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REMIFENTANIL PATIENT CONTROLLED ANALGESIA USE IN LABORING WOMEN: A FEASIBILITY AND ACCEPTABILITY STUDY

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DOCTOR OF PHILOSOPHY IN NURSING

REMIFENTANIL PATIENT CONTROLLED ANALGESIA USE IN LABORING WOMEN:

A FEASIBILITY AND ACCEPTABILITY STUDY

By

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TITLE OF DISSERTATION: Remifentanil Patient Controlled Analgesia use in Laboring Women: A Feasibility and Acceptability Study

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ABSTRACT

Background/Purpose: Interest in remifentanil patient controlled analgesia (RPCA) as a treatment for labor pain has increased due to its unique pharmacodynamics and effectiveness on pain control among parturients. Despite its promise, RPCA remains infrequently used in the US. The purpose of this study was to 1) examine the implementation and acceptability of a new RPCA protocol in the labor and delivery ward of a mid-sized hospital, and 2) identify the attitudes and beliefs of healthcare workers in a real-world clinical setting.

Theoretical/Conceptual Framework: The holistic nature of Comfort Theory can account for the proposed mechanisms contributing to the success of RPCA for labor pain.

Method: Mixed methods approach. **Quantitative.** Data were extracted from electronic health records and provider interviews. Parturients sorted in one of three groups, (1) no opioid (n=83), (2) traditional opioid (n=48), and (3) RPCA 9 (n=13), were compared on pain scores, side effects, and adverse events. **Results**: Both traditional opioid administration and RPCA showed significant reduction in pain scores when measured against the no opioid group using the Mann-Whitney U ($Z = -3.514$, $p < 0.001$; $Z = -2.064$, $p = 0.039$). Chi square analysis indicated grouping was associated with increased likelihood of receiving treatment for nausea and vomiting ($\chi^2 = 21.178$, $p < 0.001$, $df = 2$) and desaturation events ($\chi^2 = 53.394$, $p < 0.001$, $df = 2$). No significant association was seen with pruritis treatment ($\chi^2 = 5.264$, $p = 0.072$, $df = 2$) or lower APGAR score ($\chi^2 = 1.329$, $p = 0.515$, $df = 2$).

Qualitative investigation was based in the phenomenological method via individual semi-structured interviews (n=8) to gain an understanding of providers' attitudes toward

labor pain management, approach to labor pain management, and perceived or actual barriers to the implementation of the novel RPCA technique. Four themes emerged: Respect for Choice, Shielding from Family Influence, Barriers to the Implementation of a New Technique, and Overall Satisfaction with RPCA.

Conclusions and Implications: RPCA was supported by staff members at this clinical site, an indicator effective education and implementation plans are likely to achieve support. Recommendations for practice are discussed.

DEDICATION

This work is dedicated to my wife and children, their shared experience bringing life and being born inspired my interest in contributing to positive labors. Love always to Chelsia, Jason, Regan, and Rylie.

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CHAPTER I

Introduction of Problem

Silva and Halpern (2010) note pain during childbirth is widely recognized as one of the most distressing events women can experience. The anticipation or experience of labor pain may be even more troubling for women who do not have the option of or the desire for Epidural Analgesia (EA). In pursuit of ameliorating the experience of labor pain, many alternative methods for pain reduction have been explored. Empirical evidence of the superiority of patient-controlled analgesia (PCA) over other modalities is mounting (Lee et al., 2017), with a growing volume of research pointing to remifentanil as a promising medication, due to its fast onset and short half-life (Blair et al., 2005; Ohashi et al., 2016; Weibel et. al, 2017; Wilson et al., 2018). Consequently, the acceptance of PCA therapy in labor is spreading, especially outside the United States (Devabhakthuni, 2013; Murray et al., 2019).

Despite findings that point to a high safety profile and efficacious analgesic and satisfaction properties, a recent Cochrane review indicated there is not enough high-quality evidence to make a strong recommendation of support before larger trials are conducted (Weibel et. al., 2017). In contrast, other systematic reviews have found sufficient evidence to make recommendations for implementing remifentanil PCA (RPCA) into clinical practice, particularly where EA is not a viable option due to geographic limitations, comorbidities, or cultural/personal preferences (Devabhakthuni, 2013; Ohashi et. al., 2016; Velde & Carvalho, 2015). Recently, a high-quality randomized controlled trial has demonstrated a clear superiority of RPCA to intramuscular meperidine for labor pain management (Wilson et al., 2018). Practitioners

involved in labor pain management in the United States have been slow to adopt RPCA due to a variety of concerns and consequently, its use is not widespread (Markley & Rollins, 2017). In order to expand the body of evidence around RPCA, increase the acceptance of the technique in both patients and providers, and optimize implementation strategies future research is needed.

Background & Significance

Epidural analgesia for the management of labor pain has increased in popularity over the past 4 decades. The current prevalence of this technique in the United States is approximately 60% (Meng & Smiley, 2017; Silva & Halpern, 2010). However, many women are unable to receive an epidural during labor due to contraindications, for example, coagulopathy, infection, or spinal irregularity. Some parturients also elect alternative pain management strategies, such as systemic opioids, for personal or cultural reasons (Declercq et al., 2018; Roberson, 2019; Tveit et al., 2012).

Current alternative techniques (AT) for pain management in labor without EA vary from intermittent administration of opioids or other analgesics to hypnosis. The most promising alternative pharmacologic strategy is RPCA. This approach involves the self-administration of pain medication by the patient using a demand button connected to an infusion pump. An early example of research in this area by Evron et al. (2005) identified a significant improvement in both pain (35.8 compared to 58.8 on a visual analog scale) and satisfaction (3.9 versus 1.9 satisfaction score) when they examined RPCA against meperidine IV infusion. On the other hand, a meta-analysis conducted by Lee et al. (2017) looked at randomized controlled trials and found there was no significant difference on measures of maternal satisfaction between those receiving EA

and those controlling a RPCA delivery system (OR 1.3, CI 0.31-5.38). Recent systematic reviews and meta-analysis support the assertion that remifentanil provides better pain control and offers safety advantages when compared to other intravenous medications (Ohashi et. al., 2016; Weibel et al., 2017). Defining the appropriate role for RPCA in the spectrum of labor pain management options and increasing provider comfort with this technique remains an area worthy of exploration.

Labor pain is a complex multidimensional phenomenon experienced by women at the end of pregnancy. The anticipation of labor pain can be a significant source of fear and anxiety for some pregnant women; however, when passed through an individual's prism of culture, experience, and expectation, labor pain perceptions can vary significantly in both physical and psychological impact. The World Health Organization (2018) points out caregiver attitudes, resources, and environment can also influence the experience of labor pain. The duration and progression of labor are other important contributors to the overall perception of labor pain (Iizuka et al., 2018). Some experts contend the western medical approach to labor pain management has emphasized the noxious and negative aspects of childbirth (Lennon, 2018). For example, Wilson et al. (2019) note pain during childbirth is "extremely painful" and pain relief is critical to a positive childbirth experience (p. 662). Alternatively, Roberts et al. (2010) assert the positive aspects of labor pain, such as goal-oriented work toward a reward, should be emphasized and interventions should be reserved for the prevention of suffering.

Similar to labor pain itself, the decision-making process for labor pain management is complicated and multifactorial. Participation in and control of pain-related decisions have been theorized to represent a larger influence on maternal

satisfaction than the level of pain control achieved (Hodnett, 2002; Wright et al., 2000). The perception of personal control is highly subjective and has various meanings to women based on factors, for example, parity, education, expectations, and treatment by staff (Green et al., 2003). Because parturients approach labor pain management with attitudes, expectations, and circumstances that are unique, no single theory can adequately describe a universal strategy. For this reason, multiple theories for assisting women to make pain-related decisions for labor may be useful so approaches can be personalized to the greatest possible extent by healthcare staff.

Extrapolation of data from our recent pilot study indicates over 140,000 women each year in the United States could be denied access to or refuse labor epidurals for pain relief because of comorbidities or personal preference (Carr, 2019). Epidural analgesia (EA) is selected by 68% of women in California (Declercq et al., 2018). This is similar to the prevalence in the western United States (Osterman & Martin, 2011). However, many women are unable to receive an epidural during labor due to physiologic dysfunction, pharmacologic complication, or anatomic abnormality (Shnabel et al., 2018). Additionally, many parturients choose intravenous (IV) opioid pain management strategies for personal or cultural reasons (Roberson, 2019) Pilot data indicate approximately 33% of the women at this investigation site who deliver vaginally without EA elect IV opioid pain management. Most research in this area has focused on the choice to receive EA or pursue a ‘natural’ (i.e. opioid-free) childbirth plan leaving a knowledge gap around those who elect an opioid-based plan.

Purpose

Caregiver resistance to the widespread implementation of RPCA continues even though the evidence of effectiveness accumulates (Ohashi et al., 2016; Wilson et al., 2019). Fear of harmful effects that necessitate additional personnel for one-to-one care and requirements for extra equipment such as end-tidal carbon dioxide (ETCO2) monitoring may impede timely progress in collecting the breadth of data required to support widespread acceptance of RPCA on the labor ward. The purpose of this study is to evaluate the implementation of an RPCA protocol and identify the attitudes and beliefs of healthcare workers in a real-world clinical setting.

Aims

Aim I. To identify differences in labor pain scores by intervention (RPCA compared to the current clinical opioid technique and between all three groups).

Aim II. Examine the relationships among RPCA use, desaturation events, side effects requiring intervention, occurrence of a critical event, delivery type, and APGAR score among a cohort of laboring mothers.

Aim III. Gain a deeper understanding of early adoptors' reasons for implementing PCA through the conduct of structured interviews with selected staff members at the clinical site.

Conceptual Framework

The study is informed by comfort theory and the conceptual framework is derived from the literature and is comprised of the variables of relief from physical discomfort through the use of pain medication, support of psychological comfort by allowing personal control over pain relief strategy, and social comfort derived from the ability to choose how to interact with the environment. The holistic nature of this theory can

account for many of the proposed mechanisms that contribute to the demonstrated success of RPCA for labor pain. For example, physical control over the demand button on an infusion pump provides both physical and psychological comfort through direct physiologic pain receptor activity as well as reinforcing a sense of agency in the operator, in this case, the parturient. Additionally, social and environmental control can be exercised by a woman using RPCA, because of the short duration of action intermittent discontinuation of the infusion allows for ambulation, hydrotherapy, or positioning of any type according to her evolving needs.

Significance to Nursing Research, Education, Practice, and Policy

This investigation seeks to expand the knowledge base around implementation of an RPCA protocol in a practical clinical environment. Reports on this subject have largely come from outside the US and have been conducted under experimental conditions. The outcomes of this study will help to define how the unique healthcare environment that exists in the US influence the ability and willingness of nurses, midwives, and anesthesia providers to adopt a new method of pain relief during a birthing experience. A pragmatic approach will serve to identify both knowledge gaps and barriers to a more widespread usage of the RPCA technique. Current options for labor pain management vary in effectiveness and often provide undesired limitations to the parturient, for example, limited mobility after epidural placement, prolonged drowsiness, or ineffective relief after intramuscular or intravenous narcotic administration. Expanded access to RPCA represents an advantage to women in labor and a means for those involved in caring for parturients to support individual choice, self-efficacy, and relief from suffering.

CHAPTER II

Literature Review

The primary argument for utilization of remifentanil is the continued empirical support of its superiority to other opioid medications on key variables. In one relatively small study, Ng et al. (2011) found remifentanil provided significantly better pain reduction, duration of pain control, and maternal satisfaction without associated side effects. Ohashi et al. (2016) amplified these findings in their systematic review and concluded "remifentanil appears to have a significant role in pain relief during labor" (p.1026). None of the studies reviewed, including a recent meta-analysis, found equivocation about the efficacy of remifentanil when compared to other opioid medications studied, remifentanil was always superior (Weibel, et al., 2017).

Patient-controlled analgesia as a technique was identified as a possible independent contributor to increased satisfaction among the participants it may reinforce self-efficacy as a factor in satisfaction (Ng, et al., 2011). In their investigation, Ng and colleagues (2011) utilized doses of 25 or 30 mcg of remifentanil available roughly every four minutes for self-administration compared to a placebo PCA coupled with meperidine IM injection and found RPCA not only reduced relative pain scores by 44% at 2 hours but also had significantly better overall satisfaction (8 versus 6 on a measurement scale). When matched against other medications using PCA delivery, remifentanil showed better pain relief (Blair et. al., 2005; Douma, et al., 2010) with remifentanil performing nearly as well as EA on both pain and satisfaction measures, particularly early in labor (Douma, et al., 2010; Frauenfelder et. al., 2015; Tveit et al., 2012). In contrast, other researchers who have compared remifentanil to EA on pain relief measures found it often falls short

of matching the epidural group (Anim-Somuah, et al., 2011; Douma, et al., 2015; Freeman et al., 2012; Logtenberg, et al., 2016; Storac, et al., 2015).

According to Weibel et al. (2017), the evidence surrounding remifentanil PCA as it pertains to parturients is hampered by a dearth of high-quality studies. This lack of large multi-center investigations is probably the greatest weakness in the evidence base supporting remifentanil PCA. Studies have shown the effectiveness of RPCA may be short-lived, resulting in diminishing pain relief through labor progression and requiring rescue intervention (Douma, et al., 2010). A recently published study has gone a long way to address this weakness. Wilson et al. (2018) reported on their multicenter randomized controlled trial comprised of over 400 women and found a nearly 50% reduction in requirement for analgesic rescue for parturients using RPCA as compared to intramuscular meperidine. This investigation also found RPCA users had significantly lower median pain scores and were significantly less likely to require assisted birthing techniques. Investigators have argued remifentanil PCA is a higher risk medication due to episodes of respiratory depression and sedation. However, there is little if any evidence of poor outcomes associated with these episodes (Logtenberg et al., 2018; Melber et al., 2018; Murray et al., 2019; Weibel et al., 2017; Wilson, 2018).

Concept Analysis

In order to develop a holistic pain management program, a critical step is to explore the determinants for and operationalization of labor pain. Generalizations about labor pain are challenging. In their concept analysis of labor and birth, Larkin, Begley, and Devane (2007) emphasized the uniqueness of the labor pain experience by asserting it can be viewed both positively and negatively. The anticipation or experience of labor

pain may be more or less worrisome for women depending on prenatal care or social support prior to entering into labor (Van der Gucht & Lewis, 2014). Some factors that contribute to a parturients unique experience reside in the beliefs, expectations, and past experiences she brings to the labor ward (Whitburn et al., 2018). Additional key determinants of a women's labor pain are in the foundational attributes of her character, for example, coping ability and level of self-efficacy (Richardson et al., 2018; Roberts et al., 2010). A further complication of defining labor pain is it is dynamic by nature. The variability of contractions, fluctuation of hormone levels (both endogenous and exogenous), and physical anatomical alteration of the birth canal are a few of the areas in a continuous state of change. The desire to ameliorate the negative aspects of childbirth has resulted in expanded exploration into alternative methods for addressing labor pain. Psychosocial strategies, novel pain control methods, and approaches that seek to return the locus of control to the laboring women are tactics widespread in recent publications.

Etymology

Labor. The word "labor" can be used as either a noun, verb, or adjective. The *Online Etymology Dictionary* (2019) reports the noun form of the word emerged in Old French around the 12th century. The French form of the word included the concepts of work, toil, exertion, and suffering. By the mid-15th century, the verb form of the word had evolved to include childbirth, probably from foreshortening of the phase "labor of child." The experience of giving birth is the focus of this analysis; however, the concepts included with other definitions of labor i.e., "work", "distress", and "effort" inform the exploration (*Merriam-Webster's Dictionary online,* 2019).

Pain. The understanding of the word "pain" as it relates to unpleasant sensations also evolved from Old French. According to the *Online Etymology Dictionary* (2019), the noun "peine" denoted suffering, woe, and punishment when it appeared as early as the 11th century. Pain can also be used as a verb, meaning to hurt or cause distress (*Merriam-Webster's Dictionary online,* 2019). The general sense of pain as a concept is negative; however, when used to describe the sensations of childbirth some nuance is introduced.

Labor Pain. NANDA International (2014) provides a definition for the term "labor pain" that hints at the complexity brought about by combining these two words. The authority on nursing diagnoses characterizes labor pain as the "sensory and emotional experience that varies from pleasant to unpleasant, associated with labor and childbirth" (p. 444).

A review of publications addressing the experience of response to, and consequences of labor pain reveals two distinct approaches. For the purposes of this discussion, one perspective will be identified as "medical" and the other as "naturalistic," but this is not meant to imply health care providers or professions are always aligned with one perspective or another. In fact, most (if not all) health care providers are astute enough to understand a concept as mutable and multifaceted as labor pain requires flexibility of approach and adaptability of mindset.

A typical medical journal pattern when introducing the problem of labor pain is, to begin with a definition of pain. The International Association for the Study of Pain (2019) provides a widely accepted and disseminated view of pain that appears with regularity. That definition is, "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (IASP,

2019). The medical methodology then applies this understanding to the treatment of the pain of childbirth wherein the assumption the absence of unpleasant symptoms is a universal goal and women are entitled to effective pain relief.

The most common technique for managing labor pain in high-income countries, e.g., the United States, is EA. The current prevalence of this technique in the United States is approximately 60% (Meng & Smiley, 2017; Silva & Halpern, 2010). Epidural analgesia is highly effective for pain control during labor; however, for some women, EA is not an option for personal, cultural, or physiological reasons (Markley & Rollins, 2017; Roberson, 2019). Other medical approaches to labor pain management tend to focus on pharmacological methods with varying degrees of success (Logtenberg et al., 2018). Evidence of the superiority of patient-controlled analgesia (PCA) over other modalities is growing. The success of PCA over traditional administration techniques may be partially attributable to the sense of control it can bring to patients (Lee et al., 2017). Consequently, the acceptance of PCA therapy as a medical management approach to labor pain is expanding, especially outside the United States (Devabhakthuni, 2013; Murray et al., 2019).

In contrast, an article based on a naturalistic viewpoint will generally align with the statement, labor pain is not easily defined, but can be understood as an individual experience (Roberts et al., 2010). Many authors who favor a naturalistic approach point out the positive aspects of labor pain including the pain-oxytocin feedback loop (Sprawson, 2017). The focus of naturalistic approaches often begins with helping women develop and execute coping strategies that help to alter the perception of pain from negative to positive. This perspective is based on the reality labor pain does not result

from a pathological source, but rather a natural and usually desirable event. Therefore, traditional acute pain management strategies are thought to be misplaced by researchers with a naturalistic perspective (Whitburn et al., 2018). Naturalistic techniques tend to concentrate on preparation through education, one-to-one support, and reinforcement of non-pharmacological coping.

In some instances, the approach might defy straightforward categorization into medical or naturalistic. Self-administered nitrous oxide (NO2) is an example of a technique, that has features of both paradigms; the mild analgesic and anxiolytic effects of NO2 are aligned with the medical approach, while the distraction, breathing focus, and self-efficacy aspects are naturalistic. Richardson et al. (2018), found some parturients even equated the use of NO2 with natural childbirth. The same logic may be applied to the use of a PCA provided the effects of the analgesic were short-acting, such as with remifentanil. Ideally, women using RPCA could decide when and if they needed to self-administer a rapid-onset opioid analgesic without fear of long-lasting effects (Ohashi et al., 2016; Weibel et. al, 2017).

Defining Attributes of Labor Pain

Defining the key attributes of a concept is foundational to conducting a concept analysis. The defining attributes are the features of a concept that separate it from other similar concepts (Walker & Avant, 2019). The critical attributes of labor pain fall into two domains. These domains are the physical and sensory changes occurring immediately prior to childbirth and the psychological, cognitive, and emotional expectations related to pain and impending motherhood.

Physical and Sensory Changes During and Directly Preceding Childbirth

The primary physical changes defining the occurrence of labor pain are cervical dilation coupled with regular uterine contractions. Sensory changes are related to the stimulation and transmission of somatic and visceral pain signals to an intact central nervous system. The origin of these signals is the stretching of the anatomic structures of the birth canal, as well as the sensation of strong muscular contraction in a hormonally triggered effort to deliver uterine contents. Labor pain is temporally confined to the period of time directly preceding delivery of an infant or non-viable fetus and the placenta (Chestnut, 2004; The 3 Phases of Labor, n. d.).

Psychological, Cognitive, and Emotional Expectations Related to Pain and Impending Motherhood

The psychological expectations related to an impending childbirth and motherhood include coping ability, self-efficacy, perceived social support, religion, and cultural/family norms (Richardson et al., 2019; Whitburn et al., 2018). These psychological expectations influence the individual interpretation of the meaning of pain and hormonal signals triggered by imminent childbirth. Cognitive expectations related to impending motherhood are influenced by education (both pre-natal and general), financial situation, and past experiences. These cognitive elements can determine how a parturient evaluates her situation and processes her imminent role change (Roberts et al., 2010). Some examples of emotional changes brought on by labor include fear, hope, helplessness, joy, vulnerability, and confidence. Emotional responses to labor pain can serve to amplify or subdue positive or negative features associated with labor pain (Roberson, 2019).

Antecedents

Antecedents are the circumstances that must be present prior to the occurrence of the concept (Walker & Avant, 2019). The antecedents to labor pain are pregnancy, a functional nervous system, and expectations, either positive or negative, as influenced by the psychosocial individualities of the parturient.

Pregnancy.

The experience of labor pain can only take place in the context of biological pregnancy.

Functional Nervous System.

Labor pain requires the transmission of somatic and visceral pain signals to the central nervous system.

Expectations.

The term ‘expectations’ refers to the complex interplay of psychological traits, social supports, and environmental factors contributing to the cognitive and emotional processes taking place before and during imminent childbirth (Larkin et al., 2007). Expectations can be positive or negative. Emotions and attitudes can vacillate throughout the stages of labor and can even vary contraction to contraction. Expectations are also changeable depending on the course and duration of labor (Iizuka et al., 2018). Self-efficacy and coping abilities are strong modifiers of expectations. Education, experience, and preparation can strengthen a parturients capacity for self-efficacy and coping (Richardson et al., 2019; Roberts et al., 2019). Coping abilities can be bolstered or weakened depending on the traits of the laboring woman, the physical environment, and

by the quality of the support, she is offered during labor (McCauley et al., 2018; Van der Gucht et al., 2014).

Consequences

Consequences are the after-effects of the concept. Exploration of the possible outcomes of a concept can help inform the relationship of variables and point to areas of future research (Walker & Avant, 2019).

Positive labor pain experiences can facilitate a women's transition into motherhood. If labor pain was well managed or perceived to be well managed, traits such as self-efficacy, coping, and confidence can be strengthened. Fear, anxiety, and uncertainty can be supplanted by happiness and excitement, due to the sense of accomplishment that comes from surmounting labor pain (Whitburn et al., 2019). Mother-infant bonding can likewise be enhanced as a result of the personal transformation and pride often following a successful labor pain experience as defined by the woman living through it (Larkin et al., 2007). Family closeness and caregiver trust can also be enhanced by helpful and constructive social interactions during the process of labor pain.

Conversely, negative labor pain experiences can reinforce feelings of helplessness and loss of control. Poorly managed labor pain can also diminish a mother's self-perceived ability to adopt a new role (Van der Gucht et al., 2015). The unfortunate legacy of a negative labor pain episode is it can be internalized as a failure. This harmful perception can perpetuate a pessimistic outlook during future pregnancies causing an undesirable feedback loop. There is also concern that distressing labor pain events can predispose women to post-traumatic stress syndrome and depression (Lennon, 2018).

Constructed Cases

Model Case.

This is a model case because it contains all the defining attributes of labor pain. The patient has all the physical and emotional aspects of the concept. Also, she demonstrates certain traits, beliefs, and attitudes that contribute to her overall experience. Sofia wakes up from a fitful sleep to the sensation of tightening in her abdomen. She picks up her Timex from the nightstand and begins to watch the secondhand tick away as she waits for the next contraction. Satisfied she is having contractions lasting for more than 30 seconds every 5 minutes, Sofia pushes gently on her partner's shoulder. "It's time," she whispers to her husband Jim. Jim is soon wide-awake, loading the pre-packed overnight bag into the Subaru. Jim is sure he has everything prepared just as they suggested at the prenatal classes, he and Sofia attended at the hospital last month. During the car ride, Sofia feels a constant ache in her lower back, but she is able to adjust her position enough, so it is manageable. Sofia remembers her older sister had back pain when laboring too. Sofia thinks to herself, "If she can do it, so can I." After they arrive at the hospital, Jim and Sofia meet their labor and delivery nurse, Amanda. Amanda reassures Sofia pain relief measures are available if she wants them. Amanda is warm and kind, offering advice when asked, but otherwise allowing Sofia to manage her own experience. When the midwife reports cervical dilation is progressing well, Sofia can't help but to feel a rush of excitement at the prospect of meeting her daughter face to face. After a couple of hours, Jim informs Sofia the waiting room is filling up with friends and family members. Sofia has begun to focus inwardly during contractions so she can cope with the increasing discomfort and frequency of her contractions. She asks Amanda if she

"can have something to take the edge off." Amanda offers nitrous oxide, which the hospital has recently added to the ward. Sofia accepts the offer thinking back to her prenatal appointment when the midwife had mentioned the new pain management program included this approach. Sofia finds the use of the mask helps her to control her breathing and seems to reduce the intensity of her contractions. Soon it is time to push. After a few minutes, Sofia welcomes her new baby into her arms; Jim and Amanda smile to each other across the bed.

Borderline Case.

This is a borderline case because it has most of the features of a model case but is missing the important feature of imminent delivery.

Sofia and Jim are driving to a birthday party for Sofia's nephew when she feels a strong sensation of squeezing in her abdomen. She has also been experiencing cramping all morning. At 37 weeks pregnant, Sofia is beginning to happily anticipate the arrival of her first child. When she feels the tightening starting again, Sofia tells Jim to call the obstetrical nurse. The nurse asks them to head into the office for an exam. Upon arrival, Sofia is hooked up to monitors to check the baby's heart rate and the strength of her abdominal tightening. Sofia's midwife, Janet, performs a cervical check. "Still closed," Janet reports. "These are Braxton-Hicks contractions, they might be a little more intense because you need to drink a little more water," Janet explains. A little while later Sofia and Jim leave the office and head to the party just in time for some cake.

Related Case.

This is a related case because it is closely related to the concept but does not show all the attributes. Pregnancy, pain, and emotional hardships are evident in this scenario; however, coping skills, physiologic labor, and social support are lacking.

Jessica has been feeling cramping abdominal pain all day. She tells herself it is probably just indigestion from her big morning breakfast. Since she is only 30 weeks pregnant, Jessica doubts her pain could be the baby coming. When her pain is still lingering after dinner, however, she decides to drive herself to the local urgent care. When she gets there, she calls her boyfriend, but he can't get off work to come by the office. Jessica is sent for some tests and waits by herself in the radiology hallway. After her physician assistant looks at the result, she is informed she has cholecystitis and needs to be admitted to the hospital, Jessica can feel the tears welling up in her eyes. "I can't take any more bad news," she thinks to herself as the nurse starts an IV in her arm.

Contrary Case.

This is a contrary case because it contains none of the attributes that serve to define labor pain.

Andy bounded down the jetway after arriving in Spain. It was a beautiful sunny day, and he was feeling great after sleeping for almost 4 hours on the plane. After checking into his hotel room, Andy went upstairs, opened a bottle from the mini-bar, and took a long hot shower. Feeling warm, relaxed, and slightly buzzed, Andy dressed up for a night at the local club. Another drink at the hotel bar had Andy feeling even more disinhibited. When he hit the door of the club, Andy thought to himself, "I am never settling down! Why would I ever give this up?"

Empirical Referents

The most common and practical approach to measuring labor pain is the Numerical Rating Scale (NRS). The NRS is based on self-report of pain intensity on a scale of 0 (no pain) to 10 (the worst pain imaginable). Some researchers prefer the Visual Analog Scale (VAS). The VAS is measured by a patient's mark along a continuous 10-centimeter line representing the level of pain in relation to the extreme end points of the line (Iizuka et al., 2017). Other measurements such as physiological markers of stress and questionnaires have been used by researchers in this field, but the nature of labor pain makes most of these techniques impractical or intrusive. One shortcoming in using the NRS is many women report maximum pain before the end of labor resulting in loss of ability to discriminate a '10' at one point in time from a '10' at another point in time (Jones et al., 2015). Despite this potential drawback, the NRS is a pragmatic and practicable manner to collect pain data (Hjermstad et al., 2011).

Operational Definition

Labor pain is a complex sensory and emotional experience occurring with cervical dilation and uterine contractions at the end of pregnancy; it continues until delivery, is influenced by, and subsequently influences, personal expectations including psychological traits, social supports, and cognitive processes.

Anticipated Uses

The approach to labor pain research has traditionally followed one of two predetermined paths. Creating an operational definition incorporating attributes borrowed from both the medical and the naturalistic approaches to provide the opportunity for research projects that combine the best elements of each viewpoint. A blended

methodology represents the likeliest opportunity to positively influence this complicated phenomenon.

Summary

Regardless of initial perspective, there are many examples of researchers acknowledging the interplay of medical and naturalistic approaches. Certainly, either approach could embrace the beneficial effects positive social support from a family member and/or care team member provide (Lennon, 2018). Hopefully, applying the operational definition suggested in this paper may contribute a similar benefit. It is likely the appropriate strategy for addressing labor pain is best determined on a case-by-case basis and will involve both domains to varying degrees at different points during labor progression.

Remifentanil

Remifentanil is an ultra-short acting pharmaceutical agent widely used in anesthesia for surgery and for the sedation of ventilated patients. It is a mu opioid receptor agonist with a rapid onset and offset that results in profound analgesia for a brief period of time. The context-sensitive half-life of remifentanil is only three minutes, a desirable characteristic in labor and delivery due to the overarching concern of respiratory depression in infants resulting from placental transfer. Metabolism of this drug occurs outside of renal or hepatic pathways via plasma and tissue esterases (Markley & Rollins, 2017). These qualities make it suitable for PCA administration in the setting of intermittent intense pain, i.e., the pain of contraction during labor (Devabhakthuni, 2013).

Multiple randomized controlled trials have shown remifentanil consistently reduces pain scores or visual analog scales of reported pain by 3 units of measure on a 0

to 10 scale when compared to other opioids (Ohashi et. al., 2017). Applying these results to the population of interest at this clinical site, it appears RPCA has a strong potential to outperform the current practice of intermittent IV medication regardless of technique. The Cochrane review comparing remifentanil to other parenteral methods also demonstrated a standard mean satisfaction score 2.11 times higher than the alternative opioid technique (Weibel et al., 2017). Weibel and colleagues (2017) also examined other variables of interest such as adverse side effects (i.e., pruritis) and serious complications (i.e. non-reassuring fetal status) and found no evidence of increased risk or some benefit to using RPCA as compared to IV or IM opioids.

The use of remifentanil has proliferated throughout many countries in Europe where it is overtaking meperidine as the drug of choice for labor PCA. In the United Kingdom, remifentanil is the most commonly used agent and PCA use is widespread with nearly 50% of labor wards offering this strategy for pain management (Ohashi et. al., 2017). Utilization in the United States is much lower. A recent survey by Aaronson and colleagues (2017) found only 31% of academic medical centers in the United States offer RPCA to laboring women. Those hospitals using remifentanil did so infrequently, with no site using it more than 20 times in the previous year (Aaronson et. al., 2017).

Conclusions

Early identification of preferences or attitudes about labor pain management among pregnant women is a valuable strategy in fostering the best possible labor pain experience. Guiding parturients to desired birth environments and providing targeted education and interventions aligned with their individual childbirth plan is a worthwhile enterprise, that may offer the best chance at a positive birthing experience (Haken et al.,

2018). The power of a positive labor encounter can resonate for future experiences and even transfer across families and generations. Remifentanil PCA offers a unique approach to labor pain management blending many of the desirable elements of a holistic comfort-based approach.

CHAPTER III

Methods

The purpose of this project is to report on the efficacy of an RPCA program in an unaltered clinical environment. In this chapter, a description of the design, sample, data collection, and analytic techniques is presented. The protection of human subjects and study limitations are also addressed.

Specific Aims

Aim I. To identify differences in labor pain scores by intervention (RPCA compared to the current clinical opioid technique and between all three groups).

Aim II. Examine the relationships among RPCA use, desaturation events, side effects requiring intervention, occurrence of a critical event, delivery type, and APGAR score among a cohort of laboring mothers.

Aim III. Gain a deeper understanding of early adoptors' reasons for implementing PCA through the conduct of structured interviews with selected staff members at the clinical site.

Design

Cross-sectional comparative correlational design using secondary analysis of existing data examining usual care versus remifentanil PCA pain control technique for labor. Initial data will be extracted from electronic health records (EHR) of all live births at one medium-sized health system hospital located in Southern California over a 3-month period. This initial data will represent the baseline for comparison to data gathered after implementation of an RPCA protocol. RPCA recipient health records will be reviewed for relevant data over a 12 month period or until at least 20 records are

available. After quantitative data analysis is complete, semi-structured interviews with a convenience sample of providers involved in the care of RPCA recipients will be conducted.

Sample and Sampling

All live births from the labor and delivery ward at a medium-sized community hospital over a three-month period will be reviewed for inclusion in small feasibility project.

Inclusion criteria: Parturient is denied EA due to a medical condition, refusal of epidural (i.e., opioid plan), or has natural plan (non-medicated).

Exclusion criteria: Parturients delivering by caesarian section.

After the initial data is collected all women receiving the RPCA protocol during the secondary data collection period will be enrolled according to the following criteria:

Inclusion criteria: Parturient uses the RPCA protocol.

Exclusion criteria: Parturients receiving EA, usual opioid care or delivering by planned caesarian section.

Human Subject Considerations

The population of interest for this research area is a vulnerable group. Therefore, it is vital to conduct all aspects of this investigation with the utmost regard for patient rights. Institutional review board approval will be sought from both the Kaiser Permanente Department of Research and Evaluation and the University of San Diego. Informed consent is not required for the parturient portion of this data only, retrospective study. Informed consent will be obtained from the healthcare providers interviewed for inclusion in the qualitative portion of this study.

Educational Interventions

Staff teaching and stakeholder presentations were conducted in February and March 2018. Follow-up presentations were conducted for nursing staff in the form of voice-over PowerPoint presentations available on facility computer stations from February 2020 ongoing. A reinforcement presentation was conducted via video conference for OBPs, May of 2020. Additionally, an informal distribution of the voiceover PowerPoint occurred using a dedicated Facebook page used by the labor and delivery nursing staff in October 2020. Institutional Review Board (IRB) approval was obtained from Kaiser Permanente Southern California and the University of San Diego (USD) before Phase One data collection began. Phase One data collection began in October 2018 and continued for a period of 3 months. Records review during Phase One indicated no episodes of any of the adverse events of interest among the target population.

Phase Two will commence upon achieving candidacy and continue through February 2021. A dosing order set utilizing a 20-50 mcg remifentanil bolus only technique coupled with a 2-minute lockout period and allowing for incremental increases to a maximum of 50 mcg is available to the obstetrical staff. During Phase Two, data will be collected from the first 20 patients enrolled in the RPCA protocol and then compared to baseline figures on the variables of interest. Data will be collected from the EHR database to establish any effect on the following variables in labor and delivery patients enrolled in the RPCA protocol compared to those in the Phase One opioid group.

Quantitative Design

After implementation of the RPCA protocol, pain scores will be extracted from the EHR for each RPCA recipient and averaged for the entire course of administration. Average pain scores will then be compared by groups. Beyond mean pain score, variables identified for examination are rates of desaturation events, side effects requiring intervention, occurrence of a critical event, delivery type, and 5-minute APGAR. Baseline values for these complications will be identified after the implementation of the RPCA protocol. Three critical adverse events, unplanned admission of the neonate, unplanned caesarian section, and apnea requiring administration of naloxone in either the mother or the neonate, will be identified.

After 20 patients complete the remifentanil protocol, outcome measures will be analyzed to identify if expansion or discontinuation of this protocol is indicated. An increase in complication rate of > 5% will trigger a review of dosing guidelines. If 10% reduction in reported pain scores is achieved, the expansion of inclusion criteria for this RPCA program beyond parturients with contraindication to EA will be proposed to the medical staff. Probable expansion targets will be patients with a personal or cultural preference for an IV opioid pain management plan for labor.

Measurement:

The continuous variables of interest are:

- pain scores
- 5 minute APGAR scores
- dosage (initial and adjusted),

The dichotomous (yes/no) variables of interest are:

- oxygen desaturation events (SPO2 <93%),
- change of analgesic method
- complaint of nausea requiring intervention or vomiting
- complaint of pruritus requiring medication

Note: Pain scores will be calculated using data after the first report of pain during admission to the labor ward and continuing through delivery.

The following variables will be collected for descriptive purposes:

- Age
- Race/ethnicity
- Parity
- Occurrence of a critical event
    - unplanned admission of the neonate
    - unplanned caesarian section
    - apnea requiring administration of naloxone

Quantitative Analysis

Comparisons will be made based upon the pain management strategy. Participants will be placed in one of three groups: (1) those receiving no opioid medications, (2) those receiving IV push opioid medications, and (3) those receiving the RPCA protocol. The Kruskal-Wallace test will be used to compare between group differences for all three groups. The IV opioid group and the RPCA group will then be compared against each other and against the no opioid group using the Mann-Whitney rank test to determine between group differences in these three techniques. Chi-square calculations will be

performed on binomial (yes/no) data such as nausea/vomiting requiring intervention, pruritis requiring intervention.

Descriptive and inferential statistics for baseline group

Qualitative Design

Aim 3 will be addressed using a descriptive qualitative phenomenological approach to examine the attitudes toward and perceived barriers to implementation of an RPCA program. Phenomenology focuses on the lived experience of a person of a subject in time, space, body, and lived human relationships; the investigator will review the person's story and interpret meaning to the person's experience (Priest, 2002; Starks & Trinidad, 2007). The process will follow the phenomenological method utilized by the philosopher, Paul Colaizzi (1978); the lived experience can be used as a tool. Colaizzi argued operational definitions must be eliminated; true to Husserl, Colaizzi bracketed prior scientific knowledge. With this methodology, the investigator must ask questions he or she might ask of oneself; the reason for the research, and one's own personal biases. The analytical procedural steps of Coliazzi (1978) include:

(a) transcribe the whole participants' descriptions or *protocols* to understand their feeling;

(b) statements deemed significant are extracted to review each expression and description that pertains to the phenomena;

(c) meanings are formulated, deriving *meaning* versus *saying*;

(d) themes are clustered according to their meaning so as to group common themes;

(e) the themes are developed using comprehensive, in-depth descriptions;

(f) the extensive descriptions are then condensed into central structures; and these fundamental, central structures are reviewed with all participants to verify, add to, or correct the protocol.

In this specific group of health care providers, lived experiences addressing labor pain with further exploration of interest in and attitudes toward opioid pain management and remifentanil PCA will be explored. Findings may offer insight into successful implementation of RPCA as a new strategy for assisting women to cope with labor pain and allow for more self-determination of timing and amount of IV pain medication. Participants will be purposively selected from a group of providers identified as participating in the earliest cohort of RPCA recipients at the investigation site. Stratification will be employed to attain participation from a range of provider types to include at least two RNs, two Obstetricians, two CNMs, and two anesthesia providers.

Qualitative Data Collection

Data will be collected over a 1–2-month period beginning in January 2021 and continuing until data saturation is reached. The anticipated required participation is 8-10 semi-structured interviews. Interviews will be scheduled for 20 minutes 1-2 weeks after informed consent is obtained. Interviews will be recorded and transcribed verbatim and compared with notes and memos taken during data collection. Transcription and comparison are planned to take place within 48-72 hours to allow for an iterative process.

The following essential questions will be the starting point of the interview/conversation, but can evolve and transition based upon the constant comparison method as responses are grouped and coding categories are discovered:

Please tell me,

1. What are your beliefs around pharmacologic interventions for labor pain?
2. How do you think these beliefs influence your discussions with laboring women around pain management?
3. Do you think culture influences labor pain choices?
4. How did you learn about the remifentanil protocol for labor pain management?
5. Tell me what influenced your decision to use remifentanil or participate in the remifentanil protocol to treat labor pain?
6. What barriers do you see in using remifentanil for labor pain management?

Interviews will be conducted in person or by telephone by the primary researcher. All interviews will be audio recorded after appropriate consent is obtained.

Conclusions

Labor pain is a significant source of anxiety for most pregnant women. Parturients who are excluded from the most common and most effective technique to reduce this pain deserve access to the next best choice. Remifentanil PCA, due to its fast onset, short half-life and demonstrated effect at reducing pain and boosting satisfaction is a promising method. Adoption of this strategy represents an opportunity to help bring this technique into a mainstream health system. In time, this technique could improve the labor experience for women at this clinical site and help advance the best practice throughout the United States.

CHAPTER IV

Results

The purpose of this study was to examine the implementation of an RPCA protocol and identify the attitudes and beliefs of healthcare workers in a real-world clinical setting. The results presented in this chapter include both quantitative and qualitative data analysis. Results related to the specific aims are presented.

Aims

Aim I. To identify differences in labor pain scores by intervention (RPCA compared to the current clinical opioid technique and between all three groups).

Aim II. Examine the relationships among RPCA use, desaturation events, side effects requiring intervention, occurrence of a critical event, delivery type, and APGAR score among a cohort of laboring mothers.

Aim III. Gain a deeper understanding of early adoptors' reasons for implementing PCA through the conduct of qualitative interviews with selected staff members at the clinical site.

Sample Characteristics (Quantitative)

Data were extracted from the medical records of 156 laboring women who met the inclusion criteria. The investigation site was a labor and delivery ward consisting of 15 beds and 2 dedicated operating rooms, within a single medium-sized hospital in Southern California. Participants ranged in age from 18-41 (m = 29.47, sd = 4.923). Median parity on admission was 1 previous live birth (m = 1.24, sd = 1.208). The sample was diverse: Hispanic women made up the majority of the group (n = 82, 52. 6%), 49 (31.4%) White, 11 (7.1%) Asian American, 9 (5.8%) African American, 4 (2.6%)

multiethnic, and 1 (0.6%) Indigenous. Pain score data was missing from 12 records including 1 in the RPCA group. APGAR score data was missing from 12 records. For analysis the participants were divided into three groups: receiving no opioid pain medication (n = 94, 60.3%), receiving IV opioid pain medication (n = 48, 30.8%), and receiving RPCA (n = 14, 9%).

Table 1

Sample Characteristics

Group	No Opioids	IV Push Opioids	Remifentanil PCA	Total
Number	94	48	14	156
Percentage	60.3%	30.8%	9%	100%
Age (years)	29.9 ± 4.8	28.6 ± 5.2	29.5 ± 4.7	29.5 ± 4.9
Parity	1.3 ± 1.2	1.3 ± 1.2	0.4 ± 0.6	1.2 ± 1.2
Ethnicity				
Hispanic	46	29	7	82 (52.6%)
White	32	13	4	49 (31.4%)
Black	5	1	3	9 (5.8%)
Asian	9	2	0	11 (7.1%)
Other	2	3	0	5 (3.1%)

Mean raw pain scores are listed in Table 2. In nine instances patients received IV opioids prior to initiation of the RPCA protocol.

Table 2

Pain Scores

	Number (n)	Mean	SD
No Opioids	83	7.4	± 2
IV Push Opioids	48	6.1	± 1.9
Remifentanil PCA	13	5.8	± 2.5

The Kruskal-Wallace test was used to compared between group differences for all three groups ($H = 14.067$, $p < 0.001$, $df = 2$). See Table 3. The IV opioid group and the RPCA group were then compared against each other and against the no opioid group using the Mann-Whitney rank test to determine between group differences in these three techniques. The between group differences did not reach statistical significance ($Z = -0.053$, $p = 0.958$) when comparing IV opioids to RPCA, but each did reach statistical significance when compared independently against the no opioid group ($Z = -3.514$, $p < 0.001$; $Z = -2.064$, $p = 0.039$). See Table 4.

Table 3

Average Pain Scores

	Number (n)	Mean	SD	
Totals	144	6.8	± 2.1	
		Mean Rank	Kruskal-Wallis H	p value
No Opioids	83	83.7		
IV Push Opioids	48	57.3		
Remifentanil PCA	13	57.5		
			14.067	<0.001

Table 4

Comparative Pain Scores

			Mann-Whitney U	
Pairing				
	Number (n)	Mean Rank	Z Score	p value
No Opioids	83	74.8		
IV Push Opioids	48	50.7		
			-3.514	< 0.001
No Opioids	83	50.8		
Remifentanil PCA	13	33.7		
			-2.064	≤ 0.039
IV Push Opioids	48	31.1		
Remifentanil PCA	13	30.8		
			-0.053	≤ 0.958

Chi square analysis indicated pain management grouping was associated with increased likelihood of receiving treatment for nausea and vomiting e.g. ($\chi^2 = 21.178$, $p < 0.001$, $df = 2$), delivery type ($\chi^2 = 41.639$, $p < 0.001$, $df = 2$), and experiencing a desaturation event ($\chi^2 = 53.394$, $p < 0.001$, $df = 2$). There was no significant association with treatment for pruritis ($\chi^2 = 5.264$, $p = 0.072$, $df = 2$) or having a lower APGAR score ($\chi^2 = 1.329$, $p = 0.515$, $df = 2$). See Table 5. Caesarian section rates for the RPCA group as compared to the overall facility rates for the calendar year 2020 are shown in Table 6 (California Department of Public Health, 2020).

Table 5

Complications

	Nausea Treatment				
Group					
	No	Yes	Chi-Square	df	p value
No Opioids	94	0			
IV Push Opioids	41	7			
Remifentanil PCA	10	4			
			21.178	2	< 0.001
	Desaturation Event				
	No	Yes			
No Opioids	94	0			
IV Push Opioids	48	0			
Remifentanil PCA	9	5			
			53.394	2	< 0.001
	APGAR Score (5 min)				
	< 8	≥ 8			
No Opioids	2	85			
IV Push Opioids	0	44			
Remifentanil PCA	0	13			
			1.329	2	= 0.515
	Pruritis Treatment				
	No	Yes			
No Opioids	94	0			
IV Push Opioids	47	1			
Remifentanil PCA	13	1			
			5.264	2	= 0.072

Table 6

Caesarian Sections

	Number (n) / Live Births	Percentage
Baseline (CDPH, 2020)	1005 / 3247	31%
RPCA Group	4 / 14	29%

Qualitative

Qualitative methods via individual semi-structured interviews were used to gain an understanding of providers' attitudes toward labor pain management, influences on approach to labor pain management, and perceived or actual barriers to the implementation of the novel RPCA technique. Data were collected through individual semi-structured interviews, comprised of questions developed by the primary researcher based on a review of pain management literature for women in labor and clinical practice with the goal of understanding how providers' attitudes toward labor pain management influence their approach to labor pain management and their perceived or actual barriers to the implementation of the novel RPCA technique. An interview guide was comprised of open-ended questions developed by the primary researcher. The interview guide focused on six areas: (1) provider beliefs around pharmacologic interventions for labor pain; (2) how provider beliefs influence pain discussions; (3) cultural influences; (4) training adequacy on the RPCA protocol; (5) decision making when using the RPCA technique; and (6) barriers to using the RPCA technique in laboring patients.

The open-ended questions were designed to encourage participants to describe their experience with a labor pain management, RPCA technique implementation, as well as feedback about perceived and actual barriers to using RPCA. Interviews were conducted over the telephone and digitally recorded by the PI. Interview questions are provided in Figure 1.

Figure 1

Interview Questions

1.	What are your beliefs around pharmacologic interventions for labor pain?
2.	How do you think these beliefs influence your discussions with laboring women around pain management?
3.	Do you think culture influences labor pain choices?
4.	How did you learn about the remifentanil protocol for labor pain management?
5.	Tell me what influenced your decision to use remifentanil or participate in the remifentanil protocol to treat labor pain?
6.	What barriers do you see in using remifentanil for labor pain management?

Data Analysis

Each interview was transcribed verbatim and then independently analyzed to identify themes that emerged from the transcripts. First, digital recordings were transcribed verbatim and then compared to the digital recording to ensure accuracy. Identifying information (i.e. names of people or places) were removed while the recordings were checked for accuracy. The coding process began by highlighting exact words from the text that appeared to capture key thoughts or concepts during the line-by-line review. The researcher then established preliminary themes. The initial codes and

themes were reviewed, themes were aggregated into categories, and created a codebook. The preliminary codebook and transcribed interviews were reviewed, all themes were approved, and no additional consistency checks were made. Four broad themes were identified.

Sample: Eight health care providers were interviewed by telephone. The interviewees all work in the same obstetrical practice and were engaged in that practice for the duration of the study period. The clinical background of the participants included physician obstetricians (n=3), nurse midwives (n=1), nurse anesthetists (n=2), and labor and delivery registered nurses (n=2).

All respondents reported having undergone training on RPCA. Anesthesia and OB providers attended at least one instructional session, conducted in person or via live internet platform, that covered rationale supporting the effectiveness of RPCA, dosing guidelines, and order sets. In addition to this training, nursing staff members received additional training in the technical aspects of new equipment required for the RPCA protocol. All staff members had access, on-demand, to a recorded presentation that included essential aspects of RPCA implementation.

Emergent Themes

Across the provider groups, four themes emerged. The themes included respect for choice, shielding from family influence, barriers to the implementation of a new technique, and overall satisfaction with RPCA.

Respect for Choice

All the providers interviewed valued a parturients right to self-determine a course of pain management. Seven felt maximizing options was helpful to supporting a patient

centered approach. They believed a key principle in best supporting a birth experience is allowing access and information on all available pain management strategies:

> I'm a proponent of the patient getting the labor process that they desire and that can change along the way. So, they might come in thinking that they want to go medication free and then they change their mind and we honor that.

Expanded choice was viewed as an independent factor in patient satisfaction: "I think it was comforting to be able to have something because a lot of them I think were [previously] presented …that they had to be just an unmedicated birth."

Epidural was sometimes cited as the most definitive approach to labor pain management. However, in discussion, four voiced they deliberately avoided specifically stating a preference. Providers emphasized they attempted to limit the amount of influence they exerted on laboring patients. When engaging with women about pain control, comments indicated support for choice was more important than pain scores: "I think that patients tend to have a little bit better pain control with an epidural, but in terms of what the patient chooses. I just let them choose whatever they like."

Other providers described a more involved process when initiating pain management discussions with parturients while still respecting the ultimate decision is in the hands of the patient. When patient attitudes are attributable to secondhand experience, some clinicians attempt to gather more information:

> I do try to ask [about a negative experience] because I feel like, obviously, I'm not trying to push anything on anybody, but I feel like the more I understand what

> kind of experience they are drawing from… [then I can explain] maybe that's not going to be your experience [this time].

Three clinicians described tailoring pain discussions to specific clinical situations. One example highlighted the influence of fetal status to the options available. Fetal heart tracing (FHT) was mentioned as an important factor when offering IV pain medication: "I don't have any restrictions on pain management unless, of course, it's a questionable strip and so then I may not use narcotics if I am having trouble interpreting the fetal tracing." Also mentioned was stage of labor, specifically the case of imminent delivery: "Sometimes it will be precipitous delivery where they deliver really quick… and they have to attempt [an alternate pain management method]."

Shielding from Family Influence

The influence of culture and family members over pain management decisions during labor, specifically resistance to epidural analgesia, was noted by multiple respondents. The effects of each were reported to be amplified for younger or nulliparous women: "Usually, younger patients will listen to their mothers, aunts… to tell them what they can and can't have." Hispanic, Middle Eastern, East Indian, and African American populations were mentioned as potentially hesitant to epidural use. However, culture within family groups was felt to be more impactful. Female family members were often identified as the primary influencers: "They [the patients] will say, you know, my mother doesn't want me to get it [the epidural] that's usually the one I hear."

The historical context of COVID-19 was identified as a potential counterbalance to family influence. Some providers felt the hospitals restriction on visitors during

pandemic surges had a beneficial effect of increasing the autonomy of women when making decisions about pain management:

> I've grown up in the Hispanic culture and lots of times I've gone, especially pre-COVID, not so much during this pandemic…there would be lots of family members in the room…maybe mother-in-law, grandmother, mother and if they were Hispanic, they would say 'I don't know why you need this [epidural]' or [share] horror stories from other cousins.

When visitation was limited to one support person most reported an increased ability to have detailed conversations with parturients:

> So, it's been especially interesting [during the pandemic] because it's been a more direct conversation and I don't have to kind of you know tip toe around the issue, as much as thinking back to before COVID when, you know, everybody was in the room and I kind of have to be careful.

Barriers to Implementation of a New Technique

Implementing a new practice was identified by clinicians as rife with challenges. Administrative process, time to train, investment in new equipment, fear of complications, and lack of support were all mentioned during interviews. One nurse leader with administrative responsibilities lamented: "We don't have any regular education time or any regular staff meeting time. We have nothing where we can get the masses together, so our roll out was kind of hit and miss."

Lack of opportunity for additional training time or repeated exposure to RPCA instruction was also mentioned by obstetricians: “I think it would have been helpful to get kind of like a refresher because obviously I don’t remember the full presentation now… that was probably a year ago.”

Reliance on past practice is the default position when uncertainty of therapeutic and unintended effects outweighs perceived benefits to the patient. If any delay in treatment is likely: “Typically we’ll just go with what we’ve used in the past [IVP opioids].” Obstetrical physicians reported some frustration that anesthesia department staff were not more involved.

Two felt anesthesia should be primarily in charge of RPCA administration: “the only, kind of, limitation to it is that the [anesthesia] team didn’t want to order it or manage it themselves, that we had to manage it.”

Unfamiliarity with the medication was identified as a reason behind a hesitancy to use RPCA and a justification for additional anesthesia staff involvement: “The response we get [from anesthesia] is ‘we don’t do this, this is not ours’…If there’s any problems or complications you know that’s implied that that is on you.”

Obstetricians and CNMs reported lack of familiarity and distance from training time was a factor in delayed administration of RPCA: “I know the first time I ordered it, I had to look it up because it had been a while [since the training session] that was really the only struggle.”

Infrequency of use among nurses can also lead to delays in patient relief. When discussing challenges one provider highlighted the strain on nursing staff specifically:

> What I've seen so far is just the infrequency of its [RPCA] use. For me it's easy, I just have to order it, but for the nursing staff because it's not so frequently used… I don't think it is started as quickly as we would expect, like an epidural would be.

Time from order placement to medication availability was reported by nurses as a significant barrier to timely administration of RPCA. Pharmacy support was seen as critical to be able to provide effective pain relief in a rapidly progressing labor:

> Once we order it we have to wait for pharmacy to make it. So, it's a delay in getting the medication to the floor. It's not like something we can pull right out of the Pyxis [medication distribution device], if they made one or two we could just yank it out of the Pyxis and it would be quicker to get to the patient.

Overall Satisfaction with RPCA

The desire to ameliorate suffering in parturients determined to be ineligible for CLE was strongly endorsed by all respondents. A desire for emerging therapies targeted to this population was evident: "In this day and age there is no reason for moms to suffer during labor." This opinion was often shared in combination with regret the RPCA was indefinitely suspended due to loss of a maintenance contract with the manufacturer of the RPCA specific pump delivery system. With regard to RPCA as a staff and patient satisfier, all practitioners reported a valuable role for the technique moving forward: "I never heard any complaints. I only heard good stuff.

When an epidural was not available due to a patient comorbidity the majority (n = 5) of respondents identified RPCA as the next best option: “My first choice would be an epidural if not [possible], then I actually really liked remifentanil PCA, it [would] be my second choice.”

Some felt a streamlined implementation process including more frequent use would elevate RPCA in the hierarchy of pain management strategies: “I think that the only real struggle was…we don’t order it enough for them [nursing staff] to be comfortable, but once we got it up and running they were fine.”

Five also endorsed the idea a patient’s fear of epidural placement was a sufficient reason to employ RPCA” “I think that if they were maybe frightened of an epidural I would definitely recommend it, I think it would be beneficial for them.”

Avoidance of complications related to epidural placement was seen as a reasonable justification to utilizing RPCA:

> I think it should be offered as an alternative [when patients are hesitant] because there is always a possibility [of complications], you can always get a wet-tap [inadvertent dural puncture], get a nerve injury, and that’s what they [the patients] are thinking. So, if you give someone an option… that can give you a lot of relief without those other side effects, at least it gives them an alternative.

All were able to identify at least two reasons RPCA should be considered. No providers noted any perceived increase in complications when using RPCA. The most commonly recalled reason for using RPCA was thrombocytopenia. Other comorbid conditions described included retained surgical hardware in the back and history of brain aneurysm.

Provider satisfaction for instances of comorbid conditions precluding epidural: “I thought it was really helpful… for the specific situation of low platelets. That’s going to be a really good use for this protocol.”

Summation of early adopter impressions

Overall staff satisfaction with RPCA was high. All providers supported the renewal of the program: “I was pretty darn passionate about it... and I really wanted this for our patients. I know we had plenty of patients who weren’t physically able to get an epidural… and I really wanted that option for them.” Additionally, no respondents reported concerns regarding undesirable side effects of RPCA. One nurse who was personally involved in multiple RPCA administrations even mentioned a decrease in unwanted effects as compared to other IV opioids: “I don’t think I saw many side effects like morphine or Dilaudid. I don’t think they were as sedated, and I think patients would like to try it in place of an epidural.” When asked about support for continued RPCA availability as an option, practitioners were unanimous in the affirmative: “I think we just need to get it back on our unit.”

CHAPTER V

Discussion

The purpose of this study was to examine the implementation of an RPCA protocol and identify the attitudes and beliefs of healthcare workers in a real-world clinical setting. The study was informed by comfort theory and the conceptual framework is derived from the literature and comprised of the variables of relief from physical discomfort using pain medication, support of psychological comfort by allowing personal control over pain relief strategy, and social comfort derived from the ability to choose how to interact with the environment. In this chapter, a discussion of the findings and implications for nursing practice, education, research, and policy are presented.

Quantitative Findings

Overall pain and side effect data in this naturalistic implementation study failed to support much of the benefit to RPCA reported in previous experimental studies (Ohashi et al., 2016; Weibel et. al, 2017). The cause of this discrepancy may be due to any one of many deficiencies in the planning, data collection, or implementation challenges of this investigation. Pragmatic approaches outside of the artificial constraints of experimental research design necessarily introduce the possibility of obfuscation of previously identified effects. However, without early attempts at integrating new evidence into actual practice the identification of pitfalls and blind spots would be difficult or impossible. This data reveals some important caveats and provides guidance for future attempts at integrating RPCA as a novel approach to labor pain management.

Improved pain control did not reach statistical significance when comparing RPCA to IV opioids. This lack of effect is most likely due to the small sample of RPCA

recipients (n=13) included in analysis and introduction of alternate opioids prior to initiating the RPCA technique. The raw mean scores indicate the possibility of a true effect given a more highly powered study with an increased sample size (Table 2). Administration of IV opioids prior to initiating the RPCA protocol was evident in nine cases. This co-administration of additional pain medication was an unanticipated confounder of the RPCA pain scores. Receiving an alternate opioid before RPCA could have negatively impacted the pain relief experienced by parturients due to the hyperalgesia effect. This is particularly true when administering a agonist/antagonist medication such as butorphanol, as happened in eight cases. This practice should be discouraged in future attempts to introduce RPCA to the labor ward.

Statistical significance was achieved when separately comparing pain scores between the IV opioid group and the RPCA group to the no intervention group ($Z = -3.514$, $p < 0.001$; $Z = -2.064$, $p = 0.039$). When the three groups were analyzed together statistical significance persisted ($H = 14.067$, $p < 0.001$, $df = 2$), but it is unclear if this justifies the additional cost, effort, and complication profile associated with RPCA. This also introduces the possibility that the current practice is sufficient to positively impact a patient's labor pain experience when EA is either unavailable or not desired. An alternate possibility is the pain medications (typically butorphanol, nalbuphine, or fentanyl) used at this clinical site are more effective than the drug regimen studied in previously conducted research where the comparison was primarily against meperidine. The authors of this investigation consider the most likely cause of this finding is the method of pain score collection and calculation. Longer acting medications such as butorphanol (4-hour duration of action) or nalbuphine (6-hour duration of action) had a greater impact on

mean pain scores due to the fact they are typically given in early labor to avoid fetal respiratory depression. This tendency results in a larger number of lower pain scores collected during the effective time of the drug. Similarly, fentanyl is sometimes administered more than once during the first stage of labor effecting a larger number of raw data points. An opposite though potentially impactful effect could result from the tendency staff members to limit the documentation of pain scores during unmedicated (natural) labor with a higher number of data points collected when pain is more intense, for instance when delivery is imminent. It is also worth noting many (n=4) dosing regimens began at subtherapeutic doses and fell outside of the recommended dosing range. This alone may have limited the impact RPCA could exert on pain scores.

Significant associations between pain management strategy and variables of interest were observed. Treatment for nausea, delivery type, and desaturation events were all significantly higher ($\chi^2 = 21.178$, $p < 0.001$, $df = 2$; $\chi^2 = 41.639$, $p < 0.001$, $df = 2$; $\chi^2 = 53.394$, $p < 0.001$, $df = 2$). The clinical significance of these associations remains unclear because there were no documented critical events linked to these variables. Antiemetics are included in the admission order set for all patients at this facility and are available on an “as needed basis” at the discretion of the nursing staff. Treatment with antiemetics was used as a proxy for nausea instead of direct report due to limitations in the EHR. This assumption introduces the possibility nursing staff might have presumptively given a higher proportion of RPCA recipients anti-nausea medication because of a perceived higher risk rather than actual complaint. The lack of any alteration in rates of caesarian section with RPCA is also difficult to assign meaning. We consider it a strong probability patient factors that qualified parturients for RPCA, such as thrombocytopenia or previous

spinal surgery, placed them at higher initial risk for operative delivery. However, no increase of surgical delivery from baseline facility rates in this sample (31% vs 29%) does not support this assumption. It is also possible the psychological impact of being denied or denying the possibility of CLE could influence either the parturient, the clinician, or both, to more frequently elect caesarian section as a means to attenuate real or perceived suffering, but once again this was not demonstrable. Future qualitative research should investigate provider and patient beliefs around this issue. It is noteworthy that none of the four surgical deliveries in this sample were reported as related to the RPCA technique specifically. The desaturation events that occurred in the RPCA group were similar to those noted in previous studies. All low oxygen saturation events were transitory in nature and did not result in any critical event. It is quite possible women in this RPCA group were at more risk of respiratory depression than in previous studies due to the previously mentioned complication of other opioids being given prior to RPCA initiation. Ultimately, the analysis was limited by low sample size and missing data. Clearly, future research in this area should look to increase both the volume of data and the quality of collection methods.

Qualitative

Four primary themes emerged from participant interviews.

1. Providers valued increasing options for parturients as a strategy for expanding autonomy in pain management decision making.
2. Many clinicians believe external influence from family can negatively impact the ability of parturients to exercise autonomy in pain management decisions.

3. Staff members identified multiple systemic barriers to implementing RPCA as a new practice for labor pain management.
4. Practitioners caring for women in labor see RPCA as a desirable addition to existing labor pain management strategies at this clinical site.

This study sought to evaluate the attitudes and beliefs of clinical staff members toward a novel pain management strategy. Overall, findings support a perceived role for RPCA in labor pain management. Clinicians reported a core belief in expanding pain relief options that can be matched to the physiological, emotional, and psychological needs of women experiencing labor pain. Despite many systemic and historical challenges to implementation of RPCA, provider attitudes reflect a persistent endorsement for optimization of patient choice during parturition. COVID 19 disruption proved a barrier to some aspects of implementation of RPCA, but also allowed for the unanticipated perceived benefit of improved communication opportunities between providers and patients in labor. Despite multiple obstacles, staff members ultimately found RPCA to be a desirable addition to their clinical environment.

Early adopters of the RPCA technique likely represent a pervasive attitude amongst healthcare workers in the US, patient self-determination is paramount to good patient care. This viewpoint might be even more sacrosanct in the environment of labor and delivery. Anti-paternalism has emerged over the past few decades as the medical model has necessarily evolved to a more patient-centric model (Wittmann-Price & Bhattacharya, 2008). Respect for self-determination has long been considered a core value of western culture, nonetheless, only relatively recently has this idea become an

ethical imperative within the health care paradigm. Practitioners and readers should therefore find comfort in the unanimous recognition of the importance of women's voices in deciding how to best manage labor pain. Beyond cultural and family influence, the expansion of options for a labor experience that is personalized, appropriate, and gratifying to the individual should be recognized as the ultimate patient satisfier.

This respect for self-determination is evident in the support for RPCA despite many obstacles. Family inclusion has long been respected as a method of enhanced patient care relationships. However, this study found family influence has a potential, unintended, deleterious effect on a woman's ability to receive educational information around pain management approaches that provide an optimal labor experience. It should also be considered that a healthcare providers perception of value is only a reflection of an individual's particular truth. Therefore, these findings need to be evaluated against future investigations designed to examine parturient attitudes toward family influences on labor pain management.

Systematic barriers remain an integral problem and an ongoing concern among respondents in this investigation. It is interesting to note despite the many obstacles faced by clinicians in this setting, support for the integration of a novel pain management strategy was high. Therefore, it follows that unified approaches to implementation are necessary to deliver a higher likelihood of consistent and acceptable integration of evidence-based techniques. Although the historical, and perhaps unprecedented, challenges of the COVID 19 pandemic did exert significant influence in the ability to adopt the RPCA protocol, many of the challenges, i.e., time management, provider educational opportunities, and systematic support remained familiar impediments to

adopting a new technique. A combined approach with pharmacy support, managerial dedication, and inter-disciplinary cooperation were identified as key to the potential success and ultimate failure of RPCA in this service environment. Future attempts at RPCA incorporation should aim to address these pervasive challenges in order to achieve future success. Attempts to launch new programs require collaboration, cooperation, and organizational investment if innovation is to prevail. As stated by respondents in this study, patients deserve an earnest effort in support of delivering the best care.

Limitations

Study findings must be considered in the context of limitations including outside effects that included a nationwide medication shortage, institutional changes resulting in loss of required equipment, and a global pandemic. The loss of potential subjects in the quantitative analysis during the study period are the most direct result of these occurrences. Unfortunately, the limited number participants in the RPCA group is, perhaps, the most glaring weakness in that aspect of this study. The study design relied on existing processes to provide the data. This approach led to incomplete charting, missing data, and loss of statistical power on some critical variables. Given these significant flaws, any conclusions to the meaning of the findings should be critically appraised.

Strengths

Despite these limitations the most prevailing strength of this investigation resides in the applicability to real practice environments. Collecting data and conducting research outside the structure of experimental study design introduces myriad problems, but conversely girds the findings against the familiar criticism of simulated circumstances

undermining clinical significance (Polit, 2017). Concurrent data collection in both quantitative and qualitative methods help to broaden the scope of these findings and to deepen the understanding of pitfalls that may await future efforts to undertake RPCA for laboring women. Interviewing clinicians from a variety of disciplines enhanced the depth of perspectives about RPCA. Interviews were iterative by design allowing interdisciplinary bridging through question evolution. This process allowed for issues that might typically be outside the sightlines of one clinical expert to be presented for examination and comment.

Recommendations

Guidance for any future attempts at initiating an RPCA protocol includes:

- Develop a streamlined process for timely delivery of prepackaged remifentanil pump solutions that can be accessed by nursing staff immediately upon receipt of a medication order.
- Conduct initial and refresher training for nursing staff that includes a hands-on component in use of medication pumps.
- Develop guidelines for minimum required charting while patients are using the RPCA protocol.
- Include specific guidance on data collection requirements in training sessions.
- Develop a team of champions in an effort to expand the pool of subject matter experts to serve as a resource during all shifts.
- Conduct initial and refresher training for anesthesia providers that includes dosing guidelines so they can reinforce evidence-based dosing regimens.

- Design education programs for providers that includes emphasis on these critical points (a) do not prescribe other opioids prior to ordering RPCA; (b) do not prescribe doses below the minimum recommended threshold; and (c) identify potential patients early in the pre-natal process.
- Expand the number of eligible recipients to include women who would otherwise choose a traditional opioid plan.

Conclusion

Despite the limitations of this investigation, value can still be extracted for future attempts at expanding the choice of pain management strategies for parturients. Given a large pool of data exists supporting the effectiveness of RPCA as a pain control method, the lack of statistical significance observed in this analysis should not dissuade other clinical sites from investing in RPCA programs. Rather, the lessons learned from this can be applied to bolster future success. RPCA was clearly supported by staff members at this clinical site which is an indicator effective education and implementation plans are likely to achieve institutional buy-in and support. The increase in undesirable side effects observed in this sample can likely be mitigated by improving educational offerings and conducting them more frequently. It is possible had this research not coincided with national and global crises, the aims might have been more fully achieved. Ultimately, this inquiry resulted in at least one undeniable finding, the professionals providing care to women experiencing labor pain respect choice and support the expansion of available options.

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APPENDIX

USD IRB

Joshua Carr
Hahn School of Nursing & Health Science

Re: Initial - IRB-2021-261 Remifentanil Patient Controlled Analgesia Use in Laboring Women: A Feasibility and Acceptability Study

Dear Dr. Joshua Carr:

University of San Diego Human Subjects Review Board has rendered the decision below for Remifentanil Patient Controlled Analgesia Use in Laboring Women: A Feasibility and Acceptability Study.

Decision: Rely on External IRB

Findings:

Research Notes:
Internal Notes:

The USD IRB requires annual renewal of all active studies reviewed and approved by the IRB. Please submit an application for renewal prior to the annual anniversary date of initial study approval.
If an application for renewal is not received, the study will be administratively closed.

Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.

The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited or exempt review at any time.

Sincerely,

Eileen K. Fry-Bowers, PhD, JD
Administrator, Institutional Review Board

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