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Does the Use of an ON-Q Pump Improve Postsurgical Outcomes in Patients with Secondary Chronic Shoulder Pain?: A Retrospective Study

Deborah Thompson-Spencer

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DOES THE USE OF AN ON-Q PUMP IMPROVE POSTSURGICAL OUTCOMES IN
PATIENTS WITH SECONDARY CHRONIC SHOULDER PAIN?
A RETROSPECTIVE STUDY

by

Deborah Thompson-Spencer

A Doctoral Project
Submitted to the Graduate School,
the College of Nursing and Health Professions
and the School of Leadership and Advanced Nursing Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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ABSTRACT

Orthopedic shoulder surgery is a common therapy for many medical conditions, but the healing process for orthopedic shoulder surgery can be adversely impacted by chronic shoulder pain. Frequently, chronic pain is not adequately controlled by opioid analgesics provided to patients during the surgical healing process, resulting in greater pain and diminished postsurgical mobility. The focus of this Doctor of Nursing Practice project was to examine the question of whether, among male and female adult patients (40-64 years of age) with a history of secondary chronic shoulder pain lasting three or more months who have undergone orthopedic shoulder surgery, the use of an ON-Q pain pump provided after surgery with hydrocodone as the standard treatment for pain relief, compared to standard pain relief alone, promoted improved patient post-surgical outcomes in terms of two- and eight-week postsurgical pain, two- and eight-week range of shoulder motion, and length of postoperative therapy.

This project used a quantitative methodology and retrospective data review design, to analyze data previously collected by the organization that served as the project site. De-identified data provided by the organization to the researcher, of participants who met specific criteria between January 2017 and October 2018 was reviewed to evaluate the benefit of utilizing an ON-Q pain pump in conjunction with standard treatment of hydrocodone for pain relief. The retrospective data analysis used paired-samples t-tests and mixed-effects tests to compare the intervention and control conditions regarding postsurgical pain and range of motion outcomes. The project findings failed to indicate that the use of the ON-Q pain pump offers significant benefits as an adjuvant pain relief

medication to recommend its consistent use in practice; especially when cost is considered.

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DEDICATION

This project is most definitely dedicated to my children and to Gregory, who are my drive to conquer the impossible. Gregory, thank you for being my biggest cheerleader, even amid sleepless nights and dinners with books and the computer set in front of me. Even during the largest challenges, you consistently were able to remind me that this too shall pass.

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LIST OF ABBREVIATIONS

A ABD	Active Abduction
AFF	Active Forward Flexion
CI	Confidence Interval
CINAHL	Cumulative Index of Nursing and Allied Health Literature
DNP	Doctor of Nursing Practice
EBSCO	Elton B Stephens Co
HIPAA	Health Insurance Portability and Accountability Act
IASP	International Association for the Study of Pain
MEDLINE	Medical Literature Analysis and Retrieval System Online
MUA	Manipulation Under Anesthesia
NIH	National Institutes of Health
OR	Odds Ratio
P ABD	Passive Abduction
PFF	Passive Forward Flexion
PICOT	Population, Intervention, Control, Outcome, Time
RCTR	Rotator Cuff Tear Repair
RTSA	Reverse Total Shoulder Arthroplasty

CHAPTER I – INTRODUCTION

Overview

Between the years 2014-2019, it was projected that more than 19 million Americans would undergo surgery to treat orthopedic shoulder pain, which encompasses musculoskeletal and joint pain caused by injuries or physical stressors (Narvy, Ahluwalia, & Vangsness, 2016). Most orthopedic shoulder surgery patients receive complete relief of their shoulder pain after recovering from their procedures, but up to 40% of patients continue to experience pain (National Institutes of Health [NIH], 2015). These ongoing symptoms occur in patients who have two comorbid conditions in the shoulder targeted for surgery—orthopedic pain and secondary chronic pain. Secondary chronic pain is pain that lasts three months or more prior to surgery and presents with locations, characteristics, and/or causes distinct from those of the orthopedic pain (Narvy et al., 2016). The differences between the two types of pain account for orthopedic surgery's inability to address chronic pain, despite effectively alleviating the acute pain that shoulder surgery is utilized to mitigate. Comorbid orthopedic and secondary chronic shoulder pain tends to adversely impact orthopedic shoulder surgery patients' health outcomes by increasing postoperative pain and decreasing functional mobility of the affected shoulder. Ongoing pain and movement limitations impede surgical recovery processes and can lead to long-term health issues, functional impairments, and poorer quality of life outcomes (Narvy et al., 2016).

Patients who have both orthopedic and secondary chronic shoulder pain may be more likely than patients with only orthopedic pain to require readmissions for shoulder issues, ongoing outpatient pain appointments, and to experience longer recovery times

that require additional, and more intensive therapy (Matsen, Tang, Russ, Hsu, & Matsen., 2017; Shin et al., 2015). A nurse delivering care to orthopedic shoulder surgery patients who have a secondary diagnosis of chronic shoulder pain can demonstrate core nursing values and promote high-quality care by using theory-driven, evidence-based strategies for managing surgical outcomes among patients, including outcomes related to safe and effective postsurgical pain management.

Background and Significance

American adults commonly experience chronic pain with orthopedic pain, especially when those forms of pain occur in the shoulder. Annually, chronic pain affects over 45 million (14.2%) American adults, and 76.5 million (24.6%) Americans experience severe pain for periods of one day to three months (Fanelli, Cherubino, & Compagnone, 2014). Orthopedic shoulder pain impacts up to 19 million (5.3%) Americans each year, while roughly 25 million Americans (7.8%) experience chronic shoulder pain with causes that are not musculoskeletal, and, therefore, not considered to be orthopedic in nature (Jain et al., 2014; Narvy et al., 2016). More than 7.5 million (3.1%) Americans have comorbid orthopedic pain and secondary chronic pain present in the same shoulder (Narvy et al., 2016).

Pain is a pairing of sensory perception and emotional experience that is unpleasant or aversive, which generally relates to a stimulus that damages, or could potentially damage bodily tissue (International Association for the Study of Pain [IASP], 2017). Orthopedic shoulder pain and chronic shoulder pain comprise separate diagnoses, due to significant distinctions between the two conditions. Orthopedic pain originates in striated muscle, bone, or joints, and tends to be caused by repetitive stress or traumatic

injury. Orthopedic shoulder pain may occur following fall injuries or repetitive arm motions (Evanoff et al., 2014). One of the most common causes involves tears of the rotator cuff, with a surgical incidence rate of 250,000 Americans per year. The second most common cause, as a group, are fractures of the proximal humerus, which have an overall incidence rate of 184,000 adults per year in the United States, although surgeries are performed in only 36,800 cases (Jain et al., 2014).

Chronic pain definitions vary, but many clinicians, researchers, clinical guidelines, and healthcare organizations define chronic pain as pain that lasts most of the day or all day and is experienced on a nearly consistent or consistent basis for at least three months (National Institutes of Health [NIH], 2010). Chronic shoulder pain may have a variety of causes, which may occur without physical injury, such as pain caused by inflammatory autoimmune diseases, or may even emerge from dysfunctional nervous system activities, without any apparent cause (NIH, 2010). In some cases, chronic shoulder pain may involve musculoskeletal pain that emerges as a complication from the initial orthopedic shoulder pain but involves distinct injury processes and presents in a different part of the shoulder. The differences that orthopedic shoulder pain and chronic shoulder pain have in their locations, causes, and pain characteristics prevent orthopedic shoulder surgeries from alleviating chronic shoulder pain.

The societal costs of pain are enormous, creating annual healthcare expenses estimated to range from \$560-\$635 billion in the United States alone (IASP, 2017). Pain also creates additional indirect costs through work missed due to pain or medical care, reduced productivity, early retirement, and premature death (IASP, 2017; Shin & Regenstein, 2016). Chronic pain and orthopedic pain are particularly problematic in

terms of creating indirect costs because they can limit functionality to the point that certain jobs and tasks become impossible to perform. Comorbid orthopedic and chronic shoulder pain is more likely than orthopedic shoulder pain alone to engender functional limitations, individual costs, and indirect societal costs by reducing the likelihood of success for orthopedic surgeries (Shin et al., 2015). Compared to orthopedic shoulder surgery patients who do not have a comorbid chronic shoulder pain diagnosis in the same shoulder, patients who have ipsilateral chronic shoulder pain comorbid with orthopedic shoulder pain show postsurgical recovery costs that are 50% higher and require up to four additional weeks of postoperative physical and occupational therapy (Fanelli et al., 2014).

This project was significant for several groups of stakeholders. First, and most importantly, the project held significance for orthopedic shoulder surgery patients diagnosed with comorbid orthopedic shoulder pain and chronic shoulder pain in the same shoulder by providing evidence useful in improving these patients' postoperative health outcomes and quality of life. These improvements would be realized by several project effects, including possible improvement of postoperative pain, increased range of motion for the affected shoulder; and participation in rehabilitative therapies. These outcomes could reduce the need for follow-up surgeries and additional opioid prescriptions to manage shoulder pain (Matsen et al., 2017; Srikumaran, Stein, Tan, Freehill, & Wilckens, 2013). For nurses, physicians, physician assistants, sports therapists, occupational/physical therapists, and home care providers who are specialized in the field of orthopedics or postsurgical rehabilitation, the project findings could be useful in developing new guidelines for treating, benchmarking, and monitoring the recovery of patients who have had orthopedic shoulder surgeries and also have a secondary diagnosis

of chronic pain not addressed by the surgery. Organizations such as the IASP and NIH may consider incorporating positive findings into their recommendations for orthopedic shoulder surgery recovery. Nurse researchers, orthopedic centers, medical equipment developers, pharmaceutical firms, and public health care providers may also consider using the findings as a starting point for developing more effective pain pumps. These considerations should be addressed in order to provide the most effective pain management for patients who experience both chronic and orthopedic shoulder pain.

Review of the Evidence

The current literature was reviewed to determine whether there was adequate information to recommend the use of further studies to examine the merits of pain pumps such as the ON-Q pump that this study focused on. The literature search provided a basis for this study through demonstration that sufficient evidence already exists to explore the use of the ON-Q pump as an adjuvant therapy, in addition, to traditional oral opioids following orthopedic shoulder surgery in patients with secondary chronic pain in the shoulder area. The literature review also highlighted that there were gaps in the current evidence that would make such a study valuable and capable of contributing to the current knowledge on this topic. These concepts formed the basis for the review of evidence that is discussed in the subsections found below.

In order to conduct the review of the evidence, a search of the available literature was undertaken. The methodology of the literature search was as follows. The primary researcher used multiple online databases that could return full-text, peer-reviewed results from scholarly articles in academic and professional journals. The databases that were examined in this literature search included Academic Search Complete by EBSCO,

Google Scholar, MEDLINE, CINAHL Plus, the Cochrane Database of Systemic Reviews, and the Cochrane Central Register of Controlled Trials. These databases were searched with a focus on articles published in the last five years, with a few exceptions that were made for seminal theoretical or research publications, such as the cornerstone work by Watson (1979) that was applied as part of the theoretical basis for this study. The search terms that were employed included “orthopedic shoulder surgery,” “shoulder surgery,” “pain pump,” “orthopedic surgery,” “ON-Q,” “ON-Q pump,” “adjuvant therapy,” “adjuvant pain therapy,” “postsurgical therapy,” “postoperative therapy,” “chronic pain,” “secondary chronic pain,” “musculoskeletal pain,” and combinations of these search terms. Out of the several hundred results that were obtained from the search, the full-text, peer-reviewed options were checked, and the search results were limited to those after 2012, except in a few select cases as mentioned above, which allowed for the researcher to obtain roughly 50 articles. These articles' abstracts were perused carefully to ensure they would be applicable to the study, and those articles that met the criteria were selected for inclusion in the review of the literature. The primary researcher read the full texts of these relevant articles. The Literature/Evidence Matrix (see Appendix A) includes basic information on these extant pieces of literature, including (a) author, year, and title; (b) level and grade; (c) experimental design; (d) sample size, constitution, and data collection methods; (e) research findings; (f) potential limitations; and (g) recommendations.

This literature search was divided into conceptual elements, including the epidemiological and economic need for improving upon the conventional method of solely using traditional oral opioid analgesics as a postoperative pain control remedy for

orthopedic shoulder surgery in patients with secondary chronic shoulder pain, followed by examining the utility and feasibility of peripheral nerve block medication such as Marcaine, along with a pain pump delivery system, with a particular focus on the usage of these medications and delivery systems in orthopedic shoulder surgery patients. Correspondingly, the information yielded from the review of the evidence is also arranged by topic.

Epidemiological Issues and Economic Impact

The basic information on the orthopedic shoulder surgery patients who also face secondary chronic shoulder pain was one prominent theme that emerged from the literature. This theme was important because it provided a basis for conducting this study and showed the extent to which improvements upon the current state of orthopedic postoperative treatment could potentially help large numbers of patients in the United States. Clarke, Nahin, Barnes, and Strussman (2016) conducted a nationwide survey of 34,525 American adults that involved a combination of questionnaires and reviews of health records, musculoskeletal pain was an extremely frequent phenomenon among the respondents. Just over half of all the people interviewed, 54.5%, had self-reported some type of chronic musculoskeletal pain (Clarke et al., 2016). In the research conducted by Clarke et al. (2016), it is important to note that not all reports of pain were specific to the shoulder, but shoulder pain was one of the most frequently reported sources of chronic pain in other studies.

Other research studies demonstrated that orthopedic shoulder surgeries are both a common and costly phenomenon in the United States. Narvy et al. (2016) had estimated that each orthopedic shoulder surgery had a cost of around \$5,904, but repeated surgeries

tended to become more expensive due to complications. One descriptive epidemiological study that had been conducted by Jain et al. (2014) reviewed records that totaled 34.7 million hospital visits by Americans during the year of 2006. In that annual period, Jain et al. (2014) estimated that there had been more than a half million orthopedic shoulder surgeries performed. Their analysis showed 272,148 rotator cuff surgeries and 257,541 shoulder arthroscopy surgeries not involving the rotator cuff, with 55-74-year-old patients comprising the largest group who required rotator cuff surgeries (Jain et al., 2014). The analytical data reported by Jain et al. (2014) is broadly consistent with the 1% shoulder pain diagnosis prevalence reported by Tekavec et al. (2012). Likewise, Narvy et al. (2016) found the mean age of patients requiring shoulder surgery to be 54.5 years of age. Several conditions, such as impingement syndrome, bursitis, periarthrititis, and instability, some of which can result from a failure to fully recover from past surgeries, tended to be the main reasons that rotator cuff surgeries were needed (Jain et al., 2014). Kim, Szabo, and Marder (2012) conducted an epidemiological study that involved a review of retrospective medical histories from 28 million emergency department records during the year of 2008. During that time frame, some 370,000 visits were due to humeral fractures, which can, but do not always, require some form of orthopedic intervention for treatment (Kim et al., 2012). The age groups who were at the greatest risk for these injuries included women between the ages of 40 and 80 years old ($R^2=97.9\%$) and men who were between 60 and 89 years of age ($R^2 = 98.2\%$) (Kim et al., 2012). As the current workforce ages, researchers have predicted that the number of humeral fractures could surpass 490,000 by the year 2030, with the highest incidence predicted in workers who perform intense physical labor (Kim et al., 2012).

In several studies involving body mass index (BMI) as a predictor of orthopedic shoulder pain issues, as well as those involving employees of fields that demanded intense or frequent physical labor, shoulder pain had emerged as the main basis of pain-related complaints among respondents. Vincent, Struk, Reed, and Wright (2016) found obesity to be linked to a higher rate of shoulder problems and poorer recovery from orthopedic surgery. In a cohort study that had been conducted by Evanoff et al. (2014), 9,145 retired male individuals, ages 63-72 years old, were assessed in terms of their BMI and their level of physical activity prior to retirement, including whether their jobs had involved more than 10 years of frequent arm elevation or squatting. Evanoff and colleagues (2014) found that those individuals who were obese were more likely to experience shoulder pain later in life, as were individuals who had either engaged in more than 10 years of frequent arm elevation or squatting. Similarly, a study by Kim, Dutra, and Okechukwa (2014a) assessed 1,772 construction apprentices regarding work site safety practices and the number of days absent from the job due to injury. The research determined that there was a significant odds ratio (OR 1.68) linking an absence of personal and coworker safety practices to the likelihood of suffering an injury-related absence from work. Many of the work absences documented in the study involved chronic pain issues and injuries requiring orthopedic surgical remedies (Kim et al., 2014a). These associations are not limited to construction workers and laborers as other research has noted similar problematic associations among other professionals.

The field of nursing was also found to show correspondences between higher levels of physical activity and orthopedic pain (Kim et al., 2014b). Kim et al. (2014b) performed a cross-sectional study that interviewed 1,572 nurses from two teaching

hospitals in the United States, and asked questions regarding staffing levels at the workplace and determined musculoskeletal pain via the Nordic questionnaire. The logistic regression model that the researchers used to analyze the data found that there were significant associations between reported low staffing levels (OR 1.5) and higher numbers of areas on the body that the participants reported experiencing chronic pain (OR 1.42). The positive association was still present when other factors were controlled for such as the number of hours that the participants worked per week, whether the participants had a second job, and their job roles. Shoulder pain remained significantly associated with understaffing even after the physical task demands of the nurses' jobs had been controlled within the logistic regression analysis (Kim et al., 2014b). These results, along with those of Kim et al. (2014a) and Evanoff et al. (2014) indicate that, as individuals in high-employment, high-growth fields like labor and nursing get older, they may have a greater need for therapies that involve orthopedic surgery and secondary chronic pain control.

Adjuvant Medications for Pain Control

The use of adjunct medications for pain control often begins with the patients themselves. In the nationwide survey by Clarke et al. (2016), individuals with musculoskeletal pain (41.6%) were significantly more likely to have used adjuvant or alternative therapies compared to those without such pain (24.1%). However, many of these therapies could be considered truly “alternative” in that they were simply applications of natural products (24.7%) rather than practitioner-guided approaches (18.2%) or strategies that involved multiple components of the medical system (5.3%) (Clarke et al., 2016). This information suggested that individuals with chronic pain may

have received inadequate pain control. A survey conducted by Fanelli and colleagues (2014) that surveyed 143 orthopedic specialists provided some insight into the undertreatment of pain phenomenon. The work by Fanelli et al., (2014) reported that of the 143 orthopedic specialists that were surveyed, 70% had a high degree of knowledge regarding the use of opioid and medical adjuvant therapies such as nerve blocks, including Marcaine. However, less than half (45.5%) of the specialists had prescribed these medical therapies on a regular basis following orthopedic procedures. Reasons cited for the orthopedic specialists' reluctance to prescribe were side effects/adverse reactions (45%) and patient resistance to opioid therapy (29%) (Fanelli et al., 2014).

The results of these studies indicated a few issues with postoperative therapy following orthopedic shoulder surgery. First, the patient may not have received adequate levels of pain relief following surgery due to a combination of practitioner unwillingness to prescribe high levels, or in some cases any levels, of opioids (Fanelli et al., 2014). Patients and even practitioners themselves may be unaware that there are other options for pain relief aside from higher doses of opioids, which may not be completely effective in cases of chronic pain. This finding suggests there is a need for health care provider training and patient education regarding the use of options such as pain pumps following orthopedic shoulder surgery.

The information regarding adjuvant therapies for postsurgical therapy that have been researched in the literature already showed that these therapies have promise for assisting in orthopedic surgical cases, although at the same time, there have been surprisingly few studies that focused solely on issues of orthopedic shoulder surgery in patients who have also been diagnosed with secondary cases of acute shoulder pain.

Hamandi, Al-Khafaji, and Al-Atbee (2013) conducted a small case study comparison that involved the use of opioid and adjuvant therapies as treatments for orthopedic surgeries and chronic pain. They found that the combination of both medications using a pain pump helped to reduce patient-reported pain as well as objectively measured spasticity after surgery. However, it is important to note that the sample was not only small but involved delivering both opioid and non-opioid medications through pain pumps, which is a therapeutic strategy not generally used in American medicine. Moreover, their study was not solely limited to orthopedic shoulder surgeries. They noted the need to measure not only pain but muscle movement. Matsen et al. (2017) described a study of 104 persons with osteoarthritis whose ranges of movement were measured prior to surgery. The participants' ranges of movement for active abduction and several different shoulder activities were recorded for both the arthritic and the contralateral shoulder prior to surgery. Matsen and colleagues' (2017) study determined that subjective measures of shoulder movement conducted by the patients tended to show significantly less activity and poorer ranges of motion than the objective measures. These outcomes demonstrated the importance of promoting pain control, which also resulted in objective improvements in movement as a product of therapy postoperatively.

The ability of adjuvant nerve blockers and pain inhibitors to aid in pain control after orthopedic surgery has been analyzed in several studies. Patacsil (2016) conducted a systemic review of randomized controlled trials and meta-analyses and determined that nerve blockers tend to be more effective for upper-extremity surgeries, including those involving the shoulders, compared to lower-extremity surgeries. Patacsil stated that these therapies could be advantageous not only for reducing pain but because they could reduce

the number of opioids patients would require after surgery, simultaneously decreasing the risks of opioid-related side effects. Shin et al. (2015) studied arthroscopic anterior shoulder stabilization outcomes and determined that instability occurred in about 19% of patients, most of whom had previous complications from prior shoulder surgeries, and that hyperlaxity was another issue that pre-empted postoperative complications. Both issues, however, could potentially be addressed through peripheral nerve blocks, according to both Patacsil (2016) and Srikumaran et al. (2013), who examined the utilization of peripheral nerve blocks on postsurgical outcomes, and determined that these nerve blocks not only reduced pain but were effective in improving range of motion and recovery times for patients.

Synthesis of Evidence

The review of evidence supported this Doctor of Nursing Practice (DNP) project in several ways. The need to examine adjuvant pain relief methods in order to avoid increasing doses of opioids after surgery and to address chronic shoulder pain that often has a neurological basis that is not adequately controlled by opioids has been reported (Clarke et al., 2016; Fanelli et al., 2014). Nerve blockers have been found to be effective in reducing pain and promoting increased range of motion, although only a limited amount of research has focused specifically on shoulder surgery patients regarding these outcomes (Patacsil, 2016; Srikumaran et al., 2013). However, ample evidence exists to support using both a subjective measure like patient pain ratings per a Likert scale and objective provider-measured range of motion assessments to evaluate the effectiveness of adjuvant pain control methods in promoting improved patient outcomes after surgery

(Hamandi et al., 2013; Matsen et al., 2017). These issues factored into the need for this DNP project.

Needs Assessment

Pain pumps such as ON-Q and similar pieces of equipment have been studied for the past decade, but many of the studies that have been performed have not had methodologies or findings that are generalizable to orthopedic shoulder surgery patients with chronic pain. Many of the studies that have been performed on pain pumps and the use of anesthetics have focused on which medications, or combination of medications, are capable of delivering the longest lasting pain control in a limited area of the body, and how small or large of an area of tissue can be effectively provided with pain relief during a given time (Patacsil, 2016). Yet these pain studies have rarely examined range of movement, an acknowledged critical function for recovery of one's functionality in daily life and mobility (Matsen et al., 2017).

Several studies that have specifically focused on orthopedic shoulder surgery recovery outcomes and the use of anesthetics have extrapolated data from prior studies that referenced outcomes on knee or shoulder surgeries. Other studies have considered pain pumps for not only shoulder surgeries in the sample, but also surgeries affecting the arms or other areas of the upper body (Shin et al., 2015; Vincent, Struk, Reed, & Wright, 2016). Still, other shoulder surgery studies involving anesthetics have either examined inpatient or outpatient nerve blocks for shoulder surgery, which use similar medications, but not the same patient-operated delivery systems, as pain pumps (Srikumaran et al., 2013). Controlled trials comparing pain pump anesthetics along with oral opioids versus control of oral opioid medication for postsurgical patients, as opposed to comparing

different pain pumps, are also somewhat rare (Hamandi et al., 2013). Therefore, there is a pressing need for patients, practitioners, and other stakeholders in orthopedic care to examine whether pain pumps can be applied as an adjuvant therapy to the standard oral opioid therapies generally prescribed and for such a study to involve a control group.

The findings of this DNP project could impact the current and future health of the United States. Right now, hundreds of thousands of orthopedic surgery patients experience secondary chronic pain that is generally not adequately treated by the present methods and guidelines used to rehabilitate them, creating a need for practice and guideline changes (Tekavec et al., 2012; U.S. Census Bureau, 2017). Longer surgery recovery times create higher Medicaid and Medicare costs, along with higher private insurance costs, because many patients exceed eight weeks for recovery and require additional outpatient care, or inpatient readmissions due to surgical complications such as manual shoulder manipulation under anesthesia (MUA) and revision shoulder surgeries (Jain et al., 2014). Americans who work in professions with strenuous job duties such as contractors and construction workers, as well as workers with increased demand and problematic staffing levels, like hospital staff and nurses, are more likely to experience shoulder injuries requiring surgery (Kim et al., 2014a; 2014b). Shoulder injuries and chronic pain often arise between the ages of 40 and 64; as the Baby Boomer Population continues to age, this demographic continues to increase exponentially (Howden & Meyer, 2011). The growing rate of obesity in the nation, which can also cause physical strain resulting in chronic pain and shoulder injuries that require surgery, will likely mean that there will be a corresponding increase need for orthopedic shoulder surgeries among patients with secondary chronic shoulder pain (Evanoff et al., 2014; Vincent, Struk,

Reed, & Wright, 2016). This project's findings could possibly assist future generations of patients, health care providers, taxpayers, and employers as it sought to analyze de-identified data provided to the researcher from a study conducted solely by the project organization.

Problem Statement

The scope of this DNP project was to analyze pre-prepared organizational data to determine whether there were novel approaches to pain relief that may alleviate the pain experienced by patients with a dual diagnosis of both chronic and acute orthopedic shoulder pain. Decreasing postsurgical pain has been noted to decrease postoperative complications, decrease costs associated with prolonged recovery time, and increase the quality of life (Matsen et al, 2017; Srikumaran et al., 2013). The adjuvant pain control therapy that was evaluated against the standard of care for this project was an ON-Q pain pump. The ON-Q pain pump is a patient-operated device implanted via a temporary, clinically monitored catheter. The ON-Q pain pump delivers a pre-set flow of local anesthetic that may be increased by the patient in 2 mL increments to a maximum flow of 10 mL/per hour. The de-identified data provided to the project leader included patients who did and did not receive placement of an ON-Q pain pump. For the patients who did receive the adjuvant therapy a CB004 550 mL pain pump was inserted by the provider via catheter with a combination of 0.125% Marcaine 400 mL, and ketorolac 150 mL, with a baseline rate that depended on the patient's size and condition; however, all patients had the ability to increase the flow by 2 mL, with a limit of 10 mL per hour (see Appendix B). All patients who had placement of the ON-Q pain pump were provided appropriate education concerning proper care including flow adjustment practices and

how to identify when the pump was empty. The ON-Q pump's ball is identified as empty when the patient feels and sees a hard-yellow core and may then remove the ON-Q device and catheter at home which lasts approximately four to five days depending on the flow rate (Clarke et al., 2016).

For this DNP project, de-identified organizational data was retrospectively reviewed on patients who underwent shoulder surgery at the project site between January 2017 and October 2018. According to the organizational guidelines, participants were grouped according to pre-determined criteria. Dependent on insurance coverage, patients were provided an ON-Q pain pump after surgery as an adjuvant therapy alongside standard medications for postsurgical pain relief. As mentioned above, opioids such as hydrocodone 7.5-10 mg are given as a standard postsurgical medication. These medications are generally quite effective at treating the type of acute pain that patients often experience for several weeks following orthopedic shoulder surgery. When opioid analgesics are utilized for postoperative pain, in recommended doses they are generally considered safe and effective. However, development of dosage tolerance, as well as physical and mental dependence can occur when they are not taken as directed or are utilized for an extended period (Fanelli et al., 2014). Additionally, chronic pain may not be caused by internal or external stimuli that is directly contributing to tissue damage, and, therefore, may not be adequately controlled by safe, therapeutic doses of opioids that are sufficient for addressing chronic shoulder pain (Fanelli et al., 2014).

In order to provide adequate pain control for chronic pain it is recommended to provide medications or other methods that block the nociception, or pain, signals from originating from the nociceptor nerves responsible for detecting and conveying pain

signals in different areas of the body (Patacsil, 2016). The medications that are provided within pain pumps such as the ON-Q pump are regional or local anesthetics that provide long-term pain relief by eliminating the initiation and transmission of electrochemical signals from nociceptors, thereby preventing the individual from experiencing the chronic pain while the patient undergoes their rehabilitative activities and activities of daily living.

Project Purpose

This DNP project was guided by a retrospective data analysis of a single Population, Intervention, Control, Outcome, and Time (PICOT) question, “Among male and female patients, ages 40-64 years, who are living with secondary chronic shoulder pain lasting more than three months, and who have undergone orthopedic shoulder surgery (P), would the use of an ON-Q pain pump in addition to standard treatment for pain relief involving the use of 7.5-10 mg hydrocodone (I) compared to receiving the standard treatment for pain relief alone (C) improve patients' postsurgical outcomes by increasing range of motion in degrees at 2 and 8 weeks postoperatively, promoting a pain score of less than 5 on a 10 point Likert scale, and decreasing the length of postoperative therapy from 12 to 8 weeks (O) over the course of 8 weeks (T)?” This PICOT question was developed through examining the current literature on the topics of orthopedic shoulder surgery, shoulder surgery rehabilitation, and chronic shoulder pain. Although opioid analgesics are the general method of pain relief that is used for postsurgical pain, short-acting opioids are more effective solely for the acute pain of surgical recovery and may fail to impact the chronic pain that stems from different physical sources (Patacsil, 2016; Srikumaran et al., 2013).

Theoretical and Conceptual Framework

The theoretical and conceptual framework that was utilized for this project was Jean Watson's Theory of Human Caring. According to Watson (1979), this grand theory accounts for patients' health as going beyond being “disease-free” to encompass a situation where a patient's holistic needs, including biophysical needs, but also psychophysical and psychosocial needs are being simultaneously met. Exposure to stressors may prevent needs from being met or may decrease a patient’s senses of empowerment and value. Empowerment and value of self are vital for the patient’s self-care behaviors and recovery. To effectively treat patients, the nurse delivers evidence-based interventions, or curing, along with charitable actions, teaching moments, transpersonal contact, mutually respectful and trusting relations, and caring moments with their patients (Watson, 2009). This DNP project applied Watson’s theory by conceptualizing surgical recovery as a process where patients required care to manage multiple biophysical needs, like chronic pain and surgical recovery pain. The goal was to retrospectively analyze data to determine if the patient achieved optimal psychophysical and psychosocial outcomes by acquiring functional independence and mobility. Teaching moments, mutual trust, evidence-based practices, and caring/compassionate moments are all necessary from the organizational staff to successfully deliver this information to patients.

Evaluation Plan

This DNP project retrospectively reviewed, previously collected, de-identified data. The outcomes of interest for the project included (a) patients' self-reported pain scores at two and eight weeks after surgery, (b) two-week and eight-week ranges of

motion for the shoulder affected by surgery, and (c) the number of weeks patients needed for physical therapy after surgery. This data was routinely recorded during postsurgical follow-up appointments at the project site by the organizational clinical staff and treating physician. The orthopedic clinic staff routinely conducted and record the pain and range of motion assessments in patient's charts when participants presented for their two-week and eight-week follow-up evaluations. During these visits, the clinic staff also identified the physical therapy needs of the patients in their progress and therapy notes, including whether the patients no longer needed occupational/physical therapy. The outcomes of interest were then collected through a retrospective chart review that did not include the names or other forms of personally identifiable information about the participants. The only health information collected and provided to the project leader included the variables of interest and the information on participant group, as denoted by the presence or absence of an ON-Q request form, shown in Appendix B. The PICOT question was evaluated by taking the mean values of the two week and eight-week pain scores, two week and eight-week ranges of motion in degrees, and weeks required for physical therapy for the intervention and control groups. Between group, *t*-tests were conducted to compare the group mean values for these variables to determine whether the ON-Q pain pump with oral hydrocodone was associated with better postsurgical outcomes when compared to the standard care condition with only oral hydrocodone.

DNP Essentials

The DNP essential elements of the American Association of Colleges of Nursing (2006) were considered and utilized for this project. Essential I: Scientific Underpinnings for Practice was met by conducting a literature review, formulation of a hypothesis from

noted gaps in available literature and performing a retrospective data analysis. Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking, was met through determining whether a novel postsurgical treatment method could reduce rehabilitation times, thereby improving health system functionality.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice was met with the analysis and synthesis of the current literature, and the quantitative collection and analysis of data. Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care, was met using the ON-Q pump, a novel therapy for adjuvant pain control, utilization of databases to search for literature, and utilization of the facility's records to obtain needed data. Essential V: Health Care Policy for Advocacy in Health Care could be derived from the results, which might help influence future guidelines in postsurgical treatment.

Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes was met by working with interdisciplinary teams to discuss project findings as it related to the use of novel approaches of the ON-Q pumps Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health, was achieved through analysis of the data which could aid in preventing complications and readmissions related to poor patient recovery from surgery. Essential VIII: Advanced Nursing Practice was met through the role of an advanced practice nurse functioning as the project leader and conducting the project's data analysis to answer an important clinical question.

Summary

Orthopedic shoulder surgery is a common method for addressing shoulder conditions, but comorbid secondary chronic shoulder pain can impede surgical healing and worsen health outcomes, making safe, effective pain relief an important element of facilitating shoulder surgery patients' health and well-being. This DNP study investigated the PICOT question, "Among male and female patients, ages 40-64 years, who are living with secondary chronic shoulder pain lasting more than 3 months, and who have undergone orthopedic shoulder surgery (P), will the use of an ON-Q pain pump in addition to standard treatment for pain relief involving the use of 7.5-10 mg hydrocodone (I) compared to receiving the standard treatment for pain relief alone (C) improve patients' postsurgical outcomes by increasing range of motion in degrees at 2 and 8 weeks postoperatively, promote a pain score of less than 5 on a 10 point Likert scale, and decrease the length of postoperative occupational/physical therapy from 12 to 8 weeks (O) over the course of 8 weeks (T)?"

CHAPTER II – METHODS

Overview

This chapter describes the methods utilized for this DNP project. The chapter discusses the setting for the project, a private orthopedic practice clinic. This chapter then describes the target population that the project sought to investigate and contextual elements of the project. Subsequently, the chapter provides an overview of the research design and describes ethical considerations. The final section summarizes the contents of the chapter.

Setting

This DNP project was conducted in a private orthopedic practice specialty clinic located in an urban metropolitan area located in Coastal Mississippi. This clinic provides outpatient surgical procedures including reverse total shoulder arthroplasty (RTSA) and arthroscopic rotator cuff tear repair (RCTR). Between January 2017 and October 2018, the clinic provided a combined total of 156 reverse total shoulder arthroplasty procedures and arthroscopic rotator cuff tear repair procedures. The clinic also provides follow-up care to surgical patients in the form of outpatient appointments at two and eight weeks after surgery.

Target Population

The target population for this DNP project consisted of 56 male and 44 female patients, ages 40-64 years old, who received either a RTSA or arthroscopic RCTR procedures at the project setting between January 2017 and October 2018. While there were 156 patients total who received these procedures within the aforementioned time frame; there were only 100 individuals who were inside of the 40-64-year age range

inclusion criteria. Therefore, this project's target population was comprised of 100 individuals who met criteria for data review and analysis.

Contextual Elements

The contextual elements for this DNP project related to the project leader's qualifications as a registered nurse preparing for the DNP degree, who is also currently working in perioperative care at the clinic that served as the DNP project site. The project leader conducted a retrospective chart review of de-identified organizational data of patients that underwent orthopedic shoulder surgery at the project site location during the organization's predetermined time span. This project leader has knowledge of the practices required for safe and effective care for the intervention and control conditions, as aforementioned and outlined by the organizational study as well as an understanding of patient needs, and evidence-based practice required for delivery of high-quality care. Most importantly, the project leader was dedicated to the confidentiality and privacy of the patients whose charts were retrospectively reviewed for data analysis. To ensure patient confidentiality and privacy, aggregate patient data from datasets with all personally identifying information on the participating patients were removed prior to the project leader receiving the information.

Design

This DNP project used a retrospective evaluation design to evaluate and analyze the role of the ON-Q pain pump as adjuvant therapy for promoting improved outcomes among patients receiving orthopedic shoulder surgery who also had secondary chronic shoulder pain. The project leader was provided with de-identified data, previously

collected by the organization. The de-identified data that was reviewed for this project included information on patients who underwent either reverse total shoulder arthroplasty or arthroscopic rotator cuff tear repair procedures between January 2017 and October 2018 at the project site. The patients were identified during this period by the organization as eligible to receive an ON-Q pain pump, as permitted by their insurance coverage, and received either standard pain relief or the intervention conditions of standard pain relief plus the ON-Q pain pump according to pre-surgical assessments that involved their diagnosis, age, surgical procedure code, and insurance coverage. The patients received information about the ON-Q pain pump if they were eligible for participation, according to insurance coverage, and consented for surgical intervention including the use of the adjuvant therapy per the organizational guidelines.

The demographic information was collected during the patient's initial evaluation and consultation for surgery, according to the organization's usual standard of practice. The de-identified data was then reviewed retrospectively by the project leader. The employee who collected and maintained the data was a registered nurse who was an employee of the project setting and certified in HIPPA compliance. This registered nurse ensured collection of variables of interest on surgical consult patients and entered the variables into the patient's electronic medical record. Variables of interest recorded during the consultation included: (a) the type of surgical procedure the participant received, (b) the comorbidity of secondary chronic pain, (c) the date of secondary pain diagnosis, and (d) the control or intervention group assignment. This data was subsequently provided to the researcher for retrospective review and analysis.

The patients underwent their scheduled outpatient surgeries and received either the intervention or control pain relief regimen as designated per insurance coverage. At the follow-up appointments occurring at two and at eight weeks postsurgical procedure, the aforementioned registered nurse recorded the following variables in the patient's electronic medical record: (a) the patient's self-reported numeric pain level scores, (b) range of motion in degrees, and (c) usage of occupational/physical therapy services. The passive range of motion was recorded at two weeks, and the active range of motion was recorded at eight weeks. The registered nurse also recorded the variables of interest in a spreadsheet, according to their customary job duties. Variables were linked to randomly assigned numbers. The randomized number association ensured that the patient's identity was shielded from this researcher during data extraction, review, and analysis.

The data analysis approach for the project was quantitative and utilized the statistical software SPSS version 25. All data points that corresponded with the collected variables of interest from participants mentioned previously were entered in the SPSS software. The data set permitted aggregate analysis while avoiding the inclusion of personally identifying information on any participants. Using the data set, descriptive statistics were conducted for the sample and each sample group, namely, the intervention and control groups, for both demographic and study variables. A two-tail t-test was then used to compare the mean two week and eight-week values for each sample group's pain scores and range of motion in degrees. Between-group t-tests were used to compare the control and intervention sample groups in terms of their mean two-week pain scores, mean eight-week pain scores, mean two-week range of motion, mean eight-week range of motion, and mean weeks required to complete physical therapy. A two-tailed *t*-test was

used and a p-value of $p < 0.05$ to determined significance. The between-group t-test was chosen as a method to allow a hypothesis to be tested that considers whether there are differences between two different sample group means (Delorme, 2005). Mixed-effect tests were also used to assess the possibility of differences between marginal means for the pain and range of motion variables at the two- and eight-week time points, and a p-value of $p < 0.05$ to determined significance.

Ethical Considerations

The ethical considerations in the project involve the need to protect the participants' identities even in the context of a retrospective evaluation. Electronic data related to the project was stored in a password protected file located on clinic devices requiring password-protected logins with unique login identification, while all physical data was locked in file drawers. Participants' confidential health information was only accessed for data entry purposes into files that contained no identifying information. Provisions for data security and protection of physical and electronic data as applicable to state and federal regulations were followed. The data was reported in aggregate form without any identifiers regarding the identity of participants or the site of the research.

Summary

This chapter presented the methodology for this DNP project. The setting was a private practice orthopedic specialty clinic in an urban location of Coastal Mississippi. The target population was comprised of 40-64-year-old adults, male and female, receiving reverse total shoulder arthroplasty or arthroscopic rotator cuff tear repair procedures between January 2017 and October 2018. The contextual elements related to the project leader's experience in providing perioperative care to the patients whose data

was used in the study. The study was a retrospective evaluation of two- and eight-week chart data during follow-up appointments after shoulder surgery for participants. The ethical considerations involved the use of measures to protect the safety, confidentiality, and privacy of patients whose de-identified data were retrospectively reviewed for project purposes.

CHAPTER III – RESULTS

Overview

This chapter presents the findings from the project. The main section in the chapter briefly outlines the descriptive statistics for the project and then presents the results of the inferential statistics. This chapter concludes with a summary of the project findings.

Project Results

The descriptive statistics for this project showed that, out of 100 patients included in the analysis, 44 were female, and 56 were male, while 36 received the ON-Q pain pump as an adjuvant therapy with oral hydrocodone, and 64 received oral hydrocodone-only. Table 1, below, shows the mean values of the ranges of motion for passive forward flexion (PFF), active forward flexion (AFF), passive abduction (P ABD), and active abduction (A ABD), as well as self-reported pain scores at two and eight weeks for the sample as a whole.

Table 1

Outcome Mean Scores by Time Point and Sample

		Paired Samples Statistics			
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	ROM 2WK PFF	102.90	100	11.746	1.175
	ROM8 WK AFF	159.60	100	21.245	2.125
Pair 2	ROM 2WK P ABD	91.95	100	9.263	.926
	ROM 8WK A	149.90	100	27.934	2.793
	ABD				
Pair 3	PAIN 2 WK	4.02	100	2.674	.267
	PAIN 8 WK	3.51	100	2.725	.272

The first inferential statistical analysis that was conducted, shown in Table 2, involved paired-samples t-tests for the mean range of motion in degrees and mean self-reported pain scores at the two- and eight-week time points, for the entire sample. The sample showed significantly ($p=0.000$) larger mean ranges of motion in degrees at eight weeks compared to two weeks for both measures. However, the sample did not show a significantly ($p<0.05$) smaller mean self-reported pain score at eight weeks compared to two weeks.

Table 2

Paired-Sample t-test Results for Sample

Paired Samples Statistics						
		Mean	N	Std. Deviation	Std. Error	Mean
Pair 1	ROM 2WK PFF	102.90	100	11.746	1.175	
	ROM8 WK AFF	159.60	100	21.245	2.125	
Pair 2	ROM 2WK P ABD	91.95	100	9.263	.926	
	ROM 8WK A ABD	149.90	100	27.934	2.793	
Pair 3	PAIN 2 WK	4.02	100	2.674	.267	
	PAIN 8 WK	3.51	100	2.725	.272	

Note: $n=100$

The multivariate mixed-effects analysis for the range of motion scores in degrees and the self-reported pain scores, with comparisons of the marginal mean scores by sample group at two and eight weeks, are shown in Table 3 and Figures 1, 2, and 3, below. All three variables showed similar two- and eight-week scores for both sample groups and comparisons of the changes in mean score by sample group indicated no significant ($p<0.05$) difference between the intervention and control groups.

Table 3

ON-Q Effects Over Time

Multivariate Tests									
PFFAFF	Effect	Value	F	DF	DF	Sig	Partial	Noncent	Obs
						Err.	Eta	Parameter	Power
							Squared		
	Pillai's Trace	.891	803.461 ^b	1.00	98.0	.00	.891	803.461	1.00
	Wilks'	.109	803.461 ^b	1.00	98.0	.00	.891	803.461	1.00
	Lambda								
	Hotelling's	8.199	803.461 ^b	1.00	98.0	.000	.891	803.461	1.00
	Trace								
	Roy's Largest	8.199	803.461 ^b	1.00	98.0	.000	.891	803.461	1.00
	Root								
PFFAFF*	Pillai's Trace	.005	.473 ^b	1.00	98.0	.493	.005	.473	.105
ON-Q	Wilks'	.995	.473 ^b	1.00	98.0	.493	.005	.473	.105
	Lambda								
	Wilks'	.005	.473 ^b	1.00	98.0	.493	.005	.473	.105
	Lambda								
	Hotelling's	.005	.473 ^b	1.00	98.0	.493	.005	.473	.105
	Trace								

a. Design: Intercept + ONQ Within Subjects Design PFFAFF b. Exact Statistics c. Computed using alpha = .05

There was a non-significant difference between the groups in terms of how they changed across time for PFFAFF, $p = 0.49$

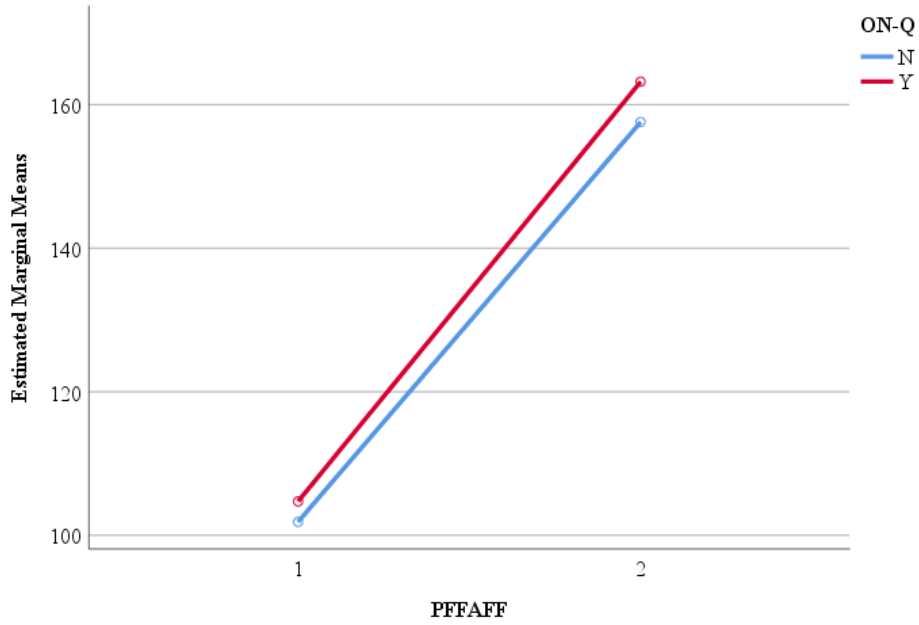


Figure 1. Range of motion two- and eight-week marginal mean scores by sample group.

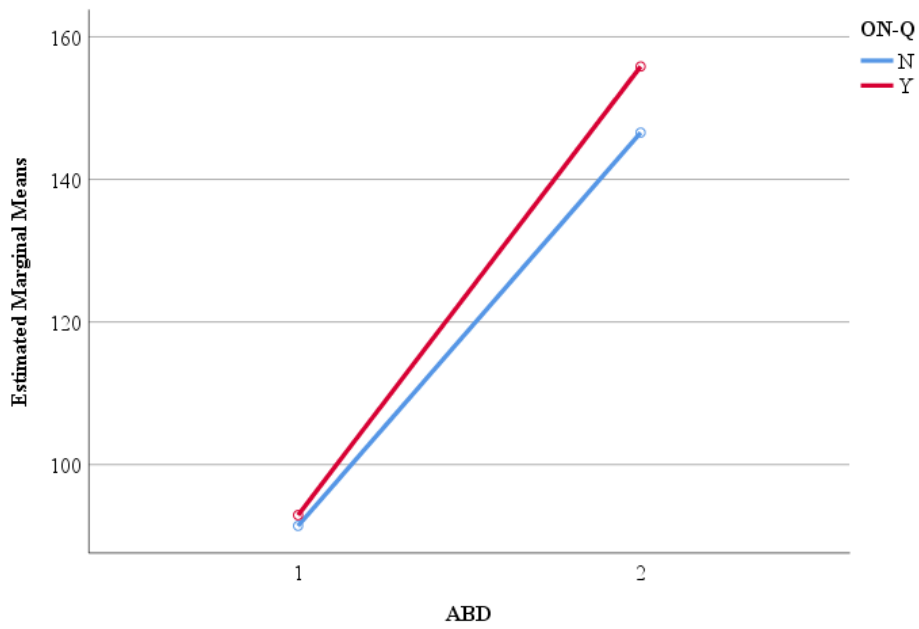


Figure 2. Range of motion two- and eight-week marginal mean scores by sample group.

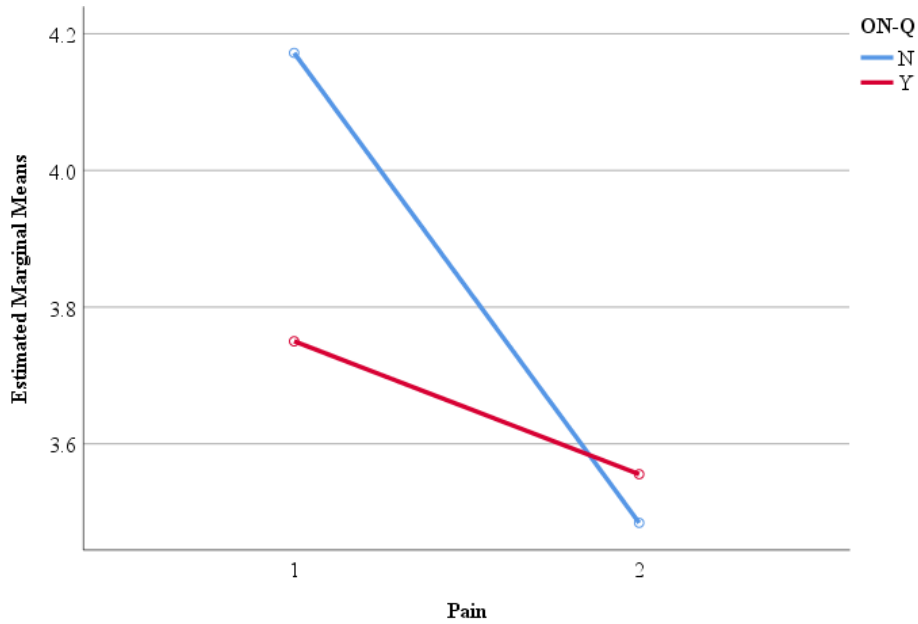


Figure 3. Self-reported pain two- and eight-week marginal mean scores by sample group.

As shown in Table 4, there were no significant ($p < 0.05$) interaction effects between the outcome variables, use of the ON-Q pain pump, or patient gender. Table 4 presents the marginal means and 95% confidence interval (CI) values of the range of motion and pain score outcomes at both time points for the intervention (with ON-Q) and control (without ON-Q) sample groups, as well as by gender.

Table 4

Outcome Score Marginal Means, CIs, and p-values for Interactions by Sample Group and Gender

Outcome	Group	Two Weeks	Eight Weeks	p-value
PFF/AFF				
	ON-Q (no)	101.9 (99.0 – 104.8)	157.6 (152.4 – 162.8)	
	ON-Q (yes)	104.7 (100.8 – 108.6)	163.2 (156.2 – 170.2)	0.49
	Female	102.0 (98.5 – 105.6)	157.1 (150.7 – 163.4)	
	Male	103.6 (100.5 – 106.7)	161.6 (156.0 – 167.2)	0.44
ABD				
	ON-Q (no)	91.4 (89.1 – 93.7)	146.6 (139.7 – 153.4)	
	ON-Q (yes)	92.9 (89.8 – 96.0)	155.8 (146.7 – 165.0)	0.16
	Female	91.7 (88.9 – 94.5)	146.6 (138.2 – 154.9)	
	Male	92.1 (89.7 – 94.6)	152.5 (145.1 – 159.9)	0.31
Pain				
	ON-Q (no)	4.2 (3.5 – 4.8)	3.5 (2.8 – 4.2)	
	ON-Q (yes)	3.8 (2.9 – 4.6)	3.6 (2.7 – 4.5)	0.36
	Female	4.4 (3.6 – 5.2)	4.3 (3.5 – 5.1)	
	Male	3.7 (3.0 – 4.4)	2.9 (2.2 – 3.6)	.013

Note: * All values are *M* (95% CI)

Summary

This chapter presented the outcomes of the data collection and analysis processes in this project. Although the analytical results indicated that the sample had significantly larger mean ranges of motion for both measures at eight weeks compared to two weeks,

there was not a comparable significant reduction in pain scores. Moreover, no significant changes in the range of motion or self-reported pain scores were observed when the intervention and control group mean for these outcome variables were compared. Likewise, the mixed-effects analyses indicated no significant ($p < 0.05$) differences between the control and intervention group marginal means for pain or range of motion outcomes, nor interactions in changes over time for these outcomes, even when controlling for participant gender. These results have implications for clinical practice and future research, which are discussed in the final chapter, below.

CHAPTER IV – DISCUSSION

Overview

The project results discussed in the previous chapter did not show that the ON-Q pain pump and oral hydrocodone intervention condition was associated with significant differences in pain or range of motion outcomes compared to the control condition of oral hydrocodone-only. These results are discussed in more detail in this chapter. The first section presents recommendations for future research. The second section details the implications of the findings from this project for nursing practice in similar settings. The third section identifies the limitations with this project. The dissemination plan for the findings is presented afterward. The chapter ends with a conclusion summarizing the points made in each section.

Recommendations

Based on the findings from the project, the ON-Q pain pump as an adjuvant therapy with oral hydrocodone did not show pain relief or range of motion benefits for arthroscopic shoulder surgery patients. This project's findings conflict with previous research that found evidence for pain pumps as showing benefits as adjuvant therapies for orthopedic surgery recovery, and those that indicated nerve blocks such as Marcaine and ketorolac delivered by other methods of administration could reduce postoperative pain for orthopedic shoulder surgery patients (Hamandi et al., 2013; Patacsil, 2016; Srikumaran et al., 2013). These previous studies did not examine patients with secondary chronic pain, so it may be necessary for future studies to compare whether patients with secondary chronic pain do not respond as well to adjuvant therapies administered using pain pumps compared to patients without chronic pain when both groups of patients are

recovering from shoulder surgeries. Additionally, it may also be beneficial to study whether other methods of administering Marcaine and ketorolac, outside of pain pumps, could be associated with more substantial benefits for pain relief and range of motion among shoulder surgery patients with chronic pain, or whether pain pumps containing other adjuvant medications might be more beneficial.

The focus of this DNP project was to retrospectively review previously collected organizational data to determine if postsurgical outcomes were improved with the utilization of an ON-Q pain pump, in addition to the standard treatment for pain relief involving the use of 7.5-10 mg hydrocodone when compared to the postsurgical outcomes of patients who received only the standard of care for pain control following orthopedic shoulder surgery. The organization collected data on both male and female patients, between the ages of 40-64 years who underwent either a reverse total shoulder arthroplasty or arthroscopic rotator cuff repair at the project setting between January 2017 and October 2018. The addition of an ON-Q pain pump following these procedures was not determined by the project site but by the patient's insurance carrier.

The scope of this DNP project was to determine if the improvement in patient outcomes was significant enough to warrant the utilization of the ON-Q pain pump for patients who had insurance carriers that did not cover this novel therapy; therefore, a cost-minimization analysis was conducted. Utilization of the cost-minimization analysis allows only the costs of an intervention to be evaluated without regard to the effect, as this method operates under the assumption that the alternative treatment offers equivalent outcomes (Frick, Cohen, & Stone, 2013). This cost-minimization analysis was utilized

because the data analysis had already determined that there was no significant difference between the measured outcomes of interest noted in either of the intervention groups.

The cost of the ON-Q pain pump is \$300.00/unit. This cost includes the ON-Q pain pump, the connecting catheter, and loading doses of both Marcaine and ketorolac (L. Bauldin, personal communication, March 24, 2017). This price per unit would result in \$3,000.00 in cost for every 10 surgery patients who were covered under insurance carriers that did not provide reimbursement for the ON-Q pain pump. The outcome results for this DNP project were not significant enough to recommend the use of the ON-Q pain pump for all patients regardless of insurance coverage.

Further collection and data review would be beneficial to perform a full economic analysis, as there are multiple considerations that could be explored, not within the scope of this DNP project. One concept for future exploration is savings of any downstream costs. These downstream costs would include estimation of future beneficial savings related to improved postsurgical outcomes including decreased utilization of occupational/physical therapy and decreased incidence of future surgeries.

Implications for Future Practice

This project has possible implications for future practice. This project's findings suggested that oral hydrocodone alone delivered similar postsurgical recovery benefits at a lower cost when compared with oral hydrocodone and the ON-Q pain pump. Although previous research, such as the study by Hamandi et al. (2013), indicated the combination of opioid and adjuvant pain relief can benefit orthopedic shoulder surgery patients, this project's findings did not agree. The findings in this study suggest that such a combination might fail to produce benefits for orthopedic shoulder surgery patients who

also have a history of secondary chronic pain in the same shoulder they have received surgery on. Therefore, these findings suggest that adjuvant therapies lack sufficient benefits for pain relief and range of motion recovery to recommend their use, especially when the added costs to the patient and provider are considered. Until more evidence on this practice issue is available, these findings imply that adjuvant therapies administered using pain pump would not benefit this patient population.

Limitations

This project had some limitations. The sample was drawn from a single geographic area and was a convenience sample of patients presenting at a single practice setting. Therefore, the sample may not represent the population of orthopedic shoulder surgery patients with secondary chronic shoulder pain, which creates limits on the generalizability of these findings. Additionally, the project was a retrospective data review and not a randomized controlled trial, so no conclusions regarding cause and effect relationships between the ON-Q pain pump and the outcome measures can be drawn.

Dissemination

The dissemination of this project's findings involves several steps. The data and project findings were formatted and provided to the project leader's collaborating physician, a certified board member, along with an executive summary (see Appendix E), at the project site. The project leader along with the collaborating physician will present the project findings to the board of directors at the project site, and the site's 17 partners, at the next quarterly board meeting to determine whether the findings indicate that a

change of practice at the project site's new surgical center should be developed based on the available data review.

Conclusion

This project compared the use of the ON-Q pain pump, an adjuvant therapy with Marcaine or Marcaine and ketorolac, as an adjuvant pain relief therapy administered with oral hydrocodone, to hydrocodone alone, for patients with a history of secondary chronic shoulder pain who received orthopedic shoulder surgery. The retrospective data review involved range of motion and self-reported pain scores at two and eight weeks after surgery indicated that the ON-Q pain pump plus hydrocodone condition was not associated with significant benefits in pain relief or range of motion among adult patients ages 40-64 compared to hydrocodone alone. These findings conflict with past research outcomes, suggesting a need for more research on adjuvant pain relief therapies among surgical patients who have a history of chronic pain. Despite the limitations of this project, the findings indicated that the ON-Q pain pump may not deliver sufficient benefits in practice for this patient population to recommend its use; however, future exploration, including a more in-depth cost-benefit analysis may provide more information to support adoption of the ON-Q pain pump as standard of care for orthopedic shoulder surgery.

APPENDIX A – Literature Matrix

Author/Year	Level Grade	Design	Sample/Data Collection	Findings	Limitations
Clarke, Nahin, Barnes, & Stussman (2016)	Level 2 Grade C	Descriptive epidemiological study involving a review of retrospective medical histories	34,525 American adults, representing a 79.7% response rate from the initial calls. Data collection involved questionnaires and reviews of health records.	Over half of all people interviewed (54.5%) had some type of musculoskeletal pain disorder involving chronic pain. Significantly more people with musculoskeletal pain (41.6%) used adjuvant or alternative therapies compared to those without such pain (24.1%), but practitioner-based approaches (18.2%) and systemic medical approaches (5.3%) were much less common than the use of natural products (24.7%).	The survey was nationwide but did not represent the entire American population, and there was a self-selection bias in the responses making it difficult to say how generalizable the results are to the entire American population.
Evanoff, Sabbath,	Level 2 Grade B	Cohort Study	9,415 participants, all	The results demon-	The study focused

<p>Carton, Czernichow, Zins, Leclerc, & Descatha, (2014</p>			<p>of whom were retired males, and between the ages of 63-72 years of age at the time of the study. 2,762 were normal weight (BMI <24.9) 3,841 were overweight (BMI between 25-29.9, and 1,032 were obese (BMI >30). Data collection included questionnaires inquiring about occupational exposures to various activities such as arm elevation and squatting. Shoulder and knee pain were also measured.</p>	<p>strated that long term (>10 years) of work involving arm elevation as well as frequent squatting motions were linked to significantly higher risk odds for severe knee and shoulder pain (rated as ≥ 5 on a 0-8 scale), obesity was found to be a risk factor (OR 1.28) for severe shoulder pain, and both obesity (OR 1.71) and overweight (OR 3.28) significantly increased the risks for severe knee pain. BMI was found to mediate the links between repetitive squatting on the job and</p>	<p>largely on working-class males in France who had spent much of their lives doing intensive physical activities. These results may generalize to people from other cultures with similar obesity rates as well as similar occupational exposures to heavy lifting and repeated motion but may not necessarily apply to people with different types of career paths.</p>
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				severe knee pain after the participants had entered retirement.	
Fanelli, Cherubino, & Compagnone (2014)	Level 2 Grade C	Descriptive survey study	143 orthopaedic specialists from Italy were provided with an online survey. The survey asked about two basic areas. First, it inquired about the level of knowledge that the orthopedic specialists had regarding the use of opioids and other forms of pain control such as adjuvant nerve blockers. Secondly, the survey inquired about the actual use, in terms of prescriptions, that the specialists provided to their patients after their surgeries.	Even though there had been a law passed two years prior to the study making opioid and non-opioid adjuvant pain control medications more accessible to orthopedic specialists, only 101 (70%) showed a high degree of being informed about the usage of these medications. Moreover, the majority, 54.5%, said that they did not even prescribe opioids as a remedy for osteo-articular pain rated as severe, largely due	This study was conducted among a very limited set of orthopedic specialists in a European nation that sees far lower proportional usage of opioid and adjuvant forms of pain control. Cultural and legal differences, plus the small sample size, may limit applicability of the results to American orthopedic specialists.

				to concerns over the side effects of the medications and to a lesser extent, because of patient resistance to their usage.	
Hamandi, Al-Khafaji, & Al-Atbee (2013)	Level 4	Case study comparison with a small sample size	Five patients at a single hospital who had undergone acute surgery and who also had chronic pain. Infusion pump usage was measured through pain ratings and spasticity.	All five patients received relief from a combination of opioids post-surgically and medication to treat spasticity and nerve blocking, resulting in significant decreases in patient-reported pain, and objectively observed spasticity as measured by physicians.	The study was conducted in the nation of Iraq, where pain pumps are relatively new, and therefore their usage in this study (combining the opioid and non-opioid adjuvant therapies in pumps) was different than the protocol that would be employed by most American orthopedic specialists, where individuals

					would receive oral opioids along with a pain pump that would be capable of delivering the adjuvant therapy. Additionally, the study was not solely concerned with shoulder surgeries but dealt with a range of chronic pain and orthopedic issues. Finally, the sample size of five individuals was extremely small.
Jain, Higgins, Losina, Collins, Blazar, & Katz (2014)	Level 2, Grade C	Descriptive epidemiological study involving a review of retrospective	34.7 million American hospital visits comprised from 52,233 records gathered from nationwide hospitals and ambulatory	272,148 rotator cuff surgeries and 257,541 shoulder arthroscopy surgeries not involving the rotator	This study was nationwide but does not represent a complete view of orthopedic

		<p>medical histories</p>	<p>surgery centers, which showed respective response rates of 75% and 74%. The data collection involved chart reviews of the types of orthopedic diagnoses and procedures that were used to treat them.</p>	<p>cuff had been performed in 2006 in the United States. The rotator cuff surgery was the most common in 65-74-year-olds (28.3 surgeries per 10,000 individuals) followed by 55-64-year-olds. Shoulder arthroscopy was usually performed due to impingement syndrome, bursitis, periarthritis, and instability.</p>	<p>surgeries for 2006 given that the response rates were not 100% for all locations where surgeries were performed. Thus, there could be a self-selection bias in the sample.</p>
<p>Kim, Szabo, & Marder (2012).</p>	<p>Level 2 Grade C</p>	<p>Descriptive epidemiological study involving a review of retrospective medical histories</p>	<p>28 million emergency department records, which included hospitals and ambulatory surgery centers nationwide.</p>	<p>There were 370,000 visits to American emergency departments in 2008 that were related to fractures of the humerus, which can require orthopedic surgery.</p>	<p>This study was nationwide but does not represent a complete view of orthopedic surgeries for 2008 given that the response rates were</p>

				<p>Women 40-80 years of age (R2=97.9%) and men 60-89 years of age (R2 = 98.2%) were at the greatest risk for these issues.</p>	<p>not 100% for all locations where surgeries were performed . Thus, there could be a self-selection bias in the sample results. Also, humerus fractures can but do not always require orthopedic shoulder surgery, so these figures may not accurately represent the growing need for postsurgical therapy.</p>
<p>Kim, Dutra, & Okechukwu (2014a)</p>	<p>Level 2 Grade B</p>	<p>Cross-Sectional Study</p>	<p>1,772 construction apprentices. Safety practices were evaluated using a simple questionnaire, and injury records were used to evaluate</p>	<p>Fewer safety practices were linked to higher and significant odds of injury-related absences (OR 1.68).</p>	<p>The sample represented only a single state's construction workers and the question-</p>

			absences due to injury.		naire was mostly focused on safety making it difficult to draw conclusions about whether the injuries led to chronic pain or precipitated surgical needs.
Kim, Okechukwu, Dennerlein, Boden, Hopcia, Hashimoto, & Sorensen (2014b)	Level 2 Grade B	Cross-Sectional Study	1,572 nurses from two teaching hospitals. Staffing was measured through the Nursing Work Index. Musculoskeletal pain was self-reported and measured with the Nordic questionnaire.	The logistic regression model used revealed clustering where inadequate staffing showed a higher odds ratio for the numbers of body areas experiencing chronic pain (OR 1.5, OR1.42 respectively) even after taking into account job duties, having a second job, and the number of	The sample size was large but represented only two hospitals that were understaffed. Moreover, understaffing used a subjective measure making it more difficult to compare objectively understaffed and overstaffed

				hours per week. Physical work factors influence back pain, but shoulder pain remained significant even when this was taken into account.	hospital nurses in terms of pain.
Matsen, Tang, Russ, Hsu, & Matsen (2017).	Level 3 Grade B	A case-control study involving range of motion tests	The sample included 104 individuals with osteoarthritis, 70 males and 30 females. The data collection involved measuring the range of motion of patients according to subjective and objective measures. The objective range of motion involved measurements with the Kinect motion capture system and the subjective measure involved the simple shoulder test that is a patient-based measure of shoulder function.	The patients' measurements of shoulder movement, in particular of active abduction, did not correlate well with the objective measures for either males ($R^2=0.25$) or females ($R^2=0.29$) before the surgery had taken place. Contralateral shoulder measures were much closer for subjective and objective measures for males ($R^2=0.46$)	The patients were collected from a single facility and the small sample size, combined with the use of only two range of motion tests that are not used in all studies on this topic, making the results possibly not apply to all patients.

			Measurements were taken before and after surgery.	and females (R2=0.54). Significant differences between injured shoulders were found between active abduction and the number of shoulder activities completed by participants for both men and women, and when comparing osteo-arthritis and contralateral shoulders.	
Narvy, Ahluwalia, & Vangsness (2016)	Level 3 Grade B	Case Control Study	26 patients requiring orthopedic surgery (28 shoulders total). Costs were calculated based on operation time, surgeries, and pre-operative information.	The mean operating time was 148 minutes, while 105 minutes was the mean recovery time. The surgeries averaged \$5,904 in cost. Moreover, the patients had a mean age of 54.5 years.	Small sample size from a single location which may not be generalizable to other environments or costing sources.

Patacsil (2016)	Level 2 Grade B	Systematic review of cohort studies and randomized controlled trials	29 articles, including 3 review articles, 4 meta-analyses, and 22 RCTs. Data collection involved comparison of quantitative results.	Several pain control methods are possible for orthopedic surgery, but there are problems with using partial opioid agonists, full opioid agonists, and acetylcholine inhibitors. Adjuvant inhibitors seemed to be more effective when combined with standard post-operative opioid pain management for upper extremity surgeries as compared to lower extremity surgeries. However, there is a need to study adjuvants other than dexamethasone	The main limitations included the fact that not all adjuvant inhibitors have been studied thoroughly, and therefore limited the amount of data that the study was able to draw on when developing its review.
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				and epinephrine although both seem to be effective. Also, adjuvant inhibitors lower the risks of adverse events due to opioid use.	
Shin et al., (2016)	Level 3 Grade B	Case-control study with pre and post-test measures	62 patients comprising 63 shoulders that received revision arthroscopic anterior shoulder stabilization. Data collection was conducted 46.9±16.8 months later, using several measures including the simple shoulder test, visual analog pain scale, and American Shoulder and elbow surgeons scores. However, there was remaining instability in 12 (19%) shoulders, which was found to be significantly related to having prior shoulder complications	The significant (p<0.001) improvements occurred in the mean simple shoulder test, visual analog pain scale, and American Shoulder and elbow surgeons scores. However, there was remaining instability in 12 (19%) shoulders, which was found to be significantly related to having prior shoulder complications	Small sample size was drawn from a single clinic and the use of the simple shoulder test rather than an objective test for shoulder movement .

				resulting in surgery as well as hyperlaxity.	
Srikumaran, Stein, Tan, Freehill, & Wilckens (2013)	Level 2 Grade A	Systematic review of studies on peripheral nerve blocks.	35 studies including meta-analyses and RCTs related to upper extremity peripheral nerve blocks.	Peripheral nerve blocks were found to improve the cost-effectiveness of postsurgical treatment, reduce perceived pain on the part of patients, and improve range of motion for the patients. They tended to have low rates of adverse effects and complications.	The sole limitation of this study was that it would be impacted by any limitations of the studies it drew its data from. Also, the study was not solely concerned with orthopedic shoulder surgery nerve blocks but rather those involving any upper extremity.
Tekavec et al, (2012)	Level 2 Grade C	Descriptive study in a population comparing shoulder pain prevalence, pain diagnoses, and medical assistance	A single country of Sweden containing a total of 1,169,464 people of which 575,895 were men, and 593,569 were women. The data was collected from	Women showed a slightly higher consultation prevalence compared to males, but this was not significant (103 per 10,000 women	Despite the large sample size, the study collected data from only a single country of Sweden, where the lifestyles,

		seeking patterns.	health care register data from public and private providers based on ICD-10 coding of pain and shoulder diagnoses.	versus 98 per 10,000 men annually). Women also showed slightly higher new consultation rates (80 per 10,000 women versus 74 per 10,000 men annually) with the respective peak ages for consultations occurring at ages 50-59 years for women (129 per 10,000) and 60-69 years for men (116 per 10,000). Twenty percent of people of either sex consulted for three months after the diagnosis, but only a few percent past two years from the initial diagnosis.	insurance coverage, barriers to care, and workforce distribution, as well as age ranges and BMI, may be very different from those of the United States, so caution should be used when generalizing.
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				Con- sultations were 1% for shoulder pain, with rotator cuff and impinge- ment conditions being the most frequent acute diagnoses.	
Vincent, Struk, Reed, & Wright (2016)	Level 2 Grade B	Cohort study comparing two groups of individuals following a total shoulder arthro- plasty or reverse shoulder	310 individuals who had a total shoulder arthroplasty or reverse shoulder arthroplasty, divided into groups of 167 non-obese individuals (BMI <25), 121 obese individuals (BMI between 30-39.9), and 22 morbidly obese individuals (BMI > 40). Data was measured by patient-reported measures that included ASES daily living assessments, shoulder pain, and disability index, shoulder rating scale, radiological	Morbidly obese individuals were more likely to have poorer daily living functional scores and motion prior to surgery and reported a worse quality of life. After surgery, however, the main significant BMI effect was related to external rotation and range of movement; BMI was significantly and negatively correlated	The study used several patient report measures which may have influenced the outcomes somewhat. However, motion ranges and health outcomes were measured by objective sources and thus were not limitations . The small number of morbidly obese

			outcomes, chronic illness, and adverse events.	with movement, as well as reporting worse overall health.	patients in the study may have also skewed the results.
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APPENDIX B – ON-Q Pharmacy Request Form

DATE: _____ TIME: _____

DRUG ALLERGIES:

_____ or

NKDA

PUMP

CB004 Total Fill to 550 mL

FILL MEDICATION

0.125% Marcaine

0.125% Marcaine 400 mL plus 150 mL ketorolac

RATE

Start flow at _____ mL per hour

Adjust flow for increase pain by 2, not to exceed 10 mL per hour

DISCONTINUE

When ON-Q ball empty (hard yellow core)

Patient home with pump, discharge instructions given.

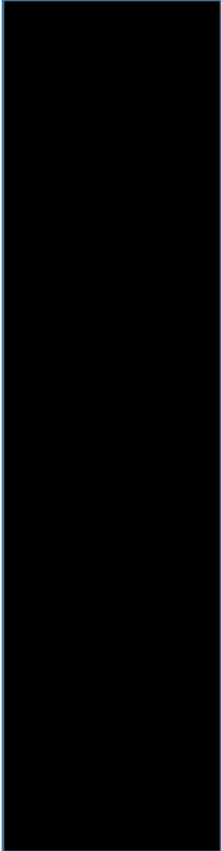
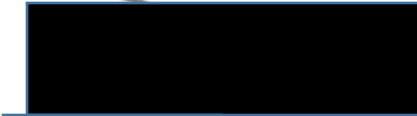
Catheter removal instructions are given.

CLINICAL INDICATION: The nature of surgery in this case will result in postsurgical pain management that is non-routine and requires a continuous catheter for postoperative pain control. Thus, I hereby refer the administration of a ON-Q pain ball.

SURGEON SIGNATURE

DATE

APPENDIX C – Project Site Letter of Support



December 19, 2019


To Whom It May Concern:

Please accept this letter as my written support for Deborah Thompson-Spencer's Doctoral Project entitled: "Does the Use of an ON-Q Pain Pump Improve Post-Surgical Outcomes in Patients with Secondary Chronic Shoulder Pain?: A Retrospective Study."

[Redacted] strives to provide multifaceted, innovative care and this project will be implemented within our patient community. [Redacted] is the largest orthopedic clinic in Mississippi with fellowship-trained [Redacted] quality specialists who focus on treating a vast population of patients, with a diagnosis of chronic shoulder pain, that could benefit from this project.

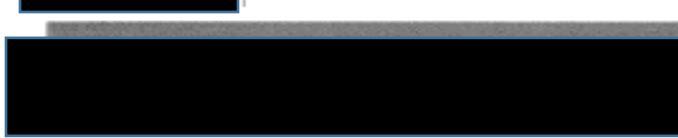
Please see attached IRB Self-Certification Form for Determining Whether a Proposed Activity is Research Involving Human Subjects. Due to the nature of the project there are no further actions needed from [Redacted].

Please feel free to contact me should you have any additional questions.

Sincerely, 

Dean Thigpen, CPA, CMPE
Chief Executive Officer

Attachment



THE ONE TO TRUST.

APPENDIX D – IRB Approval

Office of Research Integrity



118 COLLEGE DRIVE #5125 • HATTIESBURG, MS | 601.266.6576 | USM.EDU/ORI

NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

The project below has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services regulations (45 CFR Part 46), and University Policy to ensure:

- The risks to subjects are minimized and reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered involving risks to subjects must be reported immediately. Problems should be reported to ORI via the Incident template on Cayuse IRB.
- The period of approval is twelve months. An application for renewal must be submitted for projects exceeding twelve months.

PROTOCOL NUMBER: IRB-19-46

PROJECT TITLE: Does The Use of an ON-Q Pump Improve Post-Surgical Outcomes in Patients with Secondary Chronic Shoulder Pain?: A Retrospective Study.

SCHOOL/PROGRAM: College of Nursing - GP, School of LANP

RESEARCHER(S): Deborah Thompson Spencer, Patsy Anderson

IRB COMMITTEE ACTION: Exempt

CATEGORY: Exempt

Category 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

APPROVED STARTING: February 14, 2019

Donald Sacco, Ph.D.
Institutional Review Board Chairperson

APPENDIX E – Executive Summary

Of the 19 million Americans who will undergo orthopedic shoulder surgery in the next five years, 40% have two comorbid conditions affecting the same shoulder: orthopedic pain and secondary chronic pain. Patients with these comorbid conditions continue to experience post-surgical pain because orthopedic surgery does not address secondary chronic pain, which affects their postsurgical recovery and increases costs of care. Past studies of adjuvant pain relief therapies suggest that pain pumps dispensing local anesthetics may relieve postsurgical chronic pain relief and facilitate improved healing, but these studies did not specifically examine postsurgical comorbid orthopedic pain and secondary chronic pain for shoulder surgery patients or measure the range of motion as an outcome. This project accordingly investigated whether, for adult orthopedic shoulder surgery patients 40-64 years old who had a ≥ 3 month diagnostic history of secondary chronic shoulder pain, postsurgical pain relief with an ON-Q pain pump and oral hydrocodone, versus standard pain relief with oral hydrocodone alone, increased range of shoulder motion and reduced pain on a 10 point Likert scale at 2 and 8 weeks after surgery. A quantitative retrospective data analysis of patient health records was conducted for 100 men and women who received total shoulder arthroplasty or arthroscopic rotator cuff tear repair at a single clinic between January 2017 and October 2018. The findings indicated that the ON-Q pain pump with oral hydrocodone did not significantly improve pain relief or range of motion outcomes compared to oral hydrocodone alone. These findings have implications for practice and future research.

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