2017

Bupivacaine with Fentanyl to Treat Labor Pain: A Quality Improvement Initiative

Irvin Lee
Walden University

Walden University

College of Health Sciences

This is to certify that the doctoral study by

Irvin Lee

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Mary Verklan, Committee Chairperson, Health Services Faculty
Dr. Joanne Minnick, Committee Member, Health Services Faculty
Dr. Tracy Andrews, University Reviewer, Health Services Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2017

Abstract

Bupivacaine with Fentanyl to Treat Labor Pain: A Quality Improvement Initiative

by

Irvin Lee

MS, Georgetown University, 2003

BS, Southern Adventist University, 1999

Proposal Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

March 2017

Abstract

Epidurals used for labor are common regional anesthesia techniques that are easily placed

and controlled, while providing the most reliable method of pain relief in obstetrics for

parturient women. Local anesthetics, narcotics, and/or combinations of the two are

administered through epidurals to treat labor pain. Hence, the choice of medication is

important, as it can highly influence outcomes of pain relief. The purpose of this DNP

project was to evaluate the effectiveness of a new service line medication, bupivacaine

0.1% with fentanyl 2mcg/ml, to treat labor pain in parturient women at a rural community

hospital in southern California guided by the Johns Hopkins Nursing Evidence Based

Practice Model. A quantitative, time-series, retrospective, and prospective design was

used to analyze data from a convenience sampling of participants who received

ropivacaine and bupivacaine with fentanyl. Paired samples *t*-tests compared differences

in verbal pain scores before and after epidural insertion with initial boluses alongside

frequencies of top-off boluses required to achieve adequate pain relief. Findings showed

that both medications were equally effective in the treatment of labor pain within the first

hour after the intervention. However, the ropivacaine group had higher rebolus demands,

while the bupivacaine with fentanyl group had only a minimal amount. The complexity

of healthcare today demands inter and intraprofessional collaboration to improve and

sustain best outcomes for high quality care. The bupivacaine with fentanyl project

impacts social change by improving the quality of care for parturient women, addressing

the fear and anxiety of childbirth pain, and highlighting the importance of collaboration

with other clinical providers to change practice using the evidence.

Bupivacaine with Fentanyl to Treat Labor Pain: A Quality Improvement Initiative

by

Irvin Lee

MS, Georgetown University, 2003

BS, Southern Adventist University, 1999

Proposal Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

March 2017

Table of Contents

i

iii

Section 1: Overview of the Evidence

Introduction

Epidural analgesia for parturient women, is a common regional technique used during childbirth involving the use of local anesthetics, narcotics, and/or a combination of the two to decrease labor pain (Fehder & Gennaro, 1993). Epidurals eventually replaced caudal anesthesia in the 1960's because it was easier to control, easier to place, and had less inherent contamination risks (Fehder & Gennaro, 1993).

Epidural analgesia offers the most reliable pain relief with the least amount of side effects for the longest period of time in labor when compared to all other forms of pharmacological methods (Pirbudak, Tuncer, Kocoglu, Goksu, & Celik, 2002). However, the choice of anesthetic medication is important and can highly influence the outcome of pain relief. This DNP project evaluated the effectiveness of a new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, to treat labor pain in parturient women at a southern California hospital (SCH). I provide an overview of the project, a review of best evidence, and outline how this medication in the treatment of labor pain will be measured and evaluated. In section 1, I will discuss ropivacaine and bupivacaine's pharmacological properties, its role in pain relief at SCH, the surrounding circumstances that led to the development of the practice initiative, problem statement, purpose statement, purpose objectives, purpose questions, significance to practice, and operational definitions.

Background/Context

Ropivacaine and bupivacaine are two local anesthetics that are commonly used to treat labor pain with a wide amount of success (Pirbudak, Tuncer, Kocoglu, Goksu, & Celik, 2002). Ropivacaine is a newer amide local anesthetic that is structurally similar to bupivacaine but has the reduced propensity to cause motor blocks and cardiotoxicity (Feldman & Covino, 1988). With these added benefits, it has gained popularity in obstetrics for analgesia. However, recent studies have suggested that ropivacaine administered epidurally is approximately 40% less potent than bupivacaine based on an index of 50% effective dose' (Polley, Columb, Naughton, Wagner, & Van de Ven, 1999).

Ropivacaine has been in use for approximately 1.5 years at SCH after discontinuation of bupivacaine 0.125% with fentanyl 1.6 mcg/ml. Since the medication change, anesthesia peers and labor/delivery registered nurses (RNs) have voiced dissatisfaction. Anesthesia peers stated that they had higher workload demands because parturients treated with ropivacaine often require more top off boluses of bupivacaine 0.25% to provide adequate pain relief. However, top off boluses are not long-term solutions and are only effective up to approximately 60 minutes (Zaric, Nydahl, & Philipson, 1996). Labor and delivery RNs stated that patients who received ropivacaine solutions expressed higher verbal pain scores than previous patients who received bupivacaine. In light of these observations, a recent medical decision was made to switch back to bupivacaine with fentanyl, albeit, a slightly lower concentration of bupivacaine was ordered to decrease the chances of adverse events and conversions to cesarean sections, which are often attributed to bupivacaine.

The labor and delivery unit at SCH is comprised of four laboring rooms, two triage beds, and one operating room. The average monthly census ranges from 40 to 50 parturient women who deliver vaginally, of which 78% receive epidural anesthesia for labor. The national average is 61%. After receiving permission from management, a retrospective chart audit was performed that focused on top-off bolus rates for all parturients who delivered in January 2014. Results showed that at least half the patients with epidurals who received ropivacaine for labor required at least one top off bolus of additional local anesthetic between the time periods where the epidurals were placed and the fetus was delivered. The results of the January audit revealed unusually high rates of top-off boluses that could indicate that ropivacaine was not highly effective in providing adequate pain relief. Out of 46 parturient women with epidurals for labor, 22 parturient women required additional boluses. Moreover, documented verbal pain scores were all above seven out of 10 on a numeric pain rating scale, which were reported to the anesthesia provider just prior to the top off bolus.

<div align="center">**Problem Statement**</div>

Ropivacaine 0.2% administered for labor analgesia provided suboptimal relief for parturient women at SCH as noted by an increased number of patients' requests for rescue boluses, higher verbal pain scores, and feedback from labor and delivery RNs and anesthesia staff as compared to the previous discontinued medication, bupivacaine 0.125% with fentanyl 2mcg/ml.

This problem is contrary to what the literature states in regard to analgesia used during labor. Most studies indicated that ropivacaine administered through continuous

epidurals in equipotent doses was as effective as bupivacaine when used to treat labor pain (Dresner, Freeman, Calow, Quinn, & Bamber, 2000). Although the prior ropivacaine solution used for labor analgesia was equipotent to the previous bupivacaine with fentanyl solution, it failed to produce adequate pain relief. Ropivacaine was the medication used for labor analgesia from January 2014 to January 2015, while bupivacaine was the medication used prior to the switch. A retrospective chart audit of top-off boluses and verbal pain scores in January 2013 of parturient women who received bupivacaine suggests that the medication is far more effective than ropivacaine. Out of 45 parturient women, only five required additional boluses. Two out of those five parturient women had verbal pain scores above seven out of 10 on a numeric pain scale just prior to the bolus.

Purpose Statement

The purpose of this DNP project was to determine the efficacy of the new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, for the treatment of labor pain in parturient women at SCH. The purpose was to create positive labor experiences for parturient women by treating labor pain with medications that have good safety profiles, are cost-effective, and require minimal to almost no additional top off boluses. Effective pain relief medications will allow patients to allocate more quality time to other areas of labor such as breathing and relaxation techniques. For healthcare providers, effective pain relief would decrease time demands in providing comfort measures, which may permit more time for coaching and individualized care.

Project Objectives

There were two objectives for the project. The first was to achieve verbal pain scores of the parturient women of less than four out of 10 post epidural insertion/initial loading dose within 60 minutes. The zero through 10 numeric pain rating scale is a reliable diagnostic tool promoted by the National Initiative on Pain Control (NIPC) to assess the severity and quality of pain experienced by patients (McCaffery & Pasero, 1999). According to the numeric pain scale, pain scores that are less than four out of 10 indicate mild to almost no pain at all is a reasonable goal and will serve as the target threshold for this initiative. Verbal pain scores were collected by the anesthesia provider 5 minutes prior to epidural insertion and 60 minutes post epidural insertion/initial loading dose administration and patient controlled epidural analgesia (PCEA) basal rate infusions.

The second objective was to achieve a top-off bolus rate of less than 10%. This figure was obtained taking into consideration the rebolus events based on retrospective chart reviews. Bupivacaine 0.125% with fentanyl 2mcg/ml, the medication used prior to January 2014, had a rebolus rate of 11%. Ropivacaine 0.2%, the medication used just prior to January 2015, had a rebolus rate of 48%. Reboluses of additional local anesthetic introduce the potential for more adverse effects to the parturient woman and fetus, such as cardiotoxicity and delayed labor progression (Dresner, Freeman, Calow, Quinn, & Bamber, 2000). Therefore, it would be more ideal to minimize the number of reboluses the parturient women receive.

Project Questions

There were two project questions. The first question asked: Does bupivacaine 0.1% with fentanyl 2mcg/ml reduce labor pain to adequate levels safely and timely? The goal was to achieve pain scores of less than four out of 10 on a numeric pain rating scale within 60 minutes post epidural insertion/initial medication bolus. Bupivacaine 0.1% is a slightly lower concentration than the bupivacaine solution used in the past. The risks of cardiotoxicity and adverse effects are decreased with lower concentrations.

The second question asked: Does bupivacaine 0.1% with fentanyl 2mcg/ml provide sustainable labor pain relief where additional top off boluses are not required. The desired goal was a target threshold of less than 10% occurrence. Decreased rates of additional boluses may indicate that parturient women have adequate and/or tolerable pain levels.

Significance of the Project

Evidence based practice (EBP) supports clinical practice by developing strategies according to the best available scientific evidence (Strand & Parkkinen, 2014). The main role of the evidence is to associate causal inferences with the expected results from available interventions, thereby tying relevant causal knowledge to decision making in the clinical arena. Therefore, a proper understanding of the precise content of the causes and the inferences they enter into are important.

Although much of the medical literature notes that ropivacaine has a similar potency and duration to that of bupivacaine with less cardiotoxic effects (Dresner et al., 2000), the reverse seems true at SCH. Implementation of a bupivacaine initiative to

investigate its role in labor analgesia relief would add to the ever-increasing knowledge base aimed at providing high quality care at cost effective means. Finding a suitable medication that would provide adequate analgesia needing less frequent rebolusing of additional local anesthetics improves quality of care by decreasing exposure of unnecessary medications to the parturient and relieving increased workloads on anesthesia personnel.

Lastly, effective pain relief for parturient women can improve the overall birthing experience. One study indicated that labor pain was directly associated with posttraumatic stress, which in turn had a correlation with patients' overall birthing experiences (Garthus-Niegel, Knoph, Soest, Nielsen, & Eberhard-Gran, 2014). Treating labor pain effectively would decrease posttraumatic stress episodes (Garthus-Niegel et al., 2014).

Reduction of Gaps

Childbirth is often accompanied by pain. The overall goal of the bupivacaine with fentanyl initiative is to provide effective pain relief for parturient women safely, adequately, and promptly. Labor pain relief is a major component of the birthing process. Historically, pain management was often neglected because of societal expectations that women should endure the process without supplemental analgesics. However, traumatic labor experiences have been shown to cause psychologically detrimental effects (Campbell, 2003). For example, ineffective pain relief highly influenced parturient women's long-term decisions to have another baby (Iliadou, 2009).

Hence, the goal is to provide effective labor analgesia that would not dissuade parturients from future birthing experiences.

Epidural insertion rates at SCH are approximately 78% as compared to the national average of 61% (Osterman & Martin, 2011). Given SCH's above national average epidural insertion rates, it makes prudent sense to consider the management of labor pain via the epidural method a high priority. A reduction of gaps addresses the translation of evidence-based knowledge into clinical practice by use of techniques or modes of therapy that work. To be useful, evidence should enable clinicians to practice better, meaning better outcomes and satisfaction for patients. However, ropivacaine used for labor analgesia through continuous patient controlled epidural infusion in SCH's population is an example where a medication did not work effectively based on healthcare provider feedback, high number of top-off boluses, and verbal pain scores from parturient women compared to patients that received bupivacaine with fentanyl. Evidence has pointed out that lower concentrations of bupivacaine and the addition of narcotics such as fentanyl can provide high quality analgesia with minimal side effects at cost effective means (Dresner et al., 2000). As front line providers in the labor and delivery department, nurse anesthetists have a duty to provide prompt, effective, and safe labor analgesia relief so that parturient women receive the highest quality care and positive overall birthing experiences.

Implications for Social Change

Pain experienced in childbirth is a complex phenomenon that can trigger fear. Fear associated with childbirth is considered harmful, and has been shown to affect a

woman's self-esteem and her ability to handle labor pain effectively (Karlsdottir, Halldorsdottir, & Lundgren, 2014). In fact, studies have shown that women actually experience higher levels of labor pain than they had expected prior to the childbirth (Lally, Murtagh, Macphail, & Thomson, 2008; Iliadou, 2009). Unmet expectations and negative birth experiences have been shown to influence women's decisions about future childbearing (Gottvall & Waldenstrom, 2002).

The American Association of Colleges of Nursing (AACN) advocates for DNP practitioners to have a wide array of knowledge gleaned from the sciences and to be well prepared to translate that knowledge into the daily demands of clinical practice (AACN, 2006). Nursing science has created a large body of information that could guide nursing practice and has extended the scientific underpinnings of the discipline (AACN, 2006). Information received from this initiative would contribute to the body of nursing knowledge aimed at improving health care quality for the parturient woman and her family. Epidurals placed for labor coupled with safe and effective medications can allay patients' fears and anxiety during a significant period in their lives. Treating labor pain effectively and informing parturient women adequately by addressing their concerns and presenting realistic expectations about epidural pain management may increase satisfaction surrounding the childbirth experience.

Definition of Terms

The following terms were used in this initiative concerning bupivacaine with fentanyl:

Anesthesia: A partial or complete loss of sensation for the purposes of surgery or medical procedure, with or without loss of consciousness (Barash et al., 2013).

Epidural anesthesia: Anesthesia that is produced by the injection of local anesthetics into the peridural space outside the spinal cord, often used during childbirth delivery, lower extremity surgeries, and postoperative pain management (Morgan, Mikhail, & Murray, 2006).

Evidence-based practice: A problem solving approach to clinical decision making that incorporates the best available evidence along with clinical expertise and patient preferences and values (Grove, Burns, & Gray, 2013).

Labor pain: Crampy, diffused or localized lower abdominal pain, sometimes referred to the back and perineum coinciding with uterine contractions. The pain may be supplemented with nausea, vomiting, and diaphoresis (Miller et al., 2005). The operational definition of pain relief is defined as a verbal pain score of less than four out of 10 based on numeric pain rating scale ranging from zero to 10. Zero is no pain whereas 10 is extreme pain.

Patient controlled epidural analgesia: A technique of pain relief where a local anesthetic and opioid are administered by a pump into the epidural space allowing patients to self administer the analgesic mixtures on demand for supplemental doses in addition to the basal rate infusion (Miller et al., 2005).

Rescue boluses: Supplemental local anesthetic medications of bupivacaine 0.25% ranging from six to eight milliliters that are administered via the epidural catheter by anesthesia providers to achieve pain relief for the parturient (Barash et al., 2013).

Assumptions

I made several assumptions about the success of the initiative. First, the pharmacy at SCH would purchase or create enough supplies of the medication to meet the demand. Second, the labor and delivery department and obstetricians would be supportive in efforts to address labor pain management. Third, patients would have realistic expectations of what an epidural used for labor can and cannot do. Fourth, patients would be honest in reporting their pain scores to providers. Lastly, labor and delivery nurses would evaluate parturient women's pain and notify the anesthesia provider of the need for top-off boluses.

Limitations

There were three limitations of the initiative that should be noted. The first limitation related to inconsistent practices of all anesthesia providers. All anesthesia providers have varying degrees of experience and different skillsets in the placement of epidurals. There are several methods in the placement of epidurals such as the hanging drop technique, loss of resistance to air technique or the loss of resistance to saline technique (Morgan et al., 2006). All have arguable advantages and disadvantages but a "gold" standard has not been established.

The second limitation pertained to consistent implementation and compliance of pre-procedural protocols performed by labor and delivery RNs. Epidural placement is an invasive procedure that can have detrimental consequences for the parturient woman and fetus such as hypotension, excessive bleeding from the site, infection, spinal headaches, and even paralysis (Miller et al., 2005). Hence, it was imperative that nurses followed

protocols that mitigated or eliminated the expected physiological effects of local anesthetics administered through epidurals.

Lastly, one of the challenges of accurately measuring and treating labor pain was its subjective nature. The verbal pain score based on Likert scales or numeric visual analog scales have been the most commonly used and trusted tools to measure subjective pain in subjects. However, the health literacy of individuals and language barriers needed to be considered in pain assessment with those tools.

Summary

Epidural analgesia is the most reliable and longest lasting pain relief method with the least amount of side effects compared to all other forms of pharmacological methods for the birthing process. Although the literature is saturated with studies that indicate that ropivacaine is equally comparable to bupivacaine in pain relief, it is not the case at SCH.

In this section, I discussed the context of the problem in regards to labor pain relief at SCH, the initiative's purpose and objectives, and the questions that are asked relative to those objectives. Labor pain management is a high priority at SCH due to the above national average rates of epidurals used for childbirth. Addressing the pharmacological agent that is responsible for unsatisfactory relief of labor pain is an important issue to explore.

Section 2: Review of Literature and Theoretical/Conceptual Framework

Introduction

In section 2, I discuss the review of literature and search strategies that I performed to address the bupivacaine with fentanyl initiative. At the end of the section, I present a theoretical/conceptual model that was utilized to help guide the project. The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model focuses in depth on the evidence-based practice (EBP) process, which involves the identification of clinical practice questions, the discovery and evaluation of scientific evidence, and the translation of that evidence into clinical practice.

General Literature Search

I conducted a systematic literature review was done using PubMed, the Cumulative Index of Nursing and Allied Health (CINAHL), Medline, ProQuest Nursing and Allied Health Source, and Cochrane Database of Systematic Reviews. Key search terms used were *regional anesthesia, ropivacaine, bupivacaine, labor, postoperative analgesia*, and *epidural* with limitations set to full-text. A cumulative of 162 peer reviewed articles, books, and web domains were reviewed relevant to the topic. One hundred and thirty-five of those sources were rejected because they were either published in languages other than English, were dated more than two decades, sample sizes were not reported or did not include explicit comparisons between ropivacaine and bupivacaine. Inclusion criteria were that publications were peer-reviewed to assure a measure of quality, randomization of participants to either the bupivacaine or ropivacaine groups, and results reported allowed quantitative analysis. Twenty-seven studies met the

project criteria and were included for the literature review. The studies selected consisted of peer-reviewed articles, double-blind randomized controlled trials (RCT), meta-analyses, prospective and retrospective studies, and case reports with initial publication dates of 1997.

Specific Literature

Most women experience severe pain with childbirth, similar to pain caused by complex regional pain syndromes or amputations of an extremity (Melzack, 1984). Although untreated pain is not life threatening in healthy parturient women, it can have severe neuropsychological consequences, such as posttraumatic stress disorder, postnatal depression, and impaired cognitive function in the postpartum period (Hawkins, 2010). Men are also affected by pain associated with labor. Capogna, Camorcia, and Stirparo (2007) found that first-time fathers whose significant others who had received an epidural felt three times more helpful and involved and had less anxiety and stress compared to men whose significant others did not receive epidurals (Capogna, Camorcia, & Stirparo, 2007). The specific literature subsection will discuss epidurals for labor, patient controlled epidural analgesia, bupivacaine and ropivacaine profiles including motor block potential, cardiotoxicity, and potency, and the addition of narcotics to local anesthetics.

Epidurals for Labor

Effective pain relief coupled with minimal motor block are essential components of an ideal epidural for labor analgesia (Finegold, Mandell, & Ramanathan, 2000). Epidural analgesia for labor and delivery involves the use of a local anesthetic with or without the addition of an opioid into the lumbar epidural space (Catterall & Mackie,

2006). The injected medications diffuse slowly across the dura and eventually bath the spinal nerve roots causing a decrease in catecholamine production and providing segmental sympathetic and sensory nerve blockades (Hawkins, 2010). The resultant sensory nerve block is the relief of pain and the sympathetic block causes a reduction in vascular resistance significantly improving uteroplacental bloodflow in healthy parturients (Hawkins, 2010). Increased bloodflow to the uterus and placenta ensures that the fetus receives adequate oxygenation and nutrition.

Epidurals administered to provide effective labor pain relief have a longstanding history in obstetrics. Studies comparing the effectiveness of epidurals to other modes of analgesic therapy, such as intravenous narcotics, were done with positive results favouring epidurals (Dickinson, Paech, Mcdonald, & Evans, 2003; Catterall & Mackie, 2006; Hawkins, 2010). One large trial study of 992 nulliparous women indicated significantly lower pain scores after the administration of epidural analgesia compared to those who received midwifery support (Dickinson, Paech, Mcdonald, & Evans, 2003). In the study, pain scores were rated on a scale of zero to 100, with 100 being the worst pain imaginable based on a visual analog pain scale. Median pain scores prior to the intervention were 80 in the midwifery group and 85 in the epidural group. Post intervention median scores for the midwifery group were 75 and median scores for the epidural group were 27, indicating significant pain score reduction (p<0.001) (Dickinson et al., 2003).

The study is important in pointing out that epidural analgesic techniques are significantly more effective in labor pain treatment than intravenous techniques. The

bupivacaine with fentanyl initiative explored the efficacy of labor pain relief between two local anesthetic medications administered through epidurals, already established as the most efficacious and reliable method of analgesic therapy in labor. The investigation of which medication was more effective will further add to the literature with the purposes of improving the quality of care in parturient women, while trying to minimize adverse consequences and negative outcomes.

In a meta-analysis study involving 2703 nulliparous women who participated in five trials conducted in one facility, median pain scores were significantly reduced after interventions in the epidural group compared to the meperidine group ($p<0.001$) (Sharma, McIntire, Wiley, & Leveno, 2004). Additionally, 95% of women in the epidural group rated their satisfaction with pain relief as excellent or good compared with 69% of women in the meperidine group ($p<0.001$) (Sharma et al., 2004). After the administration of an epidural and an initial bolus of medication, effective maintenance of anesthesia can then be achieved through patient controlled epidural analgesia (PCEA) regimens. The study showed that medications administered through epidural catheters via PCEA regimens was an effective way to treat labor pain.

Patient controlled epidural analgesia regimens usually involve the dilution of local anesthetics with or without the addition of opioids administered through the epidural catheter with basal rate continuous infusions and patient controlled intermittent boluses (Lim, Ocampo, Supandji, Teoh, & Sia, 2008). Some of the benefits of PCEA regimens are greater patient satisfaction, lower dose requirements of local anesthetics, reduced motor blocks, and fewer interventions by anesthesia personnel (Halpern & Joseph, 2002).

Halpern and Joseph (2002) found in a meta-analysis of 640 patients in nine studies, that

there were fewer overall anesthetic interventions in the PCEA group (95 percent CI,

p<0.0001), less local anethestics infused (95 percent CI, *p*<0.0001), and less motor

blocks (95 percent CI, *p*<0.003) compared to the continuous epidural infusion group

(Halpern & Joseph, 2002). Infusion rates and bolus amounts may be adjusted depending

on individual variations to pain responses, stages of labor, and patients' expectations

about their childbirth experiences. The two most commonly used local anesthetics

administered through PCEA regimens are bupivacaine and ropivacaine. Both

bupivacaine and ropivacaine are administered via PCEA formats with continuous basal

rate infusions through epidural catheters at SCH. The DNP project showed that the

addition of fentanyl allowed bupivacaine concentrations to be lowered, while providing

effective analgesia and minimizing anesthesia interventions, such as, top-off boluses.

Bupivacaine and Ropivacaine

Bupivacaine is the most commonly used medication administered for epidural

analgesia in labor because of its widespread availability, low costs, and relative safety

profile (Sah, Vallejo, Phelps, & Mandell, 2007). It has a rapid onset and its duration is

long-lasting. Bupivacaine has also been shown to provide longer lasting analgesia than

other local anesthetics even after sensations return (Catterall & Mackie, 2006). However,

claims of bupivacaine's longer duration of analgesia are controversial. Muir, Writer, and

Douglas (1997) posited that a ropivacaine 0.25% group (*n*=34) and a bupivacaine 0.25%

group (*n*=26) had no significant differences in the onset times of pain relief, quality of

analgesia, and duration of analgesia in a prospective, double-blind, randomized multi-

center study of 60 nulliparous labouring women when medications were administered epidurally by intermittent top-ups (95 percent CI, $p<0.001$). Although the study showed the efficacy of labor pain relief through intermittent boluses of ropivacaine and bupivacaine, the results indicated that both medications had nearly identical outcomes. In fact, the bupivacaine concentration used in the study is more than twice the concentration used in the DNP project, while ropivacaine concentrations are similar. The DNP project showed that decreased bupivacaine concentrations with the addition of opioids provided effective labor pain relief as compared to moderate concentration levels of ropivacaine.

Sah, Vallejo, Phelps, and Mandell (2007) later added that there were no significant differences in visual analog pain scores and Bromage scores in the measured time intervals between ropivacaine and bupivacaine. In their prospective, randomized, double-blind study, 100 American Society of Anesthesiologists (ASA) physical status I and II, full-term, nulliparous women were placed into two groups, bupivacaine ($n=50$) and ropivacaine ($n=50$), and received initial boluses of medication and a continuous infusion of local anesthetics, either ropivacaine 0.2% or bupivacaine 0.125%. The average onset time to achieve a T10 level sensory level block in the bupivacaine group was 11 minutes as compared to the ropivacaine group, which was 9 minutes. Although the difference was statistically significant ($p<0.05$), it was clinically irrelevant. The medication concentrations used in the study are almost identical to the medication concentrations in the DNP project. The study results are important in pointing out that pain scores and motor block effects are similar. The DNP project added further evidence to the study by comparing similar concentrations in a different population sampling.

Modern obstetric analgesia teams aim to minimize motor blocks while eliminating the perception of pain from cervical dilation and uterine contractions (Lacassie, Habib, Lacassie, & Columb, 2007). Ropivacaine is an amide local anesthetic that has gained popularity over the years in obstetric epidural analgesia due to its reduced propensity for causing cardiotoxic effects and its greater affinity for sensory fibers compared with bupivacaine (Feldman & Covino, 1988). Thus, ropivacaine would be a more ideal medication choice in the labor and delivery ward. In a toxicology human study, ropivacaine proved less toxic than bupivacaine when administered by intravenous infusion with regards to signs and symptoms of mild central nervous system and cardiotoxic effects (Katz, Bridenbaugh, Knarr, Helton, & Denson, 1990). However, the cardiotoxic effects were often attributed to high concentrations of bupivacaine, such as 0.75%, and have been discontinued across all clinical settings (Albright, 1984). Bupivacaine solutions of 0.75% are not available or utilized at SCH. The DNP project used a bupivacaine solution that was 6.5 times less concentrated, therefore neurotoxicity and cardiotoxicity issues was a negligible factor.

Chang, Ladd, and Copeland (2001) performed comparative studies of the direct effects of bupivacaine and ropivacaine on sheep hearts. Doses ranging from trivial to toxic amounts were administered to explore what humans would receive if the injections were accidently administered via intravenous routes. The findings indicated that both ropivacaine and bupivacaine have similar abilities to cause fatal cardiac arrhythmias and death (Chang, Ladd, & Copeland, 2001). Although ropivacaine produced less myocardial depression and arrhythmias in the study, its lower potency requires higher

concentrations to achieve equianesthetic doses to those of bupivacaine, thereby offsetting

its intrinsic cardiac toxicity profile. The DNP project explored the efficacy of labor pain

relief between ropivacaine 0.2% and bupivacaine 0.1% with fentanyl 2mcg/ml. If higher

concentrations of ropivacaine are needed just to equal the analgesic effects of lowered

concentrations of bupivacaine at SCH, cardiotoxic and neurotoxic profiles of ropivacaine

increase. Thereby, the safety benefits of ropivacaine are dampened, risks for the

parturient woman increase, and costs for the facility escalate.

The perceived advantage of a reduced motor block potential is another popular

belief in the push for ropivacaine in obstetrics. Despite the expected advantages of

reduced motor blocks due to reduced potencies, especially for childbirth, earlier studies

that compared ropivacaine with bupivacaine for epidural analgesia for women in labor

showed no significant benefits when administered through intermittent top-ups,

continuous infusion, and continuous infusion with patient controlled top-ups (Eddleston

et al., 1996; Owen, D'Angelo, & Geranchar, 1998). Finegold, Mandell, and Ramanathan

(2000) further expanded on the notion that different intensities of motor block were

clinically similar in labor outcomes in a double-blind, randomized, 100 parturient study

in patients who received ropivacaine or bupivacaine. The researchers argued that

although the bupivacaine group had 25% higher levels of motor block within the first

hour of medication administration, outcomes of successful delivery were similar

(Finegold et al., 2000). Interestingly, out of the ropivacaine group (n=50), 11 parturient

women had to deliver via caesarean section versus eight patients in the bupivacaine group

(n=50)(Finegold et al., 2000). Although it is not the focus of the DNP project, the

findings of the project showed that bupivacaine's motor blocking effects was a nonissue in the context of labor outcomes at SCH.

Since the introduction of ropivacaine into clinical practice, its potency has been an issue. In one prospective, double-blind, randomized control trial of 126 single-term, ASA physical statuses I and II parturient women, potency ratios for ropivacaine:bupivacaine was statistically significant favouring bupivacaine ($p<0.001$). It was suggested that ropivacaine has a 0.6 relative potency rating to that of bupivacaine. Researchers have suggested that ropivacaine is approximately 40% less potent than bupivacaine (Capogna, Celleno, Fusco, Lyons, & Columb, 1999; Dresner et al., 2000; Chua, Sia, & Ocampo, 2001). Hence, large doses of ropivacaine would still be needed to evoke equal responses to that of lower doses of bupivacaine. If large doses of ropivacaine are needed to match the potency of bupivacaine, the intended benefits of safety are lost. Moreover, higher concentrations and bulk supplies of ropivacaine are more than twice the purchase costs of bupivacaine with fentanyl. It was also hypothesized that ropivacaine would provide a better quality of analgesia because of its lower potency and a more theorized rostral spread of the anesthetic. However, pain relief and cephalad spread between ropivacaine and bupivacaine were found to have similar results (Lacassie et al., 2007). Ropivacaine's concentration at SCH was 0.2%, considered equipotent to bupivacaine 0.125% by a vast majority of researchers in the literature (Capogna et al., 1999; Dresner et al., 2000; Owen et al., 1998). The bupivacaine with fentanyl initiative adds to the literature in distinguishing whether the potency of ropivacaine is a factor in labor pain relief even at equipotent doses.

The majority of studies suggest that ropivacaine and bupivacaine have equivalent effects of labor analgesia relief in parturients (Chua, Sia, & Ocampo, 2001; Polley, Columb, Naughton, Wagner, & Van de Ven, 1999; Dresner et al., 2000; Fehder & Gennaro, 1993). Although few, there are some conflicting studies that indicate better duration and quality of labor analgesia relief when bupivacaine is used compared to ropivacaine (Merson, 2001; Capogna et al., 1999). However, the cited cause of bupivacaine's effectiveness in the treatment of labor pain was attributed to the mixture of opioids. The addition of an opioid to local anesthetic solutions can help treat missed segments, perineal pressure, and maximize efficacy and maternal satisfaction (Dresner et al., 2000) while promoting the idea that smaller doses of anesthetics infused translates into better safety profiles and decreased incidences of adverse effects. Animal studies suggest that local anesthetics and opioids have a synergistic effect and that the binding of opioid receptors hyperpolarizes the membranes thereby decreasing nerve impulse transmissions (Melzack, 1984). However, some of the drawbacks of adding opioids to local anesthetics include pruritus, hypotension, neuraxial infections, urinary retention, vomiting, and respiratory depression (Bucklin, Chestnut, & Hawkins, 2002). When it comes to the addition of opioids to local anesthetic solutions, factors such as those listed previously should be taken into consideration depending on the context of the situation. The initiative showed that the addition of fentanyl, a potent opioid, to low concentrations of bupivacaine was a solution to providing high quality labor analgesia at safe, cost-effective means at SCH.

General Literature

Ropivacaine and bupivacaine are also used for other purposes alongside maternal labor – mainly postoperative pain control for patients who undergo lower limb, orthopedic, gynecological, and abdominal surgeries. Postoperative pain management is a key component of anesthetic practice because untreated pain can be detrimental (Apfelbaum, Chen, Mehta, & Gan, 2003). Effective treatment of pain helps restore normal physiological processes such as ventilation and coughing, which thereby promotes early ambulation, prevention of infections, and shortened hospital stays (Sawhney et al., 2015).

Until recently, bupivacaine was the most commonly used medication for the management of postoperative epidural analgesia. The toxic effects of bupivacaine on the central nervous system and cardiovascular system are less harsh with ropivacaine when plasma levels are comparable (Casati & Baciarello, 2006). However, the claim that ropivacaine produces less motor block while providing equivalent analgesia compared to bupivacaine is also controversial outside of maternal analgesia (Merson, 2001). Berti, Fanelli, Casati, and Albertin (2000) compared the analgesic efficacy and incidences of motor block during patient supplemented epidural analgesia with either ropivacaine/fentanyl or bupivacaine/fentanyl solutions in patients that underwent major abdominal surgeries. In the prospective, double-blind, randomized study of 32 ASA physical status I-III patients, both ropivacaine/fentanyl and bupivacaine/fentanyl mixtures provided similar relief of analgesia, motor block, levels of sedation, and pulse oximetry readings (Berti, Fanelli, Casati, & Albertin, 2000). A more recent study compared both

ropivacaine and bupivacaine for lower extremity orthopedic procedures, which indicated that there were no significant differences in block parameters (Chandran, Hemalatha, & Viswanathan, 2014). In another prospective, double-blind, randomized trial of 60 patients that underwent total knee replacements, findings suggested that there were no statistically significant differences in pain, side effects, and motor block between ropivacaine/morphine and bupivacaine/morphine groups ($p<0.05$)(Zaric, Christiansen, Haastrup, & Sandberg, 2004). Although it is desirable to have patients ambulate almost immediately after total knee replacement surgeries, the findings indicate that earlier mobilization with the use of ropivacaine compared to bupivacaine are indistinguishable. It is then when the cost factor analysis also comes to question.

At a time when facilities face economic constraints, cost-effectiveness should be taken into account when any new agents are considered. In one study, an economic evaluation of bupivacaine with fentanyl versus ropivacaine alone administered for post operative pain control after total knee replacements showed that bupivacaine with fentanyl was more cost-effective and provided more patient satisfaction than ropivacaine because it provided better quality of analgesia (Pitimana-aree, Visalyaputra, Komoltri, Muangman, & Al, 2005). Results indicated that the bupivacaine/fentanyl group ($n=35$) had higher pain satisfaction scores and an eighteen percent cost savings compared with the ropivacaine group ($n=35$). Ropivacaine is approximately double the price of bupivacaine on an equipotent basis. Facilities should perform sensitivity analyses to make reliable comparisons of medications.

Theoretical/Conceptual Framework

The Johns Hopkins Nursing evidence-based practice model (JHNEBP) was used as the framework for the project. The conceptual model consists of three major components of practice, research, and education (Buchko & Robinson, 2012). The model points out that research and non-research factors form the basis for clinical decision-making. The Johns Hopkins Nursing evidence-based practice model also indicates that both internal and external factors should be taken into consideration before a certain practice can be changed (Buchko & Robinson, 2012). The three phases of the model are practice question (P), evidence (E), and translation (T) (Buchko & Robinson, 2012). In the first phase, a practice question is identified and explored. The second phase involves a systematic review and synthesis of research and non-research components/factors (Buchko & Robinson, 2012). The synthesis may include all types of research studies and all types of non-research factors, such as, experience, quality improvement and financial data, clinical expertise, and patient preferences. The third phase is translation, where the evidence-based practice team can determine if new practice guidelines or interventions can be implemented or are feasible for implementation (Buchko & Robinson, 2012). The translation phase includes possibly piloting the study, measuring outcomes, and disseminating the findings (Buchko & Robinson, 2012). The model may shed light on relative potencies of the medications, financial costs, and additional solutions.

The Johns Hopkins Nursing evidence-based practice model (JHNEBP) and its three step process, PET, was used to help guide the bupivacaine with fentanyl project by providing a straightforward, problem-solving approach designed to meet the needs of the

practicing nurse by incorporating most recent research findings and best practices. The

first step is the practice question. For the project, effective labor analgesia relief is the

topic of interest and which medication is considered more effective in providing labor

pain relief, ropivacaine or bupivacaine with fentanyl. The second step is concerned with

the evidence that pertains to both research and non-research factors. Research evidence

deals with information that is derived from ropivacaine/bupivacaine controlled trial

studies, case reports, meta-analyses, and other widely published forms of dissemination.

Non-research evidence includes specific information obtained from the project itself,

such as, provider and patient feedback, verbal pain scores, and number of top-off boluses.

The third step focuses on translation where the new practice change is evaluated to

determine if it is feasible for implementation and whether it is sustainable. Financial and

cultural factors are two issues that may be taken into consideration. For example, would

the new medication cost the institution more revenue and would there be purchasing

issues? Would every anesthesia provider be open to administering the new medication?

Summary

Bupivacaine is a popular local anesthetic that is used in obstetrical anesthesia due

to its superior analgesic effects. It has a long-standing, successful track record and a

wide variety of uses alongside maternal labor, such as, orthopedic and abdominal

procedures. However, its cardiotoxic effects in high concentrations have pushed for the

creation of an isomer, ropivacaine. The main advantage of ropivacaine is its wide margin

of safety and motor sparing effects, something that is attractive in obstetrical anesthesia.

Most studies indicate an equivalent analgesic effect when ropivacaine and bupivacaine

are compared to each other. Decreased potencies, lesser quality of analgesia relief, and high costs of ropivacaine have been its crutch in a time where health care facilities look for cost-effective means to provide high quality care. Although a majority of the evidence seems to suggest that ropivacaine causes less motor block and has less cardiotoxic and central nervous system effects, the benefits are offset by its decreased potency. To achieve equipotent doses to that of bupivacaine, higher doses of ropivacaine are necessary, which would then increase costs. Facilities would need to perform a sensitivity analyses to determine the cost-effectiveness of ropivacaine versus bupivacaine.

Section 3: Methodology

Introduction

Section 3 includes the methodology that I utilized to explore the effectiveness of the new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, administered via PCEA infusion in parturient women at SCH. There were two objectives for the project. The first objective was to achieve verbal pain scores of less than four out of 10 on a numeric pain scale ranging from zero to 10 within 60 minutes of epidural insertion and initial loading dose. The second objective was to achieve a rebolus rate of less than 10% throughout the remainder of the course of labor until the delivery of the fetus. The project design, population and sampling, data collection, instruments, data analysis, protection of human subjects, and project evaluation plan will also be discussed.

Project Design

I used a prospective, time-series, quantitative design was used to explore the efficacy of a new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, in parturient women. I used a quantitative design because of its focus on patient groups and patterns that are unique to this special group, its investigation of the effectiveness of an intervention where outcomes are measureable, such as, verbal pain scores, and its ability to establish correlational or causal relationships between variables. Verbal pain scores before and after the intervention and number of top-off boluses are quantifiable and can be analyzed statistically to determine if there are clinically significant differences between the variables: ropivacaine and bupivacaine.

Ropivacaine was discontinued at SCH in January 2015. Therefore, data about the effects of ropivacaine on laboring parturients was obtained retrospectively from archived patient records that were electronically scanned. Verbal pain scores that were reported to the anesthesia provider just prior to the bolus and an hour after epidural administration and initial bolus was recorded and statistically analyzed through paired samples t-tests to determine clinically significant differences. Moderate to high occurrences of rebolus rates coupled with high verbal pain scores indicated that ropivacaine was not effective in relieving labor pain because verbal pain scores remained high necessitating supplemental local anesthetics. Bupivacaine with fentanyl was concurrently started along with ropivacaine in January 2015. Data such as numerical verbal pain scores, top-off boluses, epidural insertions, medication administration, preprocedural assessments, consents, and all other relevant data for the initiative were obtained and performed by one provider prospectively for 1 month.

Population and Sampling

The initiative focused on all parturients in the Morongo basin community admitted for labor at a 55-bed rural community hospital in Southern California. Both retrospective and prospective portions of the initiative had inclusion/exclusion criteria. The inclusion criteria for all parturients was that they will be American Society of Anesthesiologist's (ASA) physical statuses I or II; less than 100 kilograms in weight; less than 40 years old; cervically dilated less than five cm; and, have no previous history of cesarean section(s). The retrospective component of the initiative was based on a 1-month chart audit convenience sampling of parturient women who received epidurals

from multiple providers and were placed on ropivacaine solutions. The prospective component of the initiative was based on a 1-month convenience sampling of parturient women who labored at SCH, received epidurals from one anesthesia provider, and were placed on bupivacaine with fentanyl solutions. Both retrospective and prospective portions of the initiative were based on non-probability sampling methods due to the low number of deliveries at the facility coupled with project completion time constraints.

Data Collection

I collected the entire data set for both retrospective and prospective components of the initiative. The retrospective component involved chart audits accessed through "idoc", a computer program where past medical records were scanned and saved onto password protected computer files. First, the delivery room register was reviewed for 1 particular month. In the register, I noted the methods of delivery, anesthesia provider name, patient names, dates, and times of delivery. I filtered out any parturient women who did not have epidurals and did not deliver vaginally through the delivery register initial screening. Second, I used the medical record numbers of the parturient women to bring up their medical information on idoc. I obtained initial and post epidural verbal pain scores, top-off boluses, preanesthetic health and physical information, vital signs, and list of medications. Third, once the information was obtained, I deidentified all parturient women and assigned numerical codes.

The prospective portion included the same data as the retrospective portion of the initiative. However, the prospective component followed one standard technique by one anesthesia provider. I performed a preanesthetic evaluation to collect information about

health and physical histories. I then assigned an ASA physical status to the patient along with a numerical code at the conclusion of the interview. Then, a total of one liter of Lactated ringer's solution was given intravenously to every parturient woman 30 minutes prior to epidural insertion. During the intravenous bolus, I presented the numeric pain rating scale depicted on a chart visually and discussed the chart to ensure understanding about verbal pain scores. The numeric pain rating scale ranged from zero to 10. Zero was equated with no pain while 10 was the equivalent of the worst pain imaginable. Once an adequate understanding of verbal pain scores was addressed, I recorded a pre-block score. I used the loss of resistance to saline technique to locate the epidural space at the L3-4 or L4-5 interspace with the parturient woman in the sitting position using a seventeen-gauge Tuohy needle (Braun). Following epidural insertion and initial bolus, all parturient women were placed in the left uterine displacement position for approximately 1 hour. Verbal pain scores were obtained 5 minutes prior to epidural insertion and 1 hour post epidural insertion and initial medication bolus. I obtained data on additional top off boluses of bupivacaine 0.25% until delivery of the fetus.

Instruments

I used two instruments for the initiative. The first instrument was the facility's preanesthetic evaluation form, which contained information about the health and history of patients. Comorbidities, surgical histories, allergies, and heights/weights of the patients were examples of some of the information that was tabulated and then assigned an ASA physical status. Participants that were healthy to fairly healthy, ASA statuses of

I or II, were included for the initiative. This information can be found in SCH's

preanesthetic record (Appendix A).

The second instrument I used was a visual/verbal analog scale that depicted a pain

score on a horizontal line from zero to 10, zero being no pain and 10 being the worst pain

imaginable (Appendix B). Visual analog scales are frequently used to measure self-

reports of fear and pain in both children and adults (Chapman & Kirby-Turner, 2002).

The measures for the initiative were simplified to only include verbal pain scores ranging

from zero to 10.

Protection of Human Subjects

I sought approval from administration, the chief compliance officer of SCH, and

Walden University's internal review board (IRB) before initiation of the project. I

reassured all participants in the prospective group about the purposes of the project and

that intervention strategies were not different from the standardized norm. Data collected

for the initiative were readily accessible only to me and stored in confidential computer

files protected by an encrypted password.

<div align="center">

Data Analysis

</div>

I used a paired samples *t*-test to determine the significance between bupivacaine

with fentanyl and ropivacaine and the adequacy of pain relief based on verbal pain scores

collected pre and post intervention. Paired samples *t*-tests are parametric analyses that

compare mean differences in the same group of subjects at two different points in time

(Polit, 2010). However, the paired samples *t*-test requires that paired score differences

are independent and normally distributed (Grove et al., 2013). Frequency distributions

were used to determine top-off bolus rates of parturient women who receive bupivacaine with fentanyl or ropivacaine. Statistical analysis was performed using SPSS Version 21 for MAC, and significance levels of $p < 0.05$.

There were two project questions. The first project question asked: Does bupivacaine 0.1% with fentanyl 2mcg/ml reduce labor pain to adequate levels safely and timely? The retrospective portion of the initiative addressed the efficacy of ropivacaine in labor pain relief by comparing verbal pain scores obtained 5 minutes prior to the epidural/initial bolus and verbal pain scores obtained 60 minutes post epidural/initial bolus. Likewise, in the prospective component of the project, verbal pain scores were collected 5 minutes prior to and 60 minutes after the intervention. The goal was to achieve pain scores of less than four out of 10 on a numeric pain rating scale within 60 minutes post epidural insertion/initial medication bolus. Lower pain scores after the intervention indicated whether the intervention was effective in relieving labor pain initially.

The second question asked: Does bupivacaine 0.1% with fentanyl provide sustainable labor pain relief where additional top off boluses are not required? The desired goal was a target threshold of less than 10% occurrence. Decreased rates of additional boluses may indicate that parturients have adequate and/or tolerable pain levels and the medication provides sustainable labor pain relief negating the need for epidural replacements or rescue analgesics. The number of top-off boluses required to obtain labor pain relief were recorded from the retrospective portion of the project from parturient women who received ropivacaine. Similarly, the number of top-off boluses

required to obtain adequate labor pain relief were recorded from the prospective component of the project from parturient women who received bupivacaine with fentanyl.

Project Evaluation

I used an evaluation plan was used to determine if ropivacaine and bupivacaine with fentanyl solutions provided adequate labor pain relief and discussed the strengths and limitations of the project. The use of a summative evaluation was appropriate for the bupivacaine with fentanyl initiative because it scrutinized program outcomes to determine the effectiveness of interventions (Spaulding, 2008). I used the summative evaluation to address three aspects important to the project: Intended goals of the project, anticipated outcomes, and intended/unintended impact and a goals evaluation to address project questions by determining if the two medications, ropivacaine and bupivacaine with fentanyl, adequately decrease verbal pain scores and minimize top-off boluses, thereby, providing sustainable labor pain relief during childbirth. I used an outcomes evaluation to explore whether the program caused palpable effects on specifically defined target outcomes in parturient women. I used an impact evaluation to provide a broader assessment of how the initiative affected the organization or community. After the collection and analysis of data, I evaluated whether: (a) Ropivacaine and/or bupivacaine with fentanyl were indeed effective in providing adequate, sustainable relief of labor pain for parturient women in the Morongo basin community; (b) the sample population was representative of the community district; (c) patient and hospital personnel were satisfied

with the service provided; and (d) what processes could be improved upon to better the outcomes.

Summary

In the bupivacaine with fentanyl initiative, I explored the efficacy of ropivacaine and bupivacaine with fentanyl utilizing both retrospective and prospective, time-series, quantitative designs. Data gathered from the participants were analyzed through statistical analysis to determine clinically significant relationships of verbal pain scores pre and post epidural insertion and initial medication bolus. The long-term efficacy of each medication was determined by the analysis of number of top-off boluses that parturient women received. Participant protection rights were addressed by obtaining permission from the facility's administration, chief compliance officer, and Walden University's IRB. A summative evaluation plan was used to determine if ropivacaine and bupivacaine with fentanyl provided adequate labor pain relief in parturients at SCH.

Section 4: Findings, Discussion, and Implications

Introduction

The purpose of this DNP project was to determine the efficacy of the new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, as compared to the discontinued medication, ropivacaine 0.2%, for the treatment of labor pain in parturient women at SCH. The effectiveness of ropivacaine and bupivacaine with fentanyl in the treatment of labor pain was determined through retrospective, time-series, quantitative analysis and prospective, time-series, quantitative analysis, respectively.

I implemented the project at a rural community hospital in the Morongo Basin area located in Southern California. The bupivacaine with fentanyl proposal was first presented to the anesthesia, obstetrical, and surgical departments because ropivacaine 0.2% administered for labor analgesia seemed to provide suboptimal relief for parturient women as noted by an increased number of patients' requests for rescue boluses, higher verbal pain scores, and feedback from labor and delivery nurses and anesthesia staff as compared to the previous discontinued medication, bupivacaine 0.125% with fentanyl 1.6mcg/ml. The focus of this section will be on project findings, practice implications, project outcomes, project strengths and limitations, and a personal self-analysis relative to the project.

Summary and Evaluation of Findings

My goal in conducting this project was to evaluate the effectiveness of a new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, to treat labor pain in parturient women at SCH by investigating two questions. Does bupivacaine 0.1% with

fentanyl 2mcg/ml reduce labor pain to adequate levels safely and timely and does bupivacaine 0.1% with fentanyl 2mcg/ml provide sustainable labor pain relief where additional top off boluses are not required? To address the project questions, the following objectives were recognized:

1. To achieve pain scores of less than four out of 10 on a numeric pain rating scale within 60 minutes post epidural insertion/initial medication bolus.

2. To decrease rates of medication rebolusing of less than 10% occurrence.

I incorporated a quantitative, time-series design to determine causal or correlational relationships between the independent and dependent variables. Statistical analysis was done through SPSS version 21.0 to determine relationships between the independent variables, ropivacaine and bupivacaine with fentanyl, to the dependent variables, verbal pain scores and number of top-off boluses. The numeric pain rating scale was used to determine the efficacy of the medications by analyzing the assigned value of scores before and after epidural placement. A value of zero indicated no pain while a value of 10 indicated severe or worst imaginable pain. The participants voiced understanding after initial instruction just prior to the epidural placement and were asked to give an initial score. The participants were asked to give a follow up score 60 minutes after the initial bolus and continuous delivery of medication via patient controlled epidural analgesia (PCEA) pumps.

Project Objective 1

Thirty-two participants were included in the ropivacaine group for analysis. There were a total of 48 deliveries of which 16 participants underwent caesarean section

and six parturient women did not meet the inclusion/exclusion criteria due to age, weight, and ASA physical statuses. Ages of the participants ranged from 18 to 36 years old with a mean age of 25.3 (Table 1). All parturient women in the ropivacaine group were interviewed prior to epidural placement with the use of the preanesthesia evaluation form (Appendix A).

Twenty-nine participants were included in the bupivacaine with fentanyl group for analysis. A total of 33 parturient women received epidurals for labor. However, 4 parturient women did not meet inclusion/exclusion criteria either because of age, weight, physical ASA status, or conversion to cesarean section. Ages of the participants ranged from 19 to 33 years old with a mean age of 25 (Table 1). All parturient women in the bupivacaine with fentanyl group were interviewed prior to the placement of an epidural using the same preanesthesia evaluation form (Appendix A).

Table 1

Mean ages of parturient women

	Minimum	Maximum	Mean
Ropivacaine group	18	36	25.3
Bupivacaine group	19	33	25

Numerical pain scores before and after the intervention and number of top-off boluses were recorded on the first page of the anesthetic record (Appendix A). A paired samples *t*-test was used to determine clinically significant differences in numerical pain scores pre- and postepidural insertion with initial loading dose in the ropivacaine group. Pre- and postepidural numerical pain scores indicated mean scores of 9.0 and 1.1, respectively (Table 2).

Numerical pain scores before and after the intervention and number of top-off boluses were also recorded on the first page of the anesthetic record (Appendix A). A paired samples *t*-test was used to determine clinically significant differences in numerical pain scores pre- and postepidural insertion with initial loading dose in the bupivacaine with fentanyl group. Pre- and postepidural numerical pain scores in the bupivacaine with fentanyl group indicated mean scores of 8.7 and 0.9, respectively (Table 2).

Table 2

Pre and post pain scores

	Mean	Significance	Degrees of Freedom
Pre-epidural ropivacaine	9.0	p<0.01	31
Post-epidural ropivacaine	1.1		
Pre-epidural bupivacaine	8.7	p<0.01	28
Post-epidural bupivacaine	0.9		

Project Objective 2

In the ropivacaine group, approximately 19% of the 32 parturient women did not require top-off boluses. However, 71% of the parturient women required at least one top-off bolus to achieve adequate pain control indicated on a histogram (Figure 1). In the bupivacaine with fentanyl group, 90% of the 29 parturient women did not require top-off boluses, while only 10% required at least one top-off bolus to achieve adequate pain control (Figure 2)
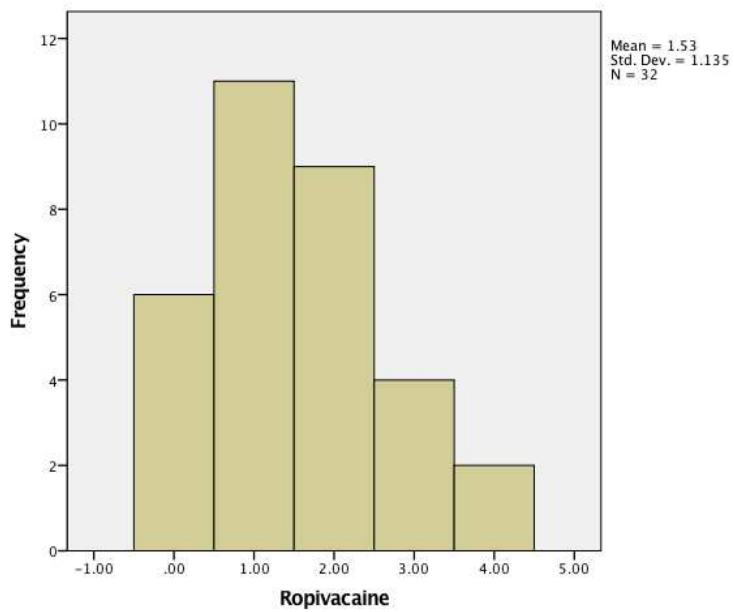
Figure 1. Top-off boluses of parturient women at SCH ropivacaine group.
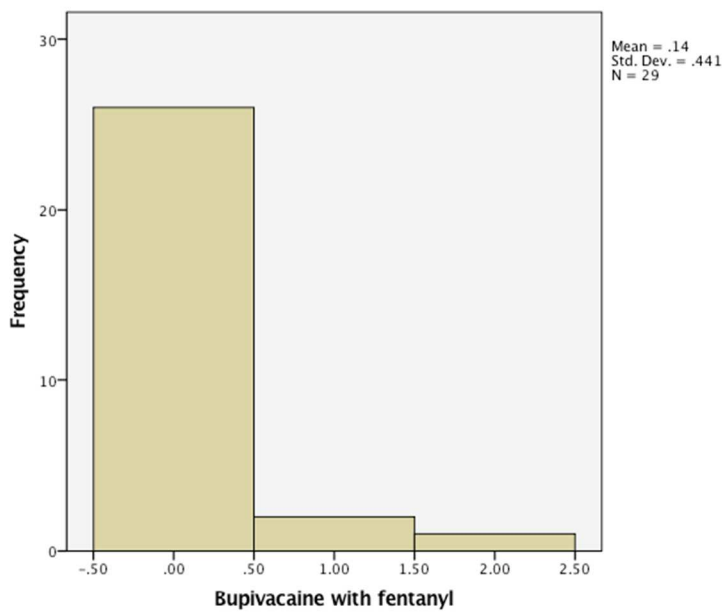

Figure 2. Top-off boluses of parturient women at SCH bupivacaine with fentanyl group.

I collected data for the ropivacaine group from retrospective chart reviews based on a 1 month (January 2015) audit of all participants who received epidurals for labor and met all inclusion/exclusion criteria. I considered a 1 month audit as adequate given that the average number of deliveries at SCH ranged from 30 to 45 per month consistently over the past 2 years. I also collected data for the bupivacaine with fentanyl group prospectively in the latter half of mid December 2016 through mid-January 2017 for a total of 4 weeks based on a convenience sampling of all participants who received epidurals for labor. The purpose in the timing of the retrospective January audit was to align as much as possible seasonal deliveries in accordance with the planned prospective portion of the project.

Discussion of Findings in the Context of Literature and Frameworks

The literature strongly supported that bupivacaine is a popular local anesthetic that is used in obstetrical anesthesia due to its superior analgesic effects (Dickinson, Paech, Mcdonald, & Evans, 2003). Bupivacaine has a long-standing, successful track record and a wide variety of uses alongside maternal labor. However, its cardiotoxic effects when given in high concentrations have pushed for the creation of an isomer, ropivacaine. The main advantage of ropivacaine is its wide margin of safety and motor sparing effects, something that is attractive in obstetrical anesthesia. Most studies indicate an equivalent analgesic effect when ropivacaine and bupivacaine are compared to each other (Dickinson, Paech, Mcdonald, & Evans, 2003; Catterall & Mackie, 2006; Finegold, Mandell, & Ramanathan, 2000).

The results of the numeric pain score analysis showed that both ropivacaine and

bupivacaine with fentanyl groups were equally effective in the treatment of labor pain within the first hour after the intervention. However, the ropivacaine group had higher occurrences of rebolus demands, while the bupivacaine with fentanyl group had only a minimal amount. Sample sizes of both groups were very similar and the results of the analysis correlate with patient and staff verbal feedback regarding medication efficacy. Additionally, parturient women in the bupivacaine with fentanyl group did not experience cardiotoxic or excessive motor block effects. The results correlate with Merson's (2001) study where bupivacaine provides better duration and quality of labor analgesia relief than ropivacaine.

The theoretical framework used for the project was the JHNEBP, which consists of three major components: practice, research, and education (Buchko & Robinson, 2012). The model accounts for both research and nonresearch factors and both internal and external factors in the context of clinical decision-making (Bondmass, 2011). In the first component of the model, practice question, I addressed the topics of effective labor analgesia relief and which medication was considered more effective in providing labor pain relief, ropivacaine or bupivacaine with fentanyl. In the second component, evidence, I incorporated both research and non-research factors, such as findings from the literature and patient/staff verbal feedback. Lastly, in the third component, translation, I focused on whether bupivacaine with fentanyl was feasible for implementation and sustainable. The pharmacy department and anesthesia staff were interviewed to receive feedback on long-term purchasing and practice issues.

Implications

Policy

Advanced practice nurses possess the knowledge, skills, and experience regarding research and evidence based practice, allowing them to be powerful advocates for healthcare policies (Terry, 2015). Healthcare policies contribute the framework for delivery of healthcare services whether in governmental regulations and/or institutional standards or procedures (Terry, 2015). In the end, they either enhance or impede healthcare delivery to patient populations. Utilizing those instruments to their full potential is a challenge that all DNPs should undertake.

This DNP project was a quality improvement initiative aimed at evaluating the effectiveness of a new service line medication, bupivacaine with fentanyl, for parturient women in a rural community hospital in southern California. The QI project is one of many examples of how advanced practice nurses can be engaged where policy decisions are made that influence and shape how rules govern nursing at an institution. Taking into consideration the safety profiles of new medications administered in an especially vulnerable patient population is of utmost importance. The institution should have some sort of formal and organized manner of evaluating the effectiveness of new medications while also monitoring and documenting unwanted side effects. Decreasing or minimizing the amount of adverse medication reactions while improving patient satisfaction is aligned with the institution's vision and goals and also with the Institute of Medicine's (2001) stance on nurses being champions of policy and social change.

Practice

The bupivacaine with fentanyl initiative provided evidence that sometimes newer and often more expensive medications do not necessarily provide better outcomes or improve patient/provider satisfaction. The initiative showed that a methodical and logical process could be implemented to evaluate the effectiveness of new service line medications administered in clinical practice. The DNP curriculum emphasizes leadership for evidence-based practice, which involves the translation of research into practice, the evaluation of evidence, the application of research in clinical decision-making, and the implementation of innovative methods and tools to change practice (Zaccagnini & White, 2011). From the results of the initiative, an older and less expensive medication provided less top-off boluses, which in turn provided more sustainable labor pain relief in parturient women at SCH.

Research

For the DNP clinician, selection of the research problem is arguably the most crucial element in the research process (Terry, 2015). If the selected problem is not viable and testable, the whole process can waste valuable hours and financial resources while also creating frustration for the researcher. The core of the idea may come from patients, fellow colleagues, or from an indirect source, such as auditing, if the provider works in a quality management or administration role (Fitzpatrick & Whall, 2005). In this case, the problem stemmed from both direct and indirect sources.

The results of the QI project showed that bupivacaine with fentanyl was more effective in providing sustainable labor pain relief as compared to ropivacaine, thereby

improving the quality of care at SCH. This finding is contrary to most current evidence in mainstream literature (Eddleston et al., 1996; Owen, D'Angelo, & Geranchar, 1998; Polley, Columb, Naughton, Wagner, & Van de Ven, 1999; Dresner et al., 2000; Fehder & Gennaro, 1993), which suggests that ropivacaine is equipotent to bupivacaine with less side effects and motor sparing benefits. Future research needs to be conducted to show the effectiveness of administering bupivacaine with fentanyl in a larger Morongo Basin population over a longer period of time to determine generalizability and reliability. The results can then determine if bupivacaine with fentanyl does provide more sustainable labor pain relief in parturient women. Future research may also explore motor sparing effects, hemodynamics, patient satisfaction, and conversion to cesarean sections.

Social Change

The first implication for social change was the collaboration of other clinical providers to change practice using the evidence. Today's complexity of healthcare demands inter and intraprofessional collaboration to improve and sustain best outcomes for high quality care (Wojciechowski, Pearsall, Murphy, & French, 2016). Teams involved in continuous quality improvement projects may magnify and reveal competing mindsets of individuals and different practice strategies. However, in dynamic healthcare environments, individuals and systems need to be fluid and adaptable. Improvement is a never-ending journey that staff members need to be made aware of. With leadership support, the goal is for all participants to contribute to problem solving and to improve the design that adds value as defined by the client (Toussaint & Gerard, 2010).

The second implication for social change was to improve the quality of care for parturient women in the Morongo Basin community by also addressing the fear and anxiety of childbirth pain. Childbirth pain is a complex phenomenon that can trigger fear to those who have not experienced it. The fear is real, considered harmful, and has been shown to affect a woman's self-esteem and the ability to handle labor pain effectively (Karlsdottir, Halldorsdottir, & Lundgren, 2014). Unmet expectations and negative birth experiences have been shown to influence women's decisions about future childbearing (Gottvall & Waldenstrom, 2002). With the Information received from the project, I would be able contribute to the body of nursing knowledge aimed at improving health care quality for the parturient and her family in an emotionally significant period in their lives. When providers place epidurals for labor and administer safe and effective medications, they can allay patients' fears and anxiety during hospitalization where levels of vulnerability are high. Treating labor pain effectively with safe medications, informing parturient women adequately by addressing their concerns, and presenting realistic expectations about epidural pain management may increase satisfaction surrounding the childbirth experience.

Project Strengths and Limitations

Strengths

Strengths of the project were the use of the numeric pain rating scale and the implementation, collection, and analysis of project data by one lead project provider. The numeric pain rating scale is a trusted, long standing diagnostic tool that has been used in numerous disciplines and practices to evaluative subjective pain (Buchko & Robinson,

2012). Since a numeric value is placed in correlation with the pain, degrees of pain can be distinguished from one another. Hence, higher scores can indicate greater pain intensity. I implemented the same practice technique for the prospective bupivacaine with fentanyl group, such as placement of epidurals at similar levels of the spine, initial bolus amounts, fluid pre-loading in participants, and communication between myself and participants. Consistent practices ensure less confounding variables.

Limitations

There were two main limitations to the project. First, the data collected from the retrospective ropivacaine group had less credibility due to confounding variables. Although retrospective studies allow investigators to quickly use past data conveniently to inform current research questions, the database should be used based on sound rationale (Abbott, Barton, Terhorst, & Shembel, 2016). A few considerations include relevant data sources, data extraction methods, statistical procedures, and cautious interpretation of the findings. Although initial medication boluses and collection of numeric pain scale scores at designated times were similar to the prospective bupivacaine with fentanyl group, multiple providers placed the epidurals, communication between the providers and patients were most likely different, basal rate infusions varied between patients depending on provider preferences, and fluid pre-loading was sometimes omitted or not charted. Additionally, retrospective studies generally do not have the methodological rigor that is necessary to eliminate bias (Abbott, Barton, Terhorst, & Shembel, 2016). However, that is not to say that the information extracted from retrospective studies are not valuable. Through the retrospective audit of ropivacaine

patients, I offered preliminary findings that base clinical importance on the detection, management, and therapy of labor pain in parturient women at SCH.

Second, a convenience sampling was used for the project in both retrospective and prospective portions of the project due to time and resource constraints. A retrospective audit was necessary for the ropivacaine group because the medication was discontinued in January 2015 at SCH. The prospective portion of the project was feasible with the bupivacaine group, which comes with more rigor and control for bias. However, due to the low volume of deliveries at the institution, a convenience sampling was used to decrease the level of sampling error. To offer some control and limit selection bias of the prospective portion of the project, I selected some stringent inclusion and exclusion criteria and collected participant data over four weeks each. Despite some of those measures, I collected data from a rural community hospital that may not be representative of the community at large further limiting the generalizability of the findings. An accurate study needs to include all facets of a population with randomization (Polit, 2010). To add generalizability of the results, project teams would need to include randomization of participants with standardized practice techniques of providers.

Recommendations for Remediation of Limitations in Future Work

A major limitation of the QI project was the comparison of two different medications from a retrospective and prospective standpoint. There is less control with retrospective studies as compared to prospective studies. Provider biases, practice techniques, communication, and fluid prebolusing can differ greatly and be widely inconsistent. Researchers who use prospective approaches have more control of

confounding variables and have more precise estimates about the outcomes or relative risks of outcomes based on exposure (Grove et al., 2013).

A more reliable and more generalizable project would be the comparison of both medications strictly from a prospective approach over a longer period of time with the randomization of larger sample sizes. Providers would need to implement a standardized technique of epidural placement and adhere to consistent communication and preintervention protocols. However, the challenge of performing a larger scale, more time consuming project as such would require adequate support from institution stakeholders, management, and most importantly, cooperation from anesthesia providers and labor/delivery RNs. Those involved in the project would need to present expected outcomes and benefits of the project in a clear manner and aligned with the institution's vision and goals.

Analysis of Self

As Scholar

Society benefits through scholarship of practice when practitioners give expert nursing care, evaluate, and constantly improve practice based on evidence-based knowledge (Loomis, Willard, & Cohen, 2007). Proponents of the DNP degree posit that nursing scholarship would be enhanced and advanced through doctoral nursing education, which would raise advanced nursing practice to new levels termed by the American Association of Colleges of Nursing (AACN) as 'scholarship of engagement' (AACN, 2006). Scholarships of engagement occur when theory and research are applied to clinical settings, tested, amended, and extended (Loomis et al., 2007).

Throughout the DNP program, I have gained a wealth of didactic knowledge that could be shared with other colleagues to improve patient outcomes and enhance quality of care. With the aging population and projected demographic shifts, the demand for advanced practice nurses and their practice requirements will only increase furthering the need for additional education. Advanced practice nurses are prepared to work in a variety of roles once they complete a doctoral program that incorporates research elements into clinical practice. I have also learned valuable problem solving approaches and how to search for evidence based knowledge using systematic methods. The information obtained could also be shared with institution leaders and other community stakeholders. In turn, I shared methods of searching for high levels of evidence to other colleagues so they too could explore feasible solutions to clinical problems.

As Practitioner

Practitioners who complete the DNP curriculum are ready for the acceptance of new advanced practice roles. Some of the major roles are at their place of employment or healthcare organization and may involve duties such as, influencing healthcare and policy development, providing leadership, and strengthening interdisciplinary relationships with other professionals (Kaplan & Brown, 2009). The DNP prepared nurse who conducts practice and provide care according to the AACN essentials will bring added value to practice environments and patients. Intangible values include quality and safety improvement, healthcare institution savings, and improved patient relationships (Mackey, 2009).

As a practitioner, the clinical experiences have given me a broader look at healthcare systems operations, workflow efficiency, outdated policies, and a way of sensing workplace culture. It has made me keenly aware of the need to develop rapport and effective communication skills with stakeholders and front line clinical staff in order to accomplish objectives. Those invaluable skills are not taught in textbooks but only learned through experiences.

As Project Developer

Project developers have many roles and responsibilities. His/her main goals are to handle tasks that move the project along toward successful completion while reaching project objectives. As a project developer, I had to understand the inner dynamics of the project, remind myself of the objectives, learn to communicate with leaders/management of the institution to move things forward, and allow those who have valuable skills to use them. Morrill, Taege, & Slater (2010) note that trained, supportive staff and the acceptance of policies mixed with environmental changes help achieve successful outcomes.

Adoption of the project is a big step in having the organization consider taking a small test of change (Terry, 2015). There were some unexpected delays and frustration when it came to approval and implementation of the project. I realized how important it was in identifying barriers early in the process, setting up realistic expectations, and appreciating the value of forming good relationships with leaders and stakeholders in the institution. Leadership, management, and development often overlap. Ultimately, I

realized that without the authority that stems from leadership and management, my project may have shown potential but never materialized.

What does this project mean for future professional development?

The DNP project has given me a strong foundation and experience for future projects and initiatives. I was able to develop closer professional relationships with key stakeholders and leaders of the institution who believe in high quality, cost-effective care. They have already voiced their desire for me to be involved in several upcoming institution projects. More importantly, I have learned to systematically search, review, interpret, plan, and implement new or existing evidence in clinical practice. Evidence-based practice has become prominent in many professions, with the emphasis on clinical decision-making based on the best available evidence from systematic research (Zaccagnini & White, 2012). I have learned that management's use of the evidence just takes it to the next level where parameters are defined for what evidence will be collected and how the data will be utilized for monitoring, measuring performance, and evaluating. The data needs to be captured, quantified, and placed on a spreadsheet in a comparative format to understand if something works or does not work. I have great satisfaction and a feeling of professional fulfillment when I present new evidence to the institution so an actual policy is created.

Summary and Conclusions

The overall goal of the development and implementation of the bupivacaine with fentanyl project was for me to explore the effectiveness of the new service line medication, bupivacaine 0.1% with fentanyl 2mcg/ml, administered via PCEA infusion in

parturient women at SCH. There were two objectives for the project. The first objective was to achieve verbal pain scores of less than four out of 10 on a numeric pain scale ranging from zero to 10 within 60 minutes of epidural insertion and initial loading dose. The second objective was to achieve a rebolus rate of less than 10% throughout the remainder of the course of labor until the delivery of the fetus. I collected data for the ropivacaine group from retrospective chart reviews based on a 1 month January 2015 audit of all participants who received epidurals for labor and met all inclusion/exclusion criteria. I also collected data for the bupivacaine with fentanyl group prospectively in mid December 2016 based on a convenience sampling of all participants who received epidurals for labor.

I incorporated a quantitative, time-series design to determine causal or correlational relationships between independent and dependent variables. Thirty-two participants were included in the ropivacaine group, while 16 participants were included in the bupivacaine with fentanyl group for analyses. The results indicated that both ropivacaine and bupivacaine with fentanyl were statistically effective in relieving labor pain to adequate levels initially. However, the high number of rebolus rates for patients in the ropivacaine group indicate that bupivacaine with fentanyl provides more sustainable labor pain relief in parturient women at SCH.

The academic and clinical preparation gleaned from the DNP curriculum has enabled me to use a wide array of knowledge from the sciences and translate them quickly to clinical practice. Patient populations and healthcare systems benefit from the evidence. The DNP curriculum has also helped me to develop, implement, and evaluate

new clinical practice approaches based on nursing theories and theories from other

disciplines. I look forward to furthering my professional development, promoting health

and patient safety, eliminating health disparities, and fostering excellence in practice.

Section 5: Scholarly Product

Communicating the findings of a research or quality improvement project is the

final step, which involves developing a report and disseminating it through presentations

and/or publications to a vast array of audiences, such as, policymakers, healthcare

professionals, and healthcare consumers (Grove, Burns, & Gray 2013). Presentations and

published findings help advance the knowledge of a discipline by providing evidence-

based practice. Furthermore, dissemination of the findings helps promote the critical

analysis of previous reports or studies, fosters the reproduction of studies, and points out

additional problems (Melnyk & Fineout-Overholt, 2010). Because the QI project was

completed at SCH to determine the efficacy of a new service line medication, I will

present the findings to the institution's governing board and surgical services staff at the

quarterly medical executive committee meeting. I will generate an abbreviated report

and give an oral presentation via PowerPoint media. PowerPoint slides are an excellent

layout of the project due to easy-to-read fonts, visuals and figures to amplify points, and

creative backgrounds (Grove, Burns, & Gray 2013). Additionally, the abbreviated report

is to be published in the monthly hospital newsletter. Publication of the findings will

alert healthcare consumers of SCH and the Morongo Basin community that quality

improvement and patient safety/satisfaction is of utmost importance to the organization

and the community.

Another setting where findings could be communicated is the annual spring

conference of the California Association of Nurse Anesthetists (CANA) through poster

presentations (Figure 3). The CANA expresses visions about leadership, advocacy, and

education for nurse anesthetists in California. Poster presentations allow researchers

and/or clinicians to share preliminary findings, answer questions, and interact with other

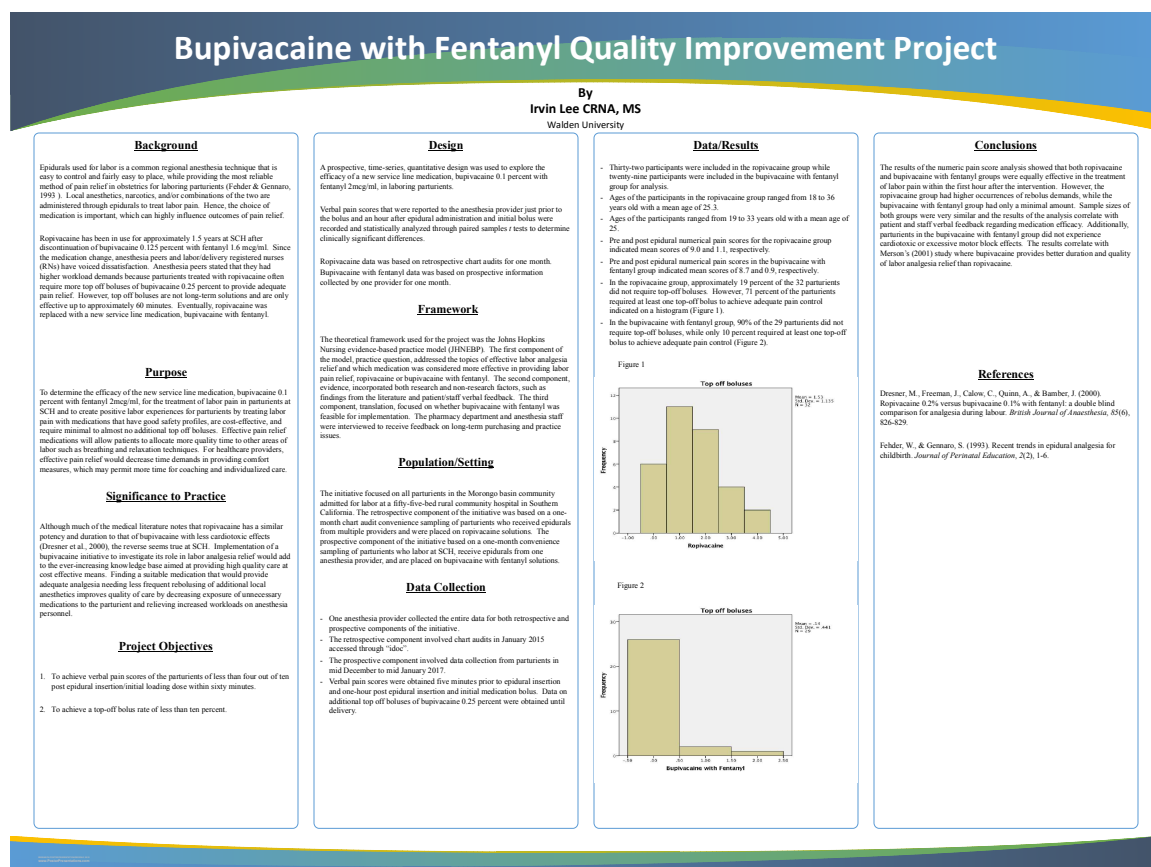researchers or providers about their studies (Grove, Burns, & Gray 2013).

Figure 3. Bupivacaine with fentanyl quality improvement poster of parturient women in SCH.

References

Abbott, K. V., Barton, F. B., Terhorst, L., & Shembel, A. (2016). Retrospective studies: A fresh look. *American Journal of Speech - Language Pathology* , *25*(2), 1-7.

Albright, G. A. (1984). Epinephrine should be used with the therapeutic dose of bupivacaine in obstetrics. *Anesthesiology*, *61*, 217-219.

American Association of Colleges of Nursing (2006). The essentials of doctoral education for advanced nursing practice. Retrieved from http://www.aacn.nche.edu/publications/position/DNPEssentials.pdf

Apfelbaum, J., Chen, C., Mehta, S., & Gan, T. (2003). Postoperative pain experience: Results from a national survey suggest postoperative pain continues to be undermanaged. *Anaesthesia and Analgesia*, *97*, 534-540.

Barash, P. G., Cullen, B. F., Stoelting, R. K., Cahalan, M. K., Stock, M. C., & Ortega, R. (2013). *Clinical anesthesia* (7th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Berti, M., Fanelli, G., Casati, A., & Albertin, A. (2000). Patient supplemented epidural analgesia after major abdominal surgery with bupivacaine/fentanyl or ropivacaine/fentanyl. *Canadian Journal of Anesthesia*, *47*(1), 27-32.

Bondmass, M. (2011). Implementation strategies for evidence-based practice: Part III of a IV-part series on evidence-based practice. *Nevada RN information*, *20*(1), 14.

Buchko, B. L., & Robinson, L. E. (2012). An evidence-based approach to decrease early post-operative urinary retention following urogynecologic surgery. *Urologic Nursing*, *32*(5), 260-273.

Bucklin, B. A., Chestnut, D. H., & Hawkins, J. L. (2002). Intrathecal opioids versus epidural local anesthetics for labor analgesia: A meta-analysis. *Regional Anesthesia and Pain Medicine*, *27*(1), 23-30.

Campbell, D. (2003). Parenteral opioids for labor analgesia. *Clinical Obstetrics & Gynaecology*, *46*(3), 616-622.

Capogna, C., Celleno, D., Fusco, P., Lyons, G., & Columb, M. (1999). Relative potencies of bupivacaine and ropivacaine for analgesia in labour. *British Journal of Anaesthesia*, *82*, 371-373.

Capogna, G., Camorcia, M., & Stirparo, S. (2007). Expectant fathers' experience during labor with or without epidural analgesia. *International Journal of Obstetrical Anesthesia*, *16*, 110-115.

Casati, A., & Baciarello, M. (2006). Enantiomeric local anaesthetics: Can ropivacaine and levobupivacaine improve our practice? *Current Drug Therapy*, *1*(1), 85-89.

Catterall, W. A., & Mackie, K. (2006). *Goodman & Gillman's the pharmacological basis of therapeutics* (11th ed.). New York: McGraw-Hill.

Chandran, S., Hemalatha, S., & Viswanathan, P. (2014). Comparison of 0.75% ropivacaine and 0.5% bupivacaine for epidural anaesthesia in lower extremity orthopaedic surgeries. *Indian Journal of Anaesthesia*, *58*(3), 336-338.

Chang, D. H., Ladd, L. A., & Copeland, S. (2001). Direct cardiac effects of intracoronary bupivacaine, levobupivacaine, and ropivacaine in the sheep. *British Journal of Pharmacology*, *132*, 649-658.

Chapman, H. R., & Kirby-Turner, N. (2002). Visual/verbal analogue scales: Examples of

brief assessment methods to aid management of child and adult patients in clinical practice. *British Dental Journal*, *193*(8), 447-450.

Chua, N. P., Sia, A. T., & Ocampo, C. E. (2001). Parturient-controlled epidural analgesia during labour: bupivacaine vs. ropivacaine. *Anaesthesia*, *56*(12), 1169-1173. http://dx.doi.org/10.1046/j.1365-2044.2001.02321.x

Coalson, D., & Glosten, B. (1991). Alternatives to epidural analgesia. *Seminars in Perinatology*, *15*, 375-385.

Dickinson, J. E., Paech, M. J., Mcdonald, S. J., & Evans, S. F. (2003). Maternal satisfaction with childbirth and intrapartum analgesia in nulliparous labor. *New Zealand Journal of Obstretrical Gynecology*, *43*, 463-468.

Dresner, M., Freeman, J., Calow, C., Quinn, A., & Bamber, J. (2000). Ropivacaine 0.2% versus bupivacaine 0.1% with fentanyl: a double blind comparison for analgesia during labour. *British Journal of Anaesthesia*, *85*(6), 826-829.

Eddleston, J. M., Holland, J. J., Griffin, R. P., Corbett, A., Horsman, E. L., & Reynolds, F. (1996). A double-blind comparison of 0.25% ropivacaine and 0.25% bupivacaine for extradural analgesia in labour. *British Journal of Anaesthesia*, *76*, 66-71.

Fehder, W., & Gennaro, S. (1993). Recent trends in epidural analgesia for childbirth. *Journal of Perinatal Education*, *2*(2), 1-6.

Feldman, H. S., & Covino, B. G. (1988). Comparative motor blocking effects of bupivacaine and ropivacaine, a new amide local anesthetic in rat and dog. *Anesthesia and Analgesia*, *67*, 1047-1052.

Feldman, H. S., & Covino, B. G. (1988). Comparative motor blocking effects of

    bupivacaine and ropivacaine, a new amide local anesthetic in rat and dog.

    Anesthesia and Analgesia, *67*, 1047-1052.

Finegold, H., Mandell, G., & Ramanathan, S. (2000). Comparison of ropivacaine 0.1%-

    fentanyl and bupivacaine 0.125% -- fentanyl infusions for epidural labour

    analgesia. *Canadian Journal of Anesthesia*, *47*(8), 740-745.

Fitzpatrick, J., & Whall, A. (2005). *Conceptual models of nursing: Analysis and*

    application. Suuper Saddle River, NJ: Pearson Prentice Hall.

Garthus-Niegel, S., Knoph, C., Soest, T., Nielsen, C. S., & Eberhard-Gran, M. (2014).

    The Role of Labor Pain and Overall Birth Experience in the development of

    posttraumatic stress symptoms: A longitudinal cohort study. *Birth: Issues In*

    Perinatal Care, *41*(1), 108-115. http://dx.doi.org/10.1111/birt.12093

Gottvall, K., & Waldenstrom, U. (2002). Doesatraumatic birth experience have an impact

    on future reproduction? *BJOG: International Journal of Obstetrics and*

    Gynecology, *109*, 254-260.

Grove, S. K., Burns, N., & Gray, J. R. (2013). *The practice of nursing research:*

    Appraisal, synthesis, and generation of evidence (7th ed.). St. Louis, MO:

    Saunders Elsevier.

Halpern, S., & Joseph, G. (2002). Patient-controlled epidural analgesia versus continuous

    infusion for labour analgesia: a meta-analysis. *British Journal of Anaesthesia*, *89*,

    459-465.

Hawkins, J. L. (2010). Epidural analgesia for labor and delivery. *The New England*

Journal of Medicine, *362*, 1503-1510.

Iliadou, M. (2009). Labour pain and pharmacological pain relief practice points. *Health Science Journal*, *3*(4), 197-201.

Institute of Medicine (2001). *Crossing the Quality Chasm. A New Health System for the 21st Century*. Washington: National Academy.

Karlsdottir, S. I., Halldorsdottir, S., & Lundgren, I. (2014). The third paradigm in labour pain preparation and management: the childbearing woman's paradigm. *Scandinavian Journal of Caring Sciences*, *28*(2), 315-327.

Katz, J. A., Bridenbaugh, P. O., Knarr, D. C., Helton, S. H., & Denson, D. D. (1990). Pharmacodynamics and pharmacokinetics of epidural ropivacaine in humans. *Anesthesia and Analgesia*, *70*, 16-21.

Lacassie, H. J., Habib, A. A., Lacassie, H. P., & Columb, M. O. (2007). Motor blocking minimum local anesthetic concentrations of bupivacaine, levobupivacaine, and Ropivacaine in labor. *Regional Anesthesia and Pain Medicine*, *32*(4), 323-329.

Lally, J. E., Murtagh, M. J., Macphail, S., & Thomson, R. (2008). More in hope than expectation: a systematic review of women's expectations and experi- ence of pain relief in labour. *BMC Medicine*, *6*, 1125-1140.

Lim, Y., Ocampo, C. E., Supandji, M., Teoh, W. L., & Sia, A. T. (2008). A randomized controlled trial of three patient-controlled epidural analgesia regimens for labor. *Anesthesia and Analgesia*, *107*, 1968-1972.

McCaffery, M., & Pasero, C. (1999). *Pain: Clinical Manual*. St. Louis: Mosby, Inc.

Melnyk, B. M., & Fineout-Overholt, E. (2010). *Evidence-based practice in nursing &*

healthcare: A guide to best practice (2nd ed.). Philadelphia: Lippincott Williams & Wilkins.

Melzack, R. (1984). The myth of painless childbirth. *Pain*, 19, 321-337.

Merson, N. (2001). A comparison of motor block between ropivacaine and bupivacaine for continuous labor epidural analgesia. *AANA Journal*, *69*(1), 54-58.

Miller, R. D., Cohen, N. H., Eriksson, L. I., Fleisher, L. A., Wiener-Kronish, J. P., & Young, W. L. (2005). *Anesthesia* (6th ed.). New York: Churchill Livingstone.

Morgan, G. E., Mikhail, M. S., & Murray, M. J. (2006). *Clinical anesthesiology* (6th ed.). New York: Lange Medical Books/McGraw Hill Medical Pub.Division.

Morrill, P., Taege, K., & Slater, K. (2010). Lessons learned: A systems approach to lean and evidence-based design. *ASQ Healthcare Update*, *8*(11), 21-25.

Muir, H. A., Writer, D., & Douglas, J. (1997). Double-blind comparison of epidural ropivacaine 0.25% and bupivacaine 0.25%, for the relief of childbirth pain. *Canadian Journal of Anaesthesia*, *44*(6), 599-604.

Osterman, M., & Martin, J. A. (2011). Epidural and spinal anesthesia use during Labor: 27-state reporting area, 2008. *National Vital Statistics Reports*, *59*(5), 1-16.

Owen, M. D., D'Angelo, R., & Geranchar, J. C. (1998). 0.125% ropivacaine is similar to 0.125% bupivacaine for labor analgesia using patient-controlled epidural infusion. *Anesthesia and Analgesia*, *86*, 527-531.

Pirbudak, L., Tuncer, S., Kocoglu, H., Goksu, S., & Celik, C. (2002). Fentanyl added to bupivacaine 0.05% or ropivacaine 0.05% in patient-controlled epidural analgesia in labour. *European Journal of Anaesthesiology*, *19*, 271-275.

Pitimana-aree, S., Visalyaputra, S., Komoltri, C., Muangman, S., & Al, E. (2005). An economic evaluation of bupivacaine plus fentanyl versus ropivacaine alone for patient-controlled epidural analgesia after total-knee replacement procedure: A double-blinded randomized study. *Regional Anesthesia and Pain Medicine*, *30*(5), 446-451.

Polit, D. (2010). *Statistics and data analysis for nursing research* (2nd ed.). Upper Saddle River, NJ: Pearson Education Inc.

Polley, L. S., Columb, M. O., Naughton, N. N., Wagner, D. S., & Van de Ven, C. J. (1999). Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. *Anesthesiology*, *90*, 944-950.

Pouzeratte, Y., Delay, J. M., Brunat, G., Boccara, G., Vergne, C., & Jaber, S. (2001). Patient-controlled epidural analgesia after abdominal surgery: Ropivacaine versus bupivacaine. *Anesthesia Analgesia*, *93*, 1587-1592.

Sah, N., Vallejo, M., Phelps, A., & Mandell, G. (2007). Efficacy of ropivacaine, bupivacaine, and levobupivacaine for labor epidural analgesia. *Journal of Clinical Anesthesia*, *19*, 214-217.

Sawhney, K. Y., Kundra, S., Grewal, A., Katyal, S., Singh, G., & Kaur, A. (2015). A randomized double blinded comparison of epidural infusion of bupivacaine, ropivacaine, bupivacaine-fentanyl, ropivacaine-fentanyl for postoperative pain relief in lower limb surgeries. *Journal of Clinical and Diagnostic Research: JCDR*, *9*(9), 19-23.

Seers, K., & Critelton, N. (2001). Quantitative research: Designs relevant to nursing and

healthcare. *Nursing Times*, *6*(1), 487-500.

Sharma, S. K., McIntire, D. D., Wiley, J., & Leveno, K. J. (2004). Labor analgesia and

cesarean delivery: an individual patient meta-analysis of nulliparous women.

Anesthesiology, *100*, 142-148.

Spaulding, D. T. (2008). *Program evaluation in practice: Core concepts and examples*

for discussion and analysis. San Francisco: Jossey-Bass.

Strand, A., & Parkkinen, V. (2014). Causal knowledge in evidence-based medicine. In

reply to Kerry et_al.'s causation and evidence-based practice: an ontological

review. *Journal of Evaluation in Clinical Practice*, 20(6), 981-984.

http://dx.doi.org/10.1111/jep.12093

Terry, A. J. (2015). *Clinical research for the doctor of nursing practice* (2nd ed.).

Burlington, MA: Jones & Bartlett Learning.

Toussaint, J. S., & Gerard, R. A. (2010). *On the mend: Revolutionizing healthcare to save*

lives and transform the industry. Cambridge, MA: Lean Enterprise Institute.

Wojciechowski, E., Pearsall, T., Murphy, P., & French, E. (2016). A case review:

Integrating lewin's theory with lean's system approach for change. *Online*

Journal of Issues in Nursing, *21*(2), 13-26.

http://dx.doi.org/dx.doi.org/10.3912/OJIN.Vol21No02Man04

Zaccagnini, M. E., & White, K. W. (2012). *The doctor of nursing practice essentials: A*

new model for advanced practice nursing (Laureate Education, Inc., custom ed.).

Sudbury, MA: Jones & Bartlett Publishers.

Zaric, D., Christiansen, J., Haastrup, U., & Sandberg, T. (2004). Epidural infusion of
bupivacaine versus ropivacaine for pain management after total knee replacement.
Regional Anesthesia and Pain Medicine, *29*(5), 49.

Zaric, D., Nydahl, P. A., & Philipson, L. (1996). The effect of continuous lumbar
epidural infusion of ropivacaine (0.1%, 0.2%, and 0.3%) and 0.25% bupivacaine
on sensory and motor block in volunteers: a double-blind study. *Regional
Anaesthesia*, *21*, 14-25.

List of Tables

Table 1

Mean ages of parturient women

	Minimum	Maximum	Mean
Ropivacaine group	18	36	25.3
Bupivacaine group	19	33	25

Table 2

Pre and post pain scores

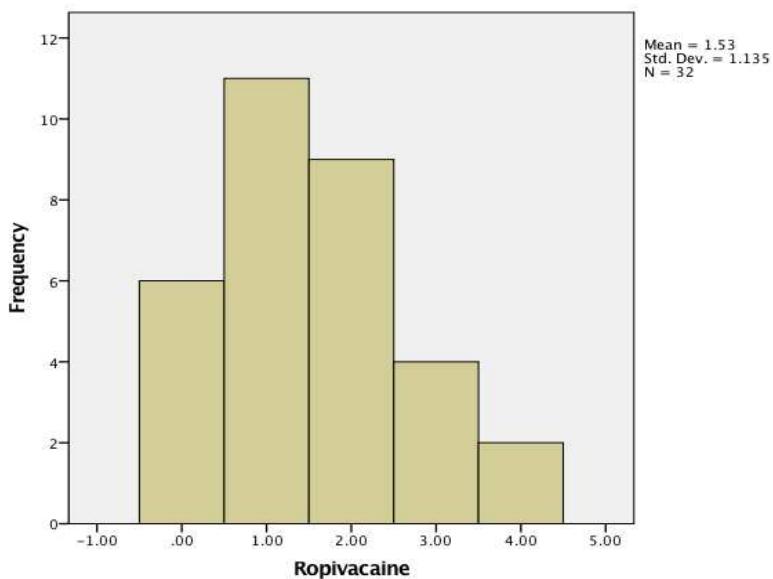|	Mean	Significance	Degrees of Freedom
Pre-epidural ropivacaine	9.0	$p<0.01$	31
Post-epidural ropivacaine	1.1		
Pre-epidural bupivacaine	8.7	$p<0.01$	28
Post-epidural bupivacaine	0.9		

List of Figures

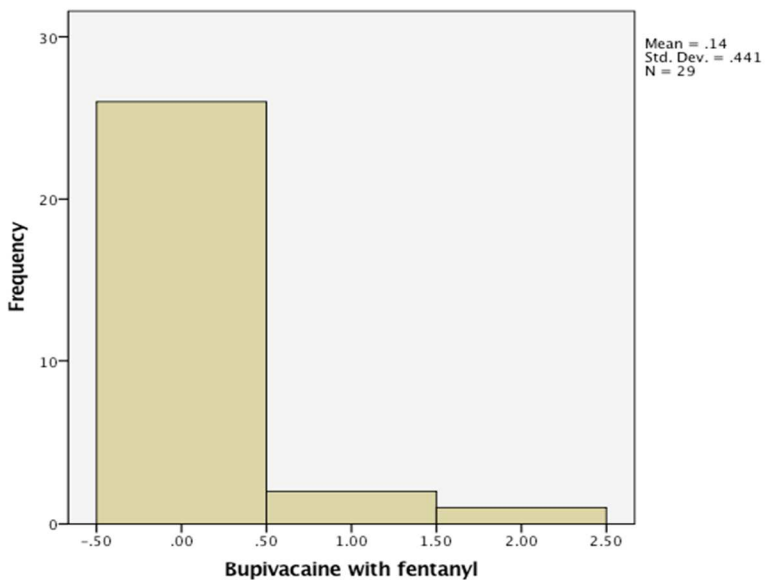*Figure 1*. Top-off boluses of parturient women at SCH ropivacaine group.

Figure 2. Top-off boluses of parturient women at SCH bupivacaine with fentanyl group.

Bupivacaine with Fentanyl Quality Improvement Project

By
Irvin Lee CRNA, MS
Walden University

Background

Epidurals used for labor is a common regional anesthesia technique that is easy to control and fairly easy to place, while providing the most reliable method of pain relief in obstetrics for laboring parturients (Fehder & Gennaro, 1993). Local anesthetics, narcotics, and/or combinations of the two are administered through epidurals to treat labor pain. Hence, the choice of medication is important, which can highly influence outcomes of pain relief.

Ropivacaine has been in use for approximately 1.5 years at SCH after discontinuation of bupivacaine 0.125 percent with fentanyl 1.6 mcg/ml. Since the medication change, anesthesia peers and labor/delivery registered nurses (RNs) have voiced dissatisfaction. Anesthesia peers stated that they had higher workload demands because parturients treated with ropivacaine often require more top off boluses of bupivacaine 0.25 percent to provide adequate pain relief. However, top off boluses are not long-term solutions and are only effective up to approximately 60 minutes. Eventually, ropivacaine was replaced with a new service line medication, bupivacaine with fentanyl.

Purpose

To determine the efficacy of the new service line medication, bupivacaine 0.1 percent with fentanyl 2mcg/ml, for the treatment of labor pain in parturients at SCH and to create positive labor experiences for parturients by treating labor pain with medications that have good safety profiles, are cost-effective, and require minimal to almost no additional top off boluses. Effective pain relief medications will allow patients to allocate more quality time to other areas of labor such as breathing and relaxation techniques. For healthcare providers, effective pain relief would decrease time demands in providing comfort measures, which may permit more time for coaching and individualized care.

Significance to Practice

Although much of the medical literature notes that ropivacaine has a similar potency and duration to that of bupivacaine with less cardiotoxic effects (Dresner et al., 2000), the reverse seems true at SCH. Implementation of a bupivacaine initiative to investigate its role in labor analgesia relief would add to the ever-increasing knowledge base aimed at providing high quality care at cost effective means. Finding a suitable medication that would provide adequate analgesia needing less frequent rebolusing of additional local anesthetics improves quality of care by decreasing exposure of unnecessary medications to the parturient and relieving increased workloads on anesthesia personnel.

Project Objectives

1. To achieve verbal pain scores of the parturients of less than four out of ten post epidural insertion/initial loading dose within sixty minutes.

2. To achieve a top-off bolus rate of less than ten percent.

Design

A prospective, time-series, quantitative design was used to explore the efficacy of a new service line medication, bupivacaine 0.1 percent with fentanyl 2mcg/ml, in laboring parturients.

Verbal pain scores that were reported to the anesthesia provider just prior to the bolus and an hour after epidural administration and initial bolus were recorded and statistically analyzed through paired samples t tests to determine clinically significant differences.

Ropivacaine data was based on retrospective chart audits for one month. Bupivacaine with fentanyl data was based on prospective information collected by one provider for one month.

Framework

The theoretical framework used for the project was the Johns Hopkins Nursing evidence-based practice model (JHNEBP). The first component of the model, practice question, addressed the topics of effective labor analgesia relief and which medication was considered more effective in providing labor pain relief, ropivacaine or bupivacaine with fentanyl. The second component, evidence, incorporated both research and non-research factors, such as findings from the literature and patient/staff verbal feedback. The third component, translation, focused on whether bupivacaine with fentanyl was feasible for implementation. The pharmacy department and anesthesia staff were interviewed to receive feedback on long-term purchasing and practice issues.

Population/Setting

The initiative focused on all parturients in the Morongo basin community admitted for labor at a fifty-five-bed rural community hospital in Southern California. The retrospective component of the initiative was based on a one-month chart audit convenience sampling of parturients who received epidurals from multiple providers and were placed on ropivacaine solutions. The prospective component of the initiative based on a one-month convenience sampling of parturients who labor at SCH, receive epidurals from one anesthesia provider, and are placed on bupivacaine with fentanyl solutions.

Data Collection

- One anesthesia provider collected the entire data for both retrospective and prospective components of the initiative.
- The retrospective component involved chart audits in January 2015 accessed through "idoc".
- The prospective component involved data collection from parturients in mid December to mid January 2017.
- Verbal pain scores were obtained five minutes prior to epidural insertion and one-hour post epidural insertion and initial medication bolus. Data on additional top off boluses of bupivacaine 0.25 percent were obtained until delivery.

Data/Results

- Thirty-two participants were included in the ropivacaine group while twenty-nine participants were included in the bupivacaine with fentanyl group for analysis.
- Ages of the participants in the ropivacaine group ranged from 18 to 36 years old with a mean age of 25.3.
- Ages of the participants ranged from 19 to 33 years old with a mean age of 25.
- Pre and post epidural numerical pain scores for the ropivacaine group indicated mean scores of 9.0 and 1.1, respectively.
- Pre and post epidural numerical pain scores in the bupivacaine with fentanyl group indicated mean scores of 8.7 and 0.9, respectively.
- In the ropivacaine group, approximately 19 percent of the 32 parturients did not require top-off boluses. However, 71 percent of the parturients required at least one top-off bolus to achieve adequate pain control indicated on a histogram (Figure 1).
- In the bupivacaine with fentanyl group, 90% of the 29 parturients did not require top-off boluses, while only 10 percent required at least one top-off bolus to achieve adequate pain control (Figure 2).
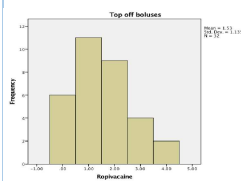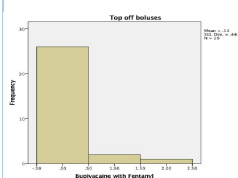
Figure 1

Top off boluses

Mean = 1.53
Std. Dev. = 1.115
N = 32

Ropivacaine

Figure 2

Top off boluses

Mean = .14
Std. Dev. = .441
N = 29

Bupivacaine with Fentanyl

Conclusions

The results of the numeric pain score analysis showed that both ropivacaine and bupivacaine with fentanyl groups were equally effective in the treatment of labor pain within the first hour after the intervention. However, the ropivacaine group had higher occurrences of rebolus demands, while the bupivacaine with fentanyl group had only a minimal amount. Sample sizes of both groups were very similar and the results of the analysis correlate with patient and staff verbal feedback regarding medication efficacy. Additionally, parturients in the bupivacaine with fentanyl group did not experience cardiotoxic or excessive motor block effects. The results correlate with Merson's (2001) study where bupivacaine provides better duration and quality of labor analgesia relief than ropivacaine.

References

Dresner, M., Freeman, J., Calow, C., Quinn, A., & Bamber, J. (2000). Ropivacaine 0.2% versus bupivacaine 0.1% with fentanyl: a double blind comparison for analgesia during labour. *British Journal of Anaesthesia, 85*(6), 826-829.

Fehder, W., & Gennaro, S. (1993). Recent trends in epidural analgesia for childbirth. *Journal of Perinatal Education, 2*(2), 1-6.

Figure 3. Bupivacaine with fentanyl quality improvement poster of parturient women in SCH.

Appendix A: Pre-anesthesia Evaluation Form

ANESTHESIA RECORD

RESPIRATORY: WNL	CARDIOVASCULAR: WNL	CNS-NEURO-MUSCULAR: WNL
ASTHMA; ATELECTASIS, OSA; CPAP COPD; URI; DYSPNEA; TB; EMPHYSEMA; COUGH; SMOKER; HYPOXEMIA; DENTURES: PARTIAL, FULL DENTITION: GOOD, FAIR, POOR Mallampati class ☐1 ☐2 ☐3 ☐4 LOOSE TEETH: ☐Y ☐N OTHER:	ANGINA; ARRHYTHMIAS; INFARCTION; CHF; HYPERTENSION; ARTERIOSCLEROSIS; PVD; HEART DISEASE; PRIOR CARDIAC SURGERY; EKG: ABNORMAL OTHER:	SEIZURES; STROKE; TIA; NUMBNESS; HERNIATED DISC; ARTHRITIS; MYASTHENIA; HEADACHE; PARALYSIS; BACKACHE; MULTIPLE SCLEROSIS OTHER:

OTHER SYSTEMS: WNL	LABS: WNL NONE REQUIRED
HYPOTHYROIDISM; HYPERTHYROIDISM; OBESITY; BLINDNESS; DIABETES MELLITUS; CLOTTING DISORDER; DEAFNESS; GLAUCOMA; JAUNDICE; NEPHRITIS; HEPATITIS; GERD; ANEMIA RENAL INSUFFICIENCY; SICKLE CELL; HIATAL HERNIA OTHER:	

PREVIOUS ANESTHETIC COMPLICATIONS/SURGICAL HISTORY	DRUG THERAPY: NONE
NONE	Beta Blocker:_____ Dosage:_____ Time:_____ Date:_____

ASA CLASSIFICATION SYSTEM (CIRCLE) 1 2 3 4 5 E	ALLERGIES: NKA OTHER:

ANESTHESIA PLAN OF CARE

☐ GENERAL ANESTHESIA	☐ REGIONAL ANESTHESIA	☐ CENTRAL LINE
☐ MAC	☐ EPIDURAL	☐ PULMONARY ARTERY CATH
☐ SPINAL	☐ ART LINE	☐ REGIONAL BLOCKS FOR POST OP PAIN

☐ OTHER:_____

Potential anesthesia problems: _____

STATEMENT OF PROCEDURE INFORMED CONSENT

I have completed the above evaluation and have spoken with the patient, or the patient's authorized representative, about the nature of the scheduled anesthetic procedure as indicated in the Anesthesia Plan of Care including the risks, possible complications and expected benefits or effects of the anesthetic procedure and medications as well as the problems related to the recovery/recuperation. Additionally, I have discussed any alternatives to the anesthetic procedure and their risks and benefits with him/her. The patient/patient's representative has accepted.

Signature:_____ Print Name:_____ License #:_____ Date:_____ Time:_____

DOB: /
PRIMARY:
ATTENDING:

PRE-ANESTHESIA EVALUATION

OR1 PAE REV 12/12

\\Nas03\d\Storage\information technology\shared\FORMFAST\forms\5_SURG.PROC\OR1 PAE

Appendix B: Numeric Pain Rating Scale