adverse events associated with the study are to be brought to the attention of the IRB without delay.

RS:flo

1638 OWEN DRIVE / FAYETTEVILLE NORTH CAROLINA 28304 / 910.609.4000 / www.capefearvalley.com

APPENDIX G: ECU IRB LETTER

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Boulevard • LSB 104 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

Martha Engelke, RN, PhD
Associate Dean for Research and Scholarship
College of Nursing
East Carolina University
Health Sciences Building
Greenville, NC 27858-4353

Dear Dr. Engelke,
Thank you for following up on our discussion and email correspondence regarding the research study "Outcomes of Continuous Local Anesthetic Infusion for pain Management at the Sternotomy after Cardiac Surgery" by Ms. Malinda (Beth) Langley. Thank you also for sending a copy of the approval letter and Research Review Summary from the Cape Fear Valley Health System Institutional Review Board.

Since Ms. Langley was a student in the Nursing PhD Program, and the study was completed, in part, to meet academic requirements in her doctoral program, this study should also have been reviewed by the ECU University and Medical Center Institutional Review Board. As soon as you became aware of the study, you contacted me, and inquired about review by the ECU UMCIRB. However, the study had already been completed, and we are unable to provide retrospective approval for a study.

Since the study was reviewed by a duly constituted IRB we will not require further action. I recommend that Ms. Langley submit the Cape Fear Valley Health System IRB approval as an appendix when she submits her dissertation to the Graduate School.

You noted that Ms. Langley would like to do further analysis of the already collected data. Prior to doing this analysis, she should submit an ECU UMCIRB Expedited Processing Form (Expedited Form if the data are identifiable, or linked to the identity of the participants, and the Exempt Form if the subjects cannot be identified, directly or through identifiers linked to the subjects).

You stated that you have completed additional education with your faculty to make sure they are aware of the need to seek review of student research by the ECU UMCIRB. Thank you for your attentiveness to the importance of protection for human research participants.

Sincerely,

Susan McCammon

Susan McCammon, PhD
Chair and Director, Behavioral and Social Sciences IRB

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418
IRB00004973 East Carolina U IRB #4 (Behavioral/SS Summer) IORG0000418