Protocol Development in the OR: Lessons Learned

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Introduction of the Problem

Clinical management from the Joint Commission on Accreditation of Healthcare Organization and The Joint Commission has led to the development of standards for pain evaluation and management (Elvir-Lazo & White, 2010). Proactive, multi-modal analgesia planning in the pre-operative period is an important consideration when controlling post-operative pain in order to optimize patient recovery (American Society of Anesthesiologists [ASA] Task Force on Acute Pain Management, 2012). A small community hospital in Central Illinois that was not utilizing multi-modal pain protocols expressed interest in the development of a protocol for laparoscopic cholecystectomy procedures for use at their facility.

Literature Review

Laparoscopic cholecystectomies have become the gold standard in treatment of gallbladder disease (Al-Qahtani, Alam, Asalamah, Akeely, & Ibrar, 2015). While ambulatory laparoscopic cholecystectomy procedures are beneficial for many reasons, pain may remain severe in 13% of patients undergoing cholecystectomies throughout the first week after the procedure (Bisgaard, 2006). Intense post-operative pain can lead to overnight hospital admissions which increases recovery time and may even lead to chronic pain, which is an unfortunate incidence occurring in 3-6% of patients (Blichfeldt-Eckhardt, Ørding, Andersen, Licht, & Toft, 2014). The term central sensitization is used to describe the phenomena of wind-up, long-term potentiation, and secondary hyperalgesia (Bridgestock & Rae, 2013). It provides the neurobiological basis for much of the pain suffered by patients long after normal tissue healing (Vadivelu et al., 2014). Patients receiving an opioid prescription within 7 days post-operative are 44% more likely to become long-term opioid users than those who received no
prescriptions (Alam et al., 2012). Although opioids have their use in pain management, they are associated with side effects that can delay the recovery of patients (Bisgaard, 2006).

The goal of the multi-modal approach is to reduce sensitization caused by pain and decrease long-term pain sensitivity at the peripheral and central levels (Vadivelu et al., 2014). Multi-modal techniques for pain management by definition includes the administration of two or more medications that have different mechanisms by means of the same route or different routes (ASA Task Force on Acute Pain Management, 2012). It is important that the medications given provide analgesia at one or more sites along the pain pathway (Gottschalk & Smith, 2001). The ASA Task Force on Acute Pain Management (2012) provided results from a survey noting that 71.7% of anesthesiologists strongly agree that a multi-modal approach to pain management should be utilized and 73.6% strongly agree that anesthesiologists should provide analgesia services within the framework of Acute Pain Services and participate in developing standardized institutional policies and procedures. Based on a critical analysis of current literature, the multi-modal approach should include at minimum a single dose of dexamethasone and regular use of nonsteroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase-2 (COX-2) inhibitors combined with continued, around the clock dosing of NSAIDs, COX-2 inhibitors, or acetaminophen for 3-4 days post-operatively (Bisgaard, 2006). Dosing regimens including the choice, route, medication, and duration should be individualized based on patient requirements or contraindications (Bisgaard, 2006).

Methodology

Purpose and Goals
This project is a non-experimental design that implements a multi-modal pain protocol for patients undergoing a laparoscopic cholecystectomy in order to review its utility by clinicians. While the overall goal of implementing a preventative multi-modal pain protocol was to reduce narcotic use and the potential of chronic pain, the main goal of this project was to determine the ease of use and feasibility of the protocol by clinicians during a 10 week implementation period for laparoscopic cholecystectomy procedures.

**Setting/Target Group**

The project’s setting was at a small community hospital in Central Illinois. All clinicians directly involved in the care of patients undergoing laparoscopic cholecystectomy procedures willing to participate in the use of the protocol was utilized in the sample size. Stakeholders include pre-operative nurses, post-operative nurses, CRNAs, anesthesiologists, surgeons, and pharmacists. Consent to participate was validated by accepting and completing the paper surveys.

**IRB Information**

Expedited IRB approval was obtained on April 10, 2017 at Southern Illinois University Edwardsville.

**Tools and Measures**

The evaluation process involved administration of a 15 question, 5-point Likert –type scale in which participating clinicians indicated their level of agreement or disagreement with each statement, with a not applicable option for those stakeholders in which the question does not apply. There are designated sections for each stakeholder for more applicable questions. Stakeholder demographics including type of provider, age, and years in practice was collected in
order to make comparisons. Objective comments about the protocol were made in the comments section. All surveys collected after the full implementation period of 10 weeks were reviewed by author and statistician for analysis.

**Resources and Threats**

The only resources required were the stakeholders time and paper in order to print the protocol and surveys. The only cost acquired was the use of paper. The major subject risk is loss of anonymity, as demographics of the stakeholders were collected in order to provide comparisons. All stakeholders’ email addresses were also acquired in order for an email to be sent out through the hospital’s intranet.

**Evaluation**

Although the chief CRNA attended board meetings along with the chief anesthesiologist and chief of general surgery in order to gain approval, the project leader was not there to hear or address any questions or concerns. While pre-approval of the protocol was gained, the subsequent meetings conducted by the project leader were not optimal. These meetings were conducted in a lounge area where there were multiple interruptions. Attending meetings one-on-one with each department two months prior to implementation and sending out reminders one month prior to implementation was not adequate, as some of the stakeholders were not present. Although the chief of surgery was supportive of the project, he was not the surgeon of record for any of the cases trialing this new protocol. An attempt was made to educate the surgeon of record on the day the surgery was scheduled, but it was difficult to calmly cover the information minutes before the surgery and address any questions.
The partner anesthesiologist (who was not present during discussions about the protocol) was available during the scheduled cases, not the chief anesthesiologist who approved the protocol. This did not affect the implementation process significantly, as the CRNAs were in charge of ordering the medications prior to the case. No issues were noted with the CRNAs, pre-operative or post-operative nurses during the implementation period, as they verbalized a clear understanding of their role. The two pharmacists that the project leader met with initially were informed of the pre-operative medications that needed to be stocked, yet the medications were not available in the Pyxis on the day of implementation. This resulted in the nurse needing to pick up the medications from the pharmacy. The lack of familiarity with the facility, surgical staff, physicians, and support staff made the process somewhat daunting to the project leader.

Obtaining a list of all potential stakeholders that would be involved in the implementation of the protocol would have been beneficial in order to ensure all participants were educated about the project prior to implementation. Involvement of the project leader in the initial meetings with each department at scheduled department meetings where all stakeholders would be available could have resulted in the development of a stronger support system throughout the implementation process and allowed for more in-depth conversations in a controlled environment. Since two of the pharmacists expressed interest in the protocol, it would have been beneficial to ask them to accompany the project leader to other department meetings in order to aid in answering questions regarding medications on the protocol and provide support.

Although the project leader’s literature review and protocol were left on a table in the physician lounge, it was unknown if any of the medical staff stopped to read the information. Drafting a short information sheet in bullet point form and posting key points in high traffic areas would have been more reader-friendly and would have increased the chance that the protocol
would have been reviewed. Additionally, reaching out to medical records to help determine an approximate number of laparoscopic cholecystectomies scheduled monthly would have allowed for a better projection on the time period needed for the implementation process.

**Impact on Practice**

Although the implementation involved only one case, which made evaluating the efficacy of the protocol difficult, the project leader gained a greater understanding of the extensive work required before implementation. By utilizing appropriate measures and time prior to implementation, there is a higher chance for full involvement of all stakeholders and greater success of a quality improvement project. While there was no immediate impact at the facility, it did require clinicians to utilize a variety of medications other than narcotics for pain control and hopefully encouraged the use of a multi-modal approach to pain in their future practice.

**Conclusions**

While an ideal combination of medications has not been established, it would be practical and timely to assess evidence-based interventions in order to develop protocols that promote a successful discharge within an appropriate time period that allows the patient to return to a normal life as soon as possible (Blichfeldt-Eckhardt et al., 2014). Proper peri-operative management of pain must have a community approach that involves multiple healthcare personnel and effective communication between team members (Elvir-Lazo & White, 2010).

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