Improving Postoperative Pain Management after Posterior Spinal Instrumented Fusion for Idiopathic Adolescent Scoliosis

Ahmed Q. Abdul Rahman, BSN, RN

Oregon Health & Science University School of Nursing

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Abstract

Background: Opioids are commonly prescribed for pain management in patients undergoing Posterior Spinal Instrumentation and Fusion (PSIF) surgeries. Opioids often lead to complications, extended hospitalizations, and reduced patient satisfaction. Adequate pain management requires a multidisciplinary strategy while considering the adverse effects of opioids, necessitating a personalized comprehensive pain management protocol.

Objective: To determine adherence to the multimodal pain management algorithm and evaluate the impact of diazepam and gabapentin on opioid usage.

Design: A descriptive single-arm design was used.
Methods: Data were obtained from patients undergoing PSIF surgery (n = 57) between January 2022 – December 2022. Data collection ended at the postoperative follow-up (~15 days later), where patients self-reported the total number of opioid doses consumed.

Results: Patients were initially prescribed 20 doses of opioids and used 23 doses on average, suggesting that our clinicians prescribed an adequate number of opioids without overprescribing. Trends indicated diazepam ($p < 0.001$) and gabapentin ($p = 0.145$) were associated with more opioid use, which could reflect higher analgesic use among patients who are in severe pain.

Conclusions: Multimodal analgesic strategies appear promising for managing postoperative pain in this patient population; however, research is needed to understand the impact and risks of these strategies for minimizing opioid use post-discharge.

Clinical Implications: This project contributes to the evolving conversation on postoperative pain management in pediatric healthcare, emphasizing the need for innovative, patient-centered approaches amidst the ongoing opioid epidemic while advocating for broader applications and continuing refinement in this patient population and beyond.

Problem Description

Idiopathic adolescent scoliosis (IAS) is a prevalent spinal deformity, affecting 2% to 4% of children aged 10 to 16 years old (Horne et al., 2014). Posterior spinal instrumented fusion (PSIF) is an extensive surgical procedure for correcting spinal deformities in adolescents with idiopathic scoliosis. Even though the surgery is effective in correcting spinal alignment and preventing the progression of the spinal curve, postoperative pain management remains a significant challenge (Lee et al., 2020). Cozowicz and colleagues (2020) noted that postoperative pain management is a challenge in spinal surgery generally because of the nature of the surgical procedure. Surgical correction causes trauma and inflammatory processes not only to the spine but to the skin, muscle, tendons, and bones. Ineffective pain management can result in increased post operative recovery period, increase length of stay in hospital, and decreased patient satisfaction.

Opioids are the first line for pain management in this patient population and the most prescribed medication for orthopedic procedures (Hudgins et al., 2019). Despite advancements in surgical techniques, postoperative pain management after PSIF remains suboptimal (Lee et al., 2020). In the immediate postoperative period, patients frequently experience severe pain. Existing pain management protocols rely heavily on opioids. Inadequate pain management can also result in an increased risk of complications that includes delayed ambulation leading to delayed discharge from hospital, and ultimately decreased patient satisfaction. This poses a double sword dilemma for healthcare providers. The need to balance effective pain management while avoiding over prescribing requires diligent assessment of patient needs and a multidisciplinary approach. The overuse of opioids is linked to several adverse effects,

including respiratory depression, constipation, and an increased risk of opioid dependence (Yang & Werner., 2019). The literature document that such a practice has resulted in an increase in opioid-related adverse effects and longer hospital stays, negatively affecting patient satisfaction and outcomes overall (Seki et al., 2018). Additionally, such practices may contribute to the ongoing opioid crisis (Center for Disease Control and Prevention, 2022).

Local data indicates that a substantial proportion of patients undergoing PSIF for idiopathic adolescent scoliosis experience moderate to severe postoperative pain, with many requiring high opioid doses to achieve adequate pain relief. Inadequate pain management can have both immediate and long-term effects on patients. Ineffective pain management can increase stress and anxiety, delay recovery, and diminish the quality of life (Glowacki, 2015; Ye et al., 2020). In addition, excessive opioid use can contribute to the ongoing opioid crisis, with the potential for addiction and long-term damage to individual patients and society (Horton,et al., 2019). A local institution established and put into practice a multimodal pain management strategy over the course of a year. Now, the institution pain management team's desire to is to assess whether healthcare providers adhered to the protocol and to determine the effectiveness of the protocol in managing patient pain, as evidenced by a reduction in requests for opioid refills.

The challenge of subpar postoperative pain management in individuals who have undergone Posterior Spinal Instrumentation and Fusion (PSIF) for Idiopathic Adolescent Scoliosis (IAS) necessitates attention to enhance patient safety and outcomes. By crafting and applying a thorough, evidence-informed multimodal pain management protocol, it is anticipated that pain control for patients with IAS will be enhanced, opioid dependence

decreased, and patient contentment and overall results improved. Such an endeavor aligns with the broader objectives of delivering top-tier, patient-focused healthcare and diminishing the adverse effects of the current opioid crisis. Furthermore, a subsequent evaluation of the protocol's suitability in meeting the specific needs of local patients is essential.

Available Knowledge

Treatment protocols for pain in children are primarily extrapolated from adult intervention without any strong evidence of value in pediatrics (Linhares , et al, 2014). Pediatric postsurgical pain management challenges continue despite advancements in surgical techniques, multimodal approaches, and advanced pain management techniques. Opioids are the “gold standard” for the treatment of moderate/severe pain despite the significant side effects (Harbaugh, et al, 2018) – Persistent opioid use (between 3-6 months) was found in ≈5% of adolescents after surgery. Adverse events associated with opioids, can negatively impact patient comfort and recovery (Chidambaran et al., 2017; Horton, et al., 2019; Monitto et al., 2017). The use PCA and pumps and catheters to prolong analgesia are cumbersome and can carry significant risks.

Reducing postoperative opioid consumption depends on a comprehensive analgesia protocol. Multimodal analgesia (MMA) is a pain management strategy that reduces dependence on opioids by using nonopioids (Shah et.al., 2020). Memtsoudis, et al., (2018) defined multimodal analgesia as “the simultaneous administration of two or more analgesic agents targeting pain pathways at various levels”.

Multimodal pain management protocols involve interventions across three-time points: preoperative, intraoperative, and postoperative settings. Multimodal pain management

involves a combination of acetaminophen, pregabalin, gabapentin, cyclooxygenase-2 (COX-2) inhibitors, steroids, and neuraxial anesthesia in addition to the use of opioid. A systematic review and meta-analysis conducted on 62 research studies documented that reducing the number of opioids used by a multimodal approach and opioid titration is the most effective way to reduce side effect (Jitpakdee & Mandee, 2014).

Pain Management Standards of Care in Pediatric Spinal Fusion

Lee and colleagues (2020) summarized and synthesized the evidence for pain management post operatively for spinal fusion surgery (PSIF) in pediatrics. They reviewed 194 manuscripts to formulate their recommendation. In their review, opioid was the "analgesic mainstay" post scoliosis surgery. Additionally, the use of MMA was found to improve patient pain experience post operatively, reduce opioid side effects, and facilitated enhanced recovery after surgery (ERAS). Their pain management recommendation starts pre operatively (PO) by educating the patient and setting expected goals collaboratively. Intraoperatively, they outlined the recommended analgesics to be used which include methadone, toradol, Intravenous acetaminophen, + epidural 0.1-0.25% bupivacaine and morphine 30-50 mg/ kg, or ketamine dose followed by an infusion. Typically, pediatric anesthesia providers manage this stage. On the day of surgery post operatively or day (POD) 0, PCA hydromorphone, or PCA morphine, or epidural hydromorphone or morphine is used. On POD day # 1, PCA and IV analgesics are stopped and switched to oral medications such as oxycodone, if patient is able to tolerate oral intake. On POD #2, oral oxycodone is continued every 4 hours, methocarbamol every 8 hours (hrs), acetaminophen every 6 hrs, and diazepam every 4 hours as needed (PRN). The patient is

typically discharged on POD 2 or 3. On discharge, patient is sent home on oxycodone every 4 hrs PRN and acetaminophen every 6 hrs.

Although this project is focused on the pharmacological aspect of pain management for children with PSIF, the use of non-pharmacological approaches is supported in the recommendations. The recommendations/guidelines encourage the use of several approaches to reduce pain and promote comfort such as the use ice packs, relaxation and breathing techniques, massage, and physical therapy.

The pain management committee consisting of representatives from nursing, pharmacy, advanced practice providers, and medical provider adopted these guidelines and developed an algorithm (appendix E) for administering multimodal pain management according to the severity of the procedure performed. The guidelines were adopted for the pediatric population with idiopathic scoliosis who required a spinal fusion by the pain committee members at the children hospital. They summarized their evidence into a table/ figure including best practices using MMA approach to pain management. The algorithm consists of minor, mild, moderate, and severe procedures. The PSIF is considered one of the severe procedures listed. This algorithm delineated multimodal pain management strategies providers should use for hospitalized patients and at discharge.

Rationale

The initiation of this project was grounded on the evidence-based assumption that the multimodal analgesia approach would provide adequate postoperative pain management and minimize opioid consumption not only during hospital stays but also, post-discharge among adolescent patients with idiopathic scoliosis. This project was also guided by the Enhanced

Recovery After Surgery (ERAS) Post Discharge Analgesia Model which emphasizes: (a) employing multimodal analgesia approaches, (b) prescribing opioids as needed rather than as scheduled, (c) using patient-specific evaluations for breakthrough pain, and (d) reinforcing pain management goals (American Association of Nurse Anesthesiology, 2018). Building on these principles, the purpose of this project was to evaluate current postoperative pain management strategies for this patient population at our hospital, regarding opioid prescription practices and the potential role of multimodal analgesics in reducing opioid use post-discharge (Appendix E).

Specific Aims

This quality improvement project aims to assess current pain management practices used in treating pain for children who underwent a PSIF procedure. The project will be done in 3 phases. These are:

Phase 1: Assess current pain management practices (chart review)

Phase 2: To determine adherence to the multimodal pain management algorithm and evaluate the impact of diazepam and gabapentin on opioid usage.

Phase 3: Offer recommendations to the clinical institution based on the data collected regarding the utilization of the multimodal pain management algorithm, highlighting areas of strengths and areas for potential improvement.

Methods

Context

Children's records who were admitted to the children's hospital for Idiopathic Scoliosis and surgical correction requiring a posterior spinal fusion will be reviewed. Children are admitted to the inpatient unit (IPU) post operatively. Post-operatively these children are

admitted to inpatient unit where pain management orders are written by the orthopedic surgeon in collaboration with pediatric anesthesia, and a team of in-patient nurse practitioners and physician assistant. The unit cares mainly for children with orthopedic needs and nursing staff is trained to care for this patient population. In addition, a team of pediatric physical therapist work with the patient closely in the post operative period.

Anticipated barriers to success on this project include the quality of documentation as baseline data was a retrospective review of patient records. In discussion with the APRN preceptor at the site, variation in pain management may occur as a result of the patient response and the provider preference. Anticipated facilitators to this project include providers involvement and desire for assuring best practices in managing pain post operatively. The institution as a whole pride itself with the highest Joint Commission Excellence Award for Safety and for patient satisfaction. As pain management is one of the key variables to drive patient satisfaction scores, all team members are invested in assuring the delivery of best practice care in pain management. Contextual factors that cannot be controlled include is the individual response to pain and to pain medication. Most children respond well but some may experience symptoms like nausea and vomiting which delays switching intravenous pain medication to oral route.

Interventions

Phase 1

A chart review was conducted. Patients were identified using the ICD code for Posterior Spinal Instrumented Fusion (PSIF) and Idiopathic Adolescent Scoliosis. Patients included were adolescents age 13-18 years admitted for surgical repair at a local children hospital.

Phase 2

Data analysis that includes patient demographics, Type dose, frequency, and amount of opioid, basic analgesics, or adjuvant analgesic used, and pain medication prescribed on discharge

Phase 3

Result of data analysis were compared with best practice guidelines. Currently, best practices guidelines are published by Lee, Merchant, & Chidambaran in 2020. The guidelines outline post operative pain management for 3 days post operatively. The guidelines were adopted for pediatric population with idiopathic scoliosis who required a spinal fusion by the pain committee members at the children hospital. The committee has representation from nursing, pharmacy, advanced practice providers, and medical provider. They summarized their evidence into a table/ figure including best practices using MMA approach to pain management.

A timeline for project activities is provided in Appendix A and findings recommendations are included in Appendix F.

Measures

The overall goal of this project is to assess current pain management practices in children who underwent a posterior spinal fusion and instrumentation. The outcome measure will be comparing the data with standards of care. As elective surgical cases were put on hold during COVID-19 pandemic, records post pandemic when the return to normal operation will be reviewed. Measures of interest are included in Appendix B and include the following:

Patient age: measured in years

Gender: measured as Male/ Female/ Transgender/ Other

Weight: measured in kilograms

Length of stay in hospital (LOS): Measured in days

Pain management regimen: Measured by the type of medication administered (Opioid, Basic analgesia (e.g. paracetamol/acetaminophen, NSAIDs, COX-2 inhibitors) as well as Adjuvant analgesics (e.g. gabapentin) Basic analgesia (e.g. paracetamol/acetaminophen, NSAIDs, COX-2 inhibitors) as well as Adjuvant analgesics (e.g. gabapentin). This measure will be collected while in hospital and at discharge

Additional need for pain medication after discharge: review the need for additional pain medication prescription. Yes vs. No

Adherence to guideline: Yes vs. No

Analysis

Chart review data were extracted and entered into an excel data sheet. Data was analyzed using R Project for Statistical Computing (The R Foundation, nd). The data was evaluated for any missing information.

Descriptive statistics were used to describe patient demographics, opioid trends, and provider adherence to the multimodal analgesia algorithm. We also explored associations between the demographic and opioid variables (total doses consumed and refill doses prescribed) using one-way analyses of variance with degrees of freedom corrections whenever assumptions of homogeneity were violated.

To evaluate whether prescribing multimodal analgesics reduced opioid use post-hospital discharge, we used negative binomial regression models to assess the impact of diazepam and

gabapentin on the total number of opioid doses consumed. The use of this modeling approach is warranted as the outcome is a count variable (number of doses) with observed overdispersion (variance was four times greater than the mean). We then performed sensitivity analyses using zero-inflated negative binomial models to assess the impact of diazepam and gabapentin on the number of refill opioid doses prescribed. These models contain two components, including a negative binomial component for modeling non-zero counts (patients who requested refills) and a logistic regression component for modeling the likelihood of being in the certain-zero group (patients who did not request refills). The use of this modeling approach is also warranted for these sensitivity analyses given that more than half the sample (65%) did not request opioid refills, resulting in a count variable with overdispersion and excess zeros (zero-inflation).

Data were analyzed in R (3.6.3) using the *mass package* for negative binomial regression models, the *pscl package* for zero-inflated models, and the *lmtest package* to evaluate model fit. It is also of note that ten patients did not provide opioid use data during their postoperative follow-up visit and were excluded from analyses involving the total number of doses consumed.

Ethical Considerations

Application for the Institutional Review Boards (IRB) was submitted for request of determination at the children hospital and the academic institutions. Each institution considered this project quality improvement as this review will not produce new knowledge (Appendix C). Data were identified. All patient identifiers were removed. Data were entered into an encrypted excel data collection document and saved on a password protected computer.

Results

A total of 57 adolescent patients (age: 14.42 ± 2.35; weight: 61.35 ± 15.00; female: 75%) with idiopathic scoliosis were admitted to our hospital for surgical corrections requiring posterior spinal fusion during the timeframe of this project. The length of stay (inpatient unit) following the procedure was three days on average, with a range of two to five days. We found that adherence to the multimodal analgesic algorithm was met for acetaminophen (100% prescription rate; 15 mg/kg every 6-hours), ibuprofen (100% prescription rate; 10 mg/kg every 6-hours), diazepam (100% prescription rate; 0.05 mg/kg every 6-hours, as needed), and opioid analgesics (oxycodone or hydromorphone: 96% or 4% prescription rate; 0.1 or 0.01 mg/kg every 4-hours, as needed, respectively). However, we also found that adherence to the algorithm was only partially met for gabapentin (75% prescription rate, 5 mg/kg every 8-hours, as needed).

Following the surgical procedure, patients were initially prescribed 20 doses (± 4 doses) of opioids, on average, with a range of 10 – 30 doses. Twenty patients (35%) also requested refills and were prescribed 12 refill doses (± 5 doses), on average, with a range of 4 – 20 doses. Regarding the total number of opioid doses consumed, patients self-reported consuming 23 doses (± 10 doses), on average, with a range of 0 – 40 doses consumed. The average proportion of doses consumed (initial + refill doses) relative to the initial doses prescribed was 113%. Further, we did not find any significant associations between the demographic variables and total doses consumed nor between the demographic variables and refill doses prescribed (Table 1).

To evaluate the impact of diazepam and gabapentin on the total number of opioid doses consumed (and the number of refill doses prescribed), gabapentin was analyzed as a binary variable (prescribed or not prescribed) and diazepam was analyzed as a count variable (total number of diazepam doses consumed; self-report; obtained from the postoperative follow-up). This was based on observed prescription patterns, where all patients were prescribed diazepam (rendering it as a binary constant), but not all patients were prescribed gabapentin (rendering it as a binary variable). Concordantly, these patterns required us to evaluate how varying doses of diazepam impacted opioid trends, while also providing us with the opportunity to evaluate differences in opioid trends between patients who were or were not prescribed gabapentin. It is also of note that six patients did not provide diazepam use data during their postoperative follow-up visit and were excluded from analyses involving the total number of doses consumed.

Interpretation

Diazepam & Opioid Trends

The negative binomial regression model for diazepam provided no evidence of violations regarding the normality of the residuals nor homogeneity of variance and demonstrated better model fit over the standard equidispersion count model (X^2 [1] = 38.85, $p < 0.001$). Diazepam was found to have a significant and positive association with the total number of opioid doses consumed ($B = 0.017$, $p < 0.001$). Specifically, the model predicts that for each additional dose of diazepam consumed, the expected number of opioid doses consumed would increase by ~1.7%, on average (95% CI [0.9%, 2.5%]). Importantly, this

association remained consistent even when including all demographic variables in the model (B = 0.017, $p < 0.001$).

We then performed a sensitivity analysis on the number of opioid refills prescribed using a zero-inflated negative binomial regression model. The zero-inflated model for diazepam also provided no evidence of violations and presented better model fit compared to the non-inflated negative binomial model (X^2 [2] = 42.15, $p < 0.001$). Regarding the count sub-model (patients who requested opioid refills), diazepam was found to have a significant and positive association with the number of opioid refill doses prescribed (B = 0.015, $p < 0.001$). Specifically, the model predicts that for each additional dose of diazepam consumed, the expected number of opioid refill doses prescribed would increase by ~1.5%, on average (95% CI [0.6%, 2.4%]). For the zero-inflated sub-model (the likelihood of not requesting opioid refills), the coefficient was found to be negative and significant (B = -0.072, p = 0.004), suggesting that for each additional dose of diazepam consumed, the odds of not requesting opioid refills decreases by ~7%, on average (95% CI [2%, 11%]). As before, these associations remained consistent even when including all demographic variables in the model (B = 0.014, p = 0.006; B = -0.093, p = 0.003).

Gabapentin & Opioid Trends

The negative binomial model for gabapentin provided no evidence of violations regarding the normality of the residuals nor homogeneity of variance and demonstrated better model fit over the standard equidispersion count model (X^2 [1] = 92.95, $p < 0.001$). Gabapentin was found to have a positive association with the total number of opioid doses consumed (B = 0.263); suggesting that among patients who were prescribed gabapentin, the expected number

of opioid doses consumed was ~30% higher, on average, relative to patients who were not prescribed gabapentin. However, this association was non-significant (p = 0.124) and remained non-significant even when including all demographic variables (B = 0.249, p = 0.145).

We then performed a sensitivity analysis on the number of opioid refills prescribed using a zero-inflated negative binomial model. The zero-inflated model for gabapentin also provided no evidence of violations and presented better model fit compared to the non-inflated negative binomial model (X^2 [2] = 437.63, $p < 0.001$). Regarding the count sub-model (patients who requested opioid refills), gabapentin was found to have a positive but borderline non-significant association with the number of opioid refill doses prescribed (B = 0.379, p = 0.074); providing weak evidence that among patients who were prescribed gabapentin, the expected number of opioid refill doses prescribed was ~46% higher, on average, relative to patients who were not prescribed gabapentin. For the zero-inflated sub-model (the likelihood of not requesting opioid refills), the coefficient was found to be positive but non-significant (B = 0.038, p = 0.953), suggesting that being prescribed gabapentin does not impact the likelihood of not requesting opioid refills. As before, these associations remained consistent even when including all demographic variables in the model (B = 0.339, p = 0.120; B = 0.082, p = 0.902).

Discussion

In this project, an interdisciplinary team of pediatric specialists developed an algorithm for prescribing multimodal analgesics among adolescent patients with idiopathic scoliosis recovering from posterior instrumented spinal fusion surgery at an orthopedic inpatient unit. The algorithm was updated annually to reflect the best practices in this patient population, with

the goal of providing adequate postoperative pain management while also reducing the amount of opioids consumed following hospital discharge. We found that adherence to this algorithm was met for most analgesics (100% prescription rate for acetaminophen, ibuprofen, diazepam, and opioid analgesics), with the exception of gabapentin (75% prescription rate). Regarding opioid prescription and use patterns, adolescent patients were initially prescribed 20 doses of opioids and consumed 23 doses in total, on average, with only twenty patients (35%) requesting opioid refills. This suggests that these pediatric providers were prescribing an adequate number of opioid doses for pain management, without overprescribing, which could contribute to the ongoing opioid epidemic (Centers for Disease Control, 2023). Further, no patient consumed more than 40 doses of opioids, in accordance with the multimodal analgesic algorithm.

However, contrary to our expectations, we also noted trends indicating diazepam and gabapentin were associated with more opioid use. Although it is possible that prescribing diazepam and gabapentin could lead to more opioid use in this patient population, it seems reasonable to assume these trends could be the result of a confounder that was unaccounted for in our models, the level of pain experienced by the patient. In other words, pain could be the common denominator, with patients who are in more pain using more diazepam, gabapentin, and opioids (whatever analgesics were available) to provide adequate pain relief. Further, when a patient was still in severe pain, our clinicians prescribed more doses of diazepam, gabapentin, and opioids, also in accordance with the multimodal analgesic algorithm. Therefore, caution is warranted when interpreting our findings, as research is needed to better understand these trends. For instance, past research using a blinded

randomized controlled trial design has shown that prescribing gabapentin reduces opioid use in this patient population (Anderson et al., 2020). This highlights the possibility that if these patients were prescribed unimodal opioid-based analgesia, their overall opioid use would have been higher (being the only analgesic available), with some patients exceeding the 40-dose limit afforded by the multimodal algorithm; increasing the risk of prolonged opioid use that is prevalent in this population (Yang & Wener, 2019).

Pediatric providers who care for adolescents with idiopathic scoliosis face a significant challenge, providing adequate postoperative pain management while also minimizing the use of opioids. This is critical as inadequate pain management and overprescribing opioids have both been shown to lengthen postoperative recovery periods, contribute to patient dissatisfaction, and increase the risk of long-term complications (e.g., chronic post-surgical pain and dependence, respectively; Lee et al., 2020; Yang & Wener, 2019). Overall, our findings were in line with past research suggesting multimodal analgesia is an effective approach for providing adequate postoperative pain management in this patient population (Ahdoot et al., 2021; Gornitzky et al., 2016; Lee et al., 2020; Murdock & Hylton, 2023; Rosenberg et al., 2017; Ye et al., 2020). Further, our findings could support the notion that this approach is effective not only during hospital stays but also, post-discharge, with the potential to minimize opioid use relative to unimodal opioid-based analgesia (American Association of Nurse Anesthesiology, 2018).

Strengths

Strengths of this project include the multimodal analgesic algorithm that was developed by an interdisciplinary team of pediatric specialists and updated annually to reflect the best practices in this patient population. We also considered the impact of various multimodal analgesics (diazepam and gabapentin) on opioid trends and conducted sensitivity analyses to better understand these associations in the context of our specific aims. Further, the composition of our sample was relatively concordant with the broader prevalence observed among adolescent patients with idiopathic scoliosis (higher prevalence among females; Thomas et al., 2021).

Limitations

There were significant limitations to this project that must be considered when interpreting our findings. First, data were obtained from cross-sectional and retrospective chart reviews, limiting causal inferences regarding the effectiveness of the multimodal algorithm in reducing opioid consumption post-discharge. It is without question that we did not account for many relevant confounders that could have influenced the observed trends (e.g., subjective pain experienced by the patient, the severity of the diagnosis, surgical factors, patient satisfaction). Second, opioid use was obtained from self-reports which are prone to recall and other biases, could not be authenticated, and introduced missing data. Further, patients were seen at a single inpatient unit, with a limited sample size, patient diversity, and follow-up durations (~15 days following the procedure), and no comparison group who received unimodal opioid-based analgesia. Third, even though our providers adhered to the multimodal algorithm,

variations in postoperative pain management were evident as a result of provider preferences that were not accounted for in this project. To this end, we did not collect data on other contextual factors, including psychosocial factors that could impact pain experiences (e.g., individual thresholds), patient responses to these analgesics (e.g., side effects, contraindications, resistance), the use of non-pharmacological strategies for pain management (e.g., stretching, ice packs, massage), and the conditions of the outpatient environment (e.g., socioeconomic status, social support, school status, insurance status, familial attitudes, exposure to substance abuse, other risk factors).

Despite these limitations, our findings suggest that this multimodal analgesic algorithm could be an effective approach for providing adequate pain management post-discharge, among adolescent patients with idiopathic scoliosis. These findings also underscore the need for clinical teams to monitor patient outcomes and adapt practices to ensure that their patients are receiving the highest quality of conceivable care. Further, the success of these endeavors often hinges on interdisciplinary collaborations, where all team members are wholeheartedly dedicated to implementing, maintaining, and advancing evidence-based and best practice standards.

Clinical Implications

The implications of this project also extend beyond the immediate context of postoperative pain management in this patient population, supporting a growing body of evidence that multimodal analgesia could be effective strategy to alleviate pain, with the potential to mitigate the risks of opioid use (e.g., Cozowicz et al., 2020; Memtsoudis et al.,

2018). This approach, particularly in pediatric settings, emphasizes the need for a more judicious use of opioids and an appropriate balance between adequate pain relief and opioid stewardship. Further, our project also highlight the importance of patient-centered approaches for pain management, tailored to the individual needs and responses of each patient, leading to better outcomes, satisfaction, and care experiences (American Association of Nurse Anesthesiology, 2018). These implications are also particularly relevant for nurses, who are integral to the success of multimodal analgesic strategies given their direct involvement in patient care, in addition to often being the first point of contact for patients who are experiencing pain. Nurses are also well-positioned to educate patients and their families about pain management (e.g., the risks of opioid analgesics, non-pharmacological strategies for management pain, reinforcing management goals) which is essential to ensure the success of multimodal analgesic protocols.

Regarding future directions, research is needed to understand the impact of multimodal analgesia (e.g., diazepam and gabapentin) on opioid trends in this patient population and beyond (Seki et al., 2018). This could include longitudinal quasi-experimental trials to compare patient outcomes between clinical teams that already are using multimodal analgesia or opioid-based analgesia for postoperative pain management (e.g., Ye et al., 2020), in addition to employing a more extensive range of variables (e.g., patient-specific and contextual factors) among larger and more diverse patient samples. Future research is also needed to better understand the risks associated with multimodal analgesia strategies, including contraindications (Lee et al., 2020). For instance, there are many significant risks associated with diazepam (e.g., dependence risks, withdrawal symptoms, respiratory depression, cognitive

and motor impairment) that could be exaggerated when prescribed in conjunction with opioids (boxed warning; Dhaliwal et al., 2023). In terms of clinical practice, there will always be an opportunity to refine and standardized multimodal analgesia protocols, ensuring their adaptation to different patient needs while maintaining a consistent standard of care (American Association of Nurse Anesthesiology, 2018). In the realm of education, ongoing training for clinical teams in multimodal analgesia principles and practices are essential to ensure the latest evidence-based standards are seamlessly integrated into patient care approaches.

Conclusion

Reflecting on this project, it seems that multimodal analgesic strategies are a promising approach for managing postoperative pain among adolescent patients with idiopathic scoliosis. However, research is needed to understand the potential impact and risks of these strategies for minimizing opioid use post-discharge, particularly regarding multimodal analgesics such as diazepam and gabapentin. This project contributes to the evolving conversation on postoperative pain management in pediatric healthcare, emphasizing the need for innovative, patient-centered approaches in the context of the opioid epidemic, while advocating for broader applications and ongoing refinement in this patient population and beyond.

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Tables

Table 1.
Demographic Characteristics

	Mean ± SD or N (%)[1]					
	Quarter 1 (n = 14)	Quarter 2 (n = 18)	Quarter 3 (n = 16)	Quarter 4 (n = 9)	Total (n = 57)	*p*
Key Demographics						
Age (Years)	13.86 (2.18)	14.44 (2.04)	14.75 (2.72)	14.67 (2.73)	14.42 (2.35)	0.76
Gender (Female)	11 (79%)	14 (78%)	12 (75%)	6 (67%)	43 (75%)	0.90†
Weight (Kg)	57.86 (11.96)	60.83 (14.67)	62.13 (12.12)	66.44 (23.59)	61.35 (15.00)	0.69‡
Diagnosis (AIS)	13 (93%)	18 (100%)	13 (81%)	8 (89%)	52 (91%)	0.22†
Surgery						
Starting Location (T1-T5)	11 (85%)	16 (89%)	12 (75%)	7 (78%)	46 (82%)	0.74†
Length of Stay (Days)	3.14 (0.86)	2.94 (0.87)	2.81 (0.75)	2.50 (0.53)	2.89 (0.80)	0.33
Oxycodone Medication						
Prescribed	13 (93%)	17 (94%)	16 (100%)	8 (100%)	54 (95%)	0.81†
Valid Data[2]	13 (100%)	15 (88%)	10 (63%)	0 (0%)	38 (100%)	***†
Mg/Kg Per Dose	0.09 (0.02)	0.09 (0.02)	0.09 (0.01)	---	0.09 (0.02)	0.77
Initial Doses Prescribed	22.77 (5.61)	19.40 (1.84)	18.8 (3.16)	---	20.39 (4.12)	0.12‡
Initial Doses Used	18.84 (7.00)	15.77 (5.85)	17.00 (5.91)	---	17.14 (6.25)	0.44
Refills Requested	3 (23%)	7 (47%)	3 (30%)	---	13 (34%)	0.43†
Refill Doses	1.85 (4.30)	5.67 (6.65)	4.00 (6.99)	---	3.92 (6.11)	0.21‡
Total Doses Used	20.69 (8.21)	21.43 (10.90)	21.00 (10.51)	---	21.07 (9.68)	0.98
Valium Medication						

Prescribed	14 (100%)	18 (100%)	16 (100%)	9 (100%)	57 (100%)	---
Valid Data[2]	14 (100%)	14 (78%)	10 (63%)	0 (0%)	38 (67%)	***†
Initial Doses Prescribed	23.00 (12.02)	30.57 (7.54)	27.00 (6.75)	---	26.84 (9.63)	0.11
Initial Doses Used	18.93 (9.71)	24.00 (14.13)	20.10 (13.02)	---	21.12 (12.24)	0.54
Refills Requested	3 (21%)	6 (43%)	3 (30%)	---	12 (32%)	0.47†
Refill Doses	2.79 (6.75)	6.71 (9.60)	3.00 (4.83)	---	4.29 (7.59)	0.33
Total Doses Used	21.71 (14.10)	30.71 (20.34)	23.10 (16.09)	---	25.39 (17.19)	0.35
Analgesic Medication						
Acetaminophen Prescribed	14 (100%)	18 (100%)	16 (100%)	9 (100%)	57 (100%)	---
Ibuprofen/ Toradol	14 (100%)	18 (100%)	16 (100%)	9 (100%)	57 (100%)	---
Other Medications						
Gabapentin	10 (71%)	13 (72%)	13 (81%)	7 (78%)	43 (75%)	0.92†
Methadone	11 (79%)	15 (83%)	12 (75%)	7 (78%)	45 (79%)	0.97†

Appendix A

Project Timeline

	Spring 2023	Summer 2023	Fall 2023	Winter 2024	Spring 2024
Finalize Project Planning, SQUIRE Sections 1-12 (703A)	X				
IRB Determination Request		X			
Letter of Stakeholder Support	X				
Create Chart Review Checklist		X			
Conduct Chart Review			X		
Finalize Data Analysis, SQUIRE Section 13 (703B)			X	X	
Share Findings with Multidisciplinary Team/ Seek Input				X	
Finalize Project Discussion, SQUIRE Sections 13-18 (703B)				X	
Prepare for Project Presentation				X	
Project Result Dissemination Locally & Nationally				X	X

Appendix B

Chart Review Checklist

Key Demographics
Age (Years)
Gender (Female)
Weight (Kg)
Diagnosis (AIS)
Surgery
Starting Location (T1-T5)
Length of Stay (Days)
Oxycodone Medication
Prescribed
Mg/Kg Per Dose
Initial Doses Prescribed
Initial Doses Used
Refills Requested
Refill Doses
Total Doses Used

Valium Medication
Prescribed
Initial Doses Prescribed
Initial Doses Used
Refills Requested
Refill Doses
Total Doses Used
Other Medications
Gabapentin
Methadone

Appendix C

Letter of Support from Clinical Agency

Letter of Support from Clinical Agency

Date: *5/30/2023*

Dear *Ahmed Abdul Rahman*,

This letter confirms that I, Nancy Jacobs, allow *Ahmed Abdul Rahman* (OHSU Doctor of Nursing Practice Student) access to complete his DNP Final Project at our clinical site. The project will take place from approximately *June 2023* to *March 2024*.

This letter summarizes core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s):**
  - Shriners Children's Portland
  - 3101 SW Sam Jackson Park Rd, Portland OR 97239
- **Project Plan: Use the following guidance to describe your project in a brief paragraph.**

Treatment protocols for pain in children are primarily extrapolated from adult intervention without any strong evidence of value in pediatrics (Linhares MBM, et al). Pediatric postsurgical pain management challenges continue despite advancements in surgical techniques, multimodal approaches, and advanced pain management techniques. Opioids are the "gold standard" for the treatment of moderate/severe pain despite the significant side effects (Harbaugh, et al, 2018) – Persistent opioid use (between 3-6 months) was found in ≈5% of adolescents after surgery. Adverse events associated with opioids, can negatively impact patient comfort and recovery (Chidambaran, 2017; Horton,2019; Monitto, 2017) The use of PCA and pumps and catheters to prolong analgesia are cumbersome and can carry significant risks. use of Basic analgesia (e.g. paracetamol/acetaminophen, NSAIDs, COX-2 inhibitors) as well as adjuvant analgesics gabapentin) postoperatively is the current practice recommendation that aid in reducing the need for opioid.

This project will entail the following:
Phase 1: Assess current pain management practices including opioid use as well as basic and adjuvant analgesia (chart review)
Phase 2: Compare and contrast existing practices with the best evidence available on multimodal pain management in children & adolescents diagnosed with Idiopathic Scoliosis
Phase 3: Develop and share recommendations with the clinical agency

During the project implementation and evaluation, *Ahmed Abdul Rahman* wil provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP p If we have any concerns related to this project, we will contact *Ahmed Abdul Rahman <abdulahm@ohsu.edu>* and *Dr. Lynne-Kim Yang* (student's DNP Project Chairperson) *<kimyang@ohsu.edu>.*

Regards,

Nancy Jacobs, MSN, CNS, APRN

5/31/2023
Date Signed

Appendix D

IRB Approvals

1) **Shriners Hospital for Children**

From: CRSTsubmissions <CRSTsubmissions@shrinenet.org>
Date: Tuesday, August 8, 2023 at 10:01 AM
To: Sienko, Susan
Subject: RE: Request for determination
RE: Determination of Research- Quality Improvement
Improving Postoperative Pain Management after Posterior Spinal Instrumented Fusion for Idiopathic Adolescent Scoliosis
Responsible Party: Nancy Jacobs, MSN, CNS, DNP, Project Preceptor
Site: SHC-POR

The project referenced above has been reviewed by Research Programs to determine if the project meets the threshold of research involving human subjects. It is the regulatory opinion that the project does not meet the definition of research and as such does not need to be reviewed by a formal IRB. The activities described in the summary submitted are limited to: (a) implementing a practice to improve the quality of patient care, and/or (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes. These activities do not meet the definition of research under 45 CFR 46.102(d) and therefore, the HHS regulations for the protection of human subjects do not apply to such quality improvement activities.

As this project will not be reviewed by an IRB, it important to understand that any PHI you use and/or disclose will not be covered under a *HIPAA Authorization to Use and Disclose Information Under Research*. This data needs to be collected per SHC clinical policies, limiting the use of PHI according to the *Minimum Necessary* standard and appropriately safeguarding the data. If you have any questions regarding the use and disclosure of PHI in association with this quality improvement, please contact the Corporate Privacy & Security Officer.

If there is intent to publish any work conducted under this project, the following statement should be included in any publication: "*This project was undertaken as a Quality Improvement Initiative at Shriners Hospitals for Children and, as such, was not formally supervised by an Institutional Review Board."* With this in mind, it is important to note that the determination of non-research is for the objectives and process as stated. At the time manuscript preparation, the project cannot be rewritten to fit the objectives of a potential journal, e.g. patient centric. When this happens, the article often ends up describing a research question/process for which you have no IRB approval and/or HIPAA Research Authorization.

Please note that any future changes to the project may affect the project's determination. If changes are made to the project, you will need to resubmit to HQ prior to implementing any changes.

Thank you,
Shannon Terkoski, RN, MS, CCRP
Corporate Director, Clinical Research
Department of Research Programs

Shriners Children's, International Headquarters
2900 Rocky Point Dr.
Tampa, FL 33607

2) **OHSU IRB**

From: Electronic IRB <eirb@ohsu.edu>
Sent: Friday, October 6, 2023 2:03 PM
To: Sharon Norman

Template:IRB_T_Post-Review_NotHumanResearch

Notification of Not Human Research Determination

To:	Sharon Norman
Link:	STUDY00026429
P.I.:	Sharon Norman
Title:	Pain Management Post Spinal Fusion in Adolescents
Description:	The committee reviewed this submission and assigned a determination of Not Human Research. For additional details, click on the link above to access the project workspace.

Appendix E

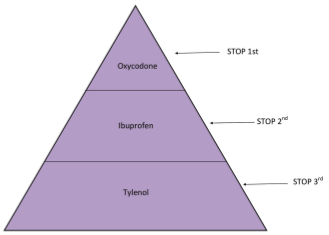
ALGORITHM FOR OPIOID PRESCRIBING

- Optimize use of non opioid-analgesic
  - Around-the-clock use of Tylenol and Ibuprofen (may be given together)
  - Check with surgical attending for contraindications
- Avoid combination products (eg, Lortab, Norco, Percocet).
- Consider analgesic adjuncts (eg, Valium, Gabapentin, Clonidine)
- Opioid therapy must be accompanied by multi-modal analgesia AND non-pharmacological strategies of pain management.
- Consider nerve block or neuraxial anesthesia

- Optimize non-pharmacological measures
  - Refer to Child Life Specialist or Psychologist
  - Music therapy, pet therapy, massage, aromatherapy
  - Age-appropriate apps for mind-body work
  - Physical rehabilitation
  - Emphasize functional recovery
- Conduct risk assessment of opioid misuse/abuse/diversion and PDMP screening
  - patients < 12 years old: Family risk assessment
  - patients > 12 years old: CRAFFT tool
- Early screening for psychosocial risk factors that impact pain experience

MINOR PROCEDURES	**MILD PROCEDURES**	**MODERATE PROCEDURES**	**SEVERE PROCEDURES**
Tylenol 15 mg/kg q 6 hours x 1-2 days, then as needed* *may be given together with* Ibuprofen 10mg/kg q 6 hours x 1-2 days, then as needed** Opioid analgesics	Tylenol 15 mg/kg q 6 hours x 2-3 days, then as needed* *may be given together with* Ibuprofen 10 mg/kg q 6 hours x 2-3 days, then as needed** Oxycodone 0.1 mg/kg q 4 hours PRN for up to 15 doses (3 days) Pills: round down to nearest whole mg Oxycodone elixir concentration 1 mg/ml Consider nerve block or neuraxial anesthesia	Tylenol 15 mg/kg q 6 hours x 4-5 days, then as needed* *may be given together with* Ibuprofen 10 mg/kg q 6 hours x 4-5 days, then as needed** Oxycodone 0.1 mg/kg q 4 hours PRN for up to 25 doses (5 days) Pills: round down to nearest whole mg Oxycodone elixir concentration 1 mg/ml Consider Valium 0.05 mg/kg q 6 hours PRN for spasm Valium elixir concentration 1 mg/ml Consider nerve block or neuraxial anesthesia	Tylenol 15 mg/kg q 6 hours x 6-7 days, then as needed* *may be given together with* Ibuprofen 10 mg/kg q 6 hours x 6-7 days, then as needed** Oxycodone 0.1 mg/kg q 4 hours PRN for up to 40 doses (7 days) Pills: round down to nearest whole mg Oxycodone elixir concentration 1 mg/ml Consider Valium 0.05-0.1 mg/kg q 6 hours PRN for spasm Valium elixir concentration 1 mg/ml Consider Gabapentin 5 mg/kg (max 200 mg for < 60 kg, max 300 mg for > 80 kg) q 8-12 hours for up to 14 days Consider nerve block or neuraxial anesthesia
0 **Minor** ***No opioids recommended***	**1** **Mild: 2-3 days** ***Up to 10 doses of opioids***	**2** **Moderate: 3-5 days** ***Up to 25 doses of opioids***	**3** **Severe: 7 days** ***Up to 40 doses of opioids***
Arthrogram Arthroscopy (diagnostic) Cast change Closed reduction (elbow, forearm, finger) Dental extraction EUA External fixation removal Halo application Hardware removal (incision <1 cm) Ingrown toenail repair Irrigation and debridement Joint aspiration Mehta cast application Percutaneous Achilles lengthening/tenotomy (clubfoot) Percutaneous pinning Simple polydactyly Steroid injection Suture removal Tendon or soft tissue procedure Trigger finger release	Accessory navicular excision Alveolar cleft bone graft Anterior tibial tendon transfers Bone cyst curettage /packing Cleft lip Epiphysiodesis (screw) Ganglion cyst excision Green transfer Hamstring lengthening Hardware removal (incision >1cm) Hemi-epiphysiodesis Iliopsoas release Knee arthroscopy for meniscus repair LeFort and/or Sagittal split osteotomy Nuss bar removal ORIF (elbow, humerus, radius, ulna) Osteochondroma excision Palatoplasty/ pharyngoplasty Pinning SCFE Plantar fascia release Tarsal coalition excision Toe reconstruction (e.g. hammertoe or arthrodesis)	Ankle arthroscopy Calcaneal osteotomy Complex polydactyly (ray excision) Drill epiphysiodesis Fasciotomy Hand reconstruction (hand osteotomy/fusion) Hemivertebrectomy Humerus osteotomy IM nail Knee arthroscopy, MPFL reconstruction MAGEC rods placement and revision Macrodactyly MPFL reconstruction Nuss Procedure (with cryoablation) Radius osteotomy Rotationplasty Rotator cuff repair Short segment spine fusion revision Soft tissue foot reconstruction w/minor bone osteotomies, includes midfoot posteromedial release) Ulnar osteotomy Vulpius tendon lengthening	Acetabuloplasty (Dega/Pemberton/Shelf) Advancement of trochanter ACL reconstruction Amputation of limb Anterior release (with instrumentation or w/PSF) Femur osteotomy Hindfoot arthrodesis Hip/pelvic osteotomy Hip arthroscopy for labral repair Long bone osteotomies Multiple foot osteotomies Nuss Procedure (without cryoablation) ORIF (ankle, clavicle, femur, hip, pelvis) Osteotomy with Ex-fix application Posterior Spine Fusion Sprengle's repair Tibial/Fibular osteotomy (ORIF or ex-fix) Vascular malformation reconstruction

PYRAMID OF DISCONTINUATION:



EDUCATE FAMILY:

- Safe storage of opioid medication
- Proper disposal of unused of opioid/ prescription medication
- Bowel regimen

*Tylenol 10 mg/kg for infant 1-6 months
**Ibuprofen 10 mg/kg only > 6 months

Appendix F

Recommendations Based on Pain Management Data Analysis

Following a comprehensive data analysis of our inpatient unit's pain management practices and best practice published guidelines, we have identified several key findings and recommendations that can contribute to enhancing patient outcomes and aligning with best practices in pain management.

Adherence to Multi-Modal Pain Management Guidelines:
Our analysis indicates commendable adherence to evidence-based guidelines for prescribing opioids, valium, acetaminophen, and non-steroidal anti-inflammatory drugs (NSAIDs) in post-PSI surgery pain management. This consistency reflects a commitment to providing comprehensive care and aligning with established best practices.

Addressing Gaps in Gabapentin Prescribing:
We observed a discrepancy in adherence to guidelines concerning gabapentin prescription. We recommend a closer examination of this aspect and consideration of strategies to improve compliance, ensuring that patients receive the full spectrum of recommended pain management modalities.

Investigating the Relationship Between Gabapentin, Valium, and Opioid Use:
The data reveals an intriguing relationship between the use of gabapentin and valium in conjunction with opioids. We propose conducting a more in-depth investigation into this relationship to understand potential correlations and implications for patient care. This analysis could shed light on optimal pain management strategies and contribute to refining our current practices.

Figure 1.
Multimodal Analgesic Algorithm