Official Title: Toward Zero Prescribed Opioids for Outpatient General Surgery Procedures: a Prospective Cohort Trial

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Title of Project: Opioid Free General Surgery

Introduction and Background: Laparoscopic general surgery is the mainstay of treatment for benign biliary disease, including symptomatic gallstones. While laparoscopic cholecystectomy is generally considered less painful than open surgery, pain is one of the reasons for delayed discharge and overnight admission after outpatient surgery. To optimize same day discharge, patients are routinely prescribed narcotic pain medication. There has been a dramatic rise in prescription opioid abuse along with the associated morbidity and mortality, with a major contributor being the diversion of excess, unused prescriptions. Thomas Jefferson University Hospital has recently implemented guidelines for the recommended dosage and length of time of opioid pain medications to prescribe after general surgery procedures.

During the last two decades, there has been an increase in the implementation of Enhanced Recovery After Surgery (ERAS) pathways, which includes a focus on multimodal pain management. This component allows for the optimization of patient recovery and may assist with the reduction of opioid utilization.

We plan to assess the impact of implementing a new standardized multimodal pain care bundle on postoperative pain control and patient satisfaction for elective, outpatient laparoscopic cholecystectomy procedures.

Primary Objective: We aim to assess whether implementation of a multimodal pre-, intra-, and postoperative enhanced recovery bundle can result in the decrease of postoperative opioid use in patients undergoing elective laparoscopic cholecystectomy.

Secondary Objective: We will also assess patient satisfaction with the overall quality of pain management after the procedure and patient function in the first and second postoperative weeks. Patient-reported average pain level in the first 7 postoperative days; patient satisfaction with the overall quality of pain management after operation; patient ability to return to daily activities and work in the first and second postoperative weeks; phone call to clinic secondary to pain; return to the ED secondary to pain, return to the clinic secondary to pain; if prescription is filled, morphine equivalents utilized by patients

Study Design: Prospective, cohort study

Other Predictors: age, sex, race, Comorbidity/Charlson Comorbidity Index, complications, SSI

Inclusion Criteria: Elective procedure, urgent/emergent procedure discharged within 24 hours, no major cardiac, respiratory, or renal conditions, no advanced liver disease (Child A acceptable), opioid naïve, BMI less than 45, previous abdominal surgeries, previous cholecystostomy tube, age less than 70 years

Exclusion Criteria: Open procedure, Child B liver disease or above, opioid tolerant, BMI greater than 45, age greater than 70 years

Methods:

Patients who undergo elective laparoscopic cholecystectomy or emergent/urgent laparoscopic cholecystectomy discharged within 24 hours will be included. We plan to review 25 patients in the pre-intervention cohort and 100 patients for the intervention.

The intervention involves the implementation of patient education; healthcare provider education (surgeons, anesthetists, residents, nurse practitioners, and nurses); and preoperative, intraoperative, and postoperative multimodal analgesia with opioid reduction strategies. Patients are to receive verbal and written education on expectations surrounding pain and discomfort after the procedure, instructions on optimal use of multimodal analgesic medications, and contact information of the provider team if pain is not controlled. Healthcare providers, including surgeons, anesthetists, residents, nurse practitioners, and nurses will be educated in large group formats (divisional rounds, nursing meetings) and through email. Education will focus on understanding the need for opioid reduction, multimodal analgesic strategies, and supporting patient/caregiver expectations.

Patients will receive a preoperative multimodal oral pain regimen of ibuprofen 800mg, acetaminophen 1000mg, and pregabalin 75 mg in the Short Procedure Unit (SPU) administered by nursing.

Intraoperatively, the anesthesiologist will minimize opioid use by utilizing IV lidocaine and IV ketamine administration. We will follow along with the agreed upon PONV interventions.

The surgeon will inject local anesthesia into the trocar sites prior to insertion of the trocars. The anesthesiologist will administer ketorolac 30 mg IV at the end of the case, once confirmed with surgeon that it is appropriate based on difficulty of case.

In the PACU, the patient's pain will be assessed at one hour and two hours postoperatively by the PACU nurse.

Upon discharge, patient will receive detailed instructions on how to utilize ibuprofen and acetaminophen postoperatively for 7 days and who to contact if the pain is not well-controlled. A prescription for ibuprofen 800 mg tid x 21 pills will be written in addition to acetaminophen 1,000 mg qid x 28 pills. The patient will receive a phone call at POD 1 and POD 7 from a nurse/student and a brief survey will be administered to assess pain, return to daily activity, and return to work. The patient will follow-up in the clinic at POD 14. At this time, the patient will complete an SF-12 assessment in the clinic waiting room and pain will be assessed by the surgeon. A final follow-up call will be made at 30-days postoperatively by nurse/student to assess pain, return to daily activity and work.

If patient's pain is not well-controlled on prescribed regimen, second line treatment can be Tramadol 50 mg q6 hours x 8 pills (40 morphine mg equivalents) or oxycodone 5 mg q8 hours x 6 pills (45 morphine mg equivalents).

A detailed timeline that will be followed for each patient is outlined below:

Baseline Visit – Enrollment and Initiation of ERAS Pathway

Enrollment

Measure vitals, height, weight (BMI)

Demographics

PMH, PSH, History of opioid use

Laparoscopic Cholecystectomy (Outpatient Procedure)
Preoperative Regimen - At Home

NPO at midnight vs 4-6 hours prior

Review patient education handout

Ambulation, breathing exercises

Laparoscopic Cholecystectomy (Outpatient Procedure)
Preoperative Regimen – SPU/Holding

Receive ibuprofen 800 mg x 1 dose, acetaminophen 1,000 mg x 1 dose, pregabalin 75 mg x 1 dose

Laparoscopic Cholecystectomy (Outpatient Procedure)
Intraoperative Regimen

Anesthesia: dexamethasone 8mg, lidocaine infusion, ketamine
Trocar site injection with local anesthesia (bupivacaine 0.25-0.5%) prior to placement
Ketorolac (30 mg IV) at end of case

Laparoscopic Cholecystectomy (Outpatient Procedure)
Postoperative Regimen

PACU:

No fentanyl

Need to change postop Anesthesia PACU order set

Pain Assessment at 1 hour, 2 hour by APMS nurse

Discharge:

Detailed instructions

Postoperative Follow-up Visits

Assessment of complications/patient reported outcomes at each call/visit

Nurse/NP/Student (POD 1)

Phone call, brief survey on pain

Nurse/NP/Student (POD 7)

Phone call, brief survey on pain

Surgeon (2 weeks postop)

SF12 to be completed in waiting room

Pain assessment during visit

Nurse/NP/Student (POD 30)

Phone call, brief survey on pain

Women/Minorities/Children: All patients who undergo an elective laparoscopic cholecystectomy within the eligible time frame are to be included, regardless of age, sex, or ethnicity

Human Subjects: Active patient enrollment is needed. There are no risks to the patients included in this study.

Data Safety: Data input will be via a dedicated encrypted server. Only key personnel will have access to patient identifiers. Local patient identifiers will be stored securely. Data will only be shared via encrypted networks. This will facilitate patient data entry at different time points by different team members and enable cross checking of data entry by different team members to ensure accuracy of data collection.

Statistics Analysis Plan:

Data Collection. Demographic, clinical, and perioperative variables were collected by retrospective review of the electronic medical record and included age, sex, race/ethnicity, BMI, American Society of Anesthesiologists (ASA) class, smoking status, history of substance abuse, procedure, technique (open, laparoscopic, or robotic), whether the minimally invasive inguinal repair was trans-abdominal pre-peritoneal (TAPP) or totally extra-peritoneal (TEP), length of procedure, estimated blood loss, total intravenous fluid given during the procedure, total local anesthetic given during the procedure, total intraoperative morphine milliequivalents administered, length of stay after procedure, and patient-reported pain scores at 1 hour after the procedure and at discharge.

Outcomes. Outcome variables were obtained by the electronic medical record and/or by utilization of a brief telephone survey (intended for internal use only) which was administered by members of the study team who contacted the patients 14 days after discharge (Figure S1). Outcomes of interest included: total morphine milligram equivalents (MMEs) in the post-anesthesia care unit (PACU), patient-reported total MMEs after discharge, and patient-reported average pain scores and satisfaction scores after discharge. Satisfaction scores were on a scale of 1 to 10 with 1 being extremely dissatisfied and 10 being extremely satisfied. Additionally, number of calls to the surgeon's office with a complaint of pain and number of pain medication refills prescribed were recorded for 30 days following the procedure. For MME calculations, patients were asked how many pills of each pain medication they had taken after discharge and based on their responses these were converted and recorded by the research team.

Statistical Analysis. Chi-square and analysis of variance (ANOVA) tests were used to compare categorical and continuous variables, respectively. For all comparisons two-sided statistical significance was set a priori at $p<0.05$. All statistical analyses were performed using Stata/MP 17.1 (Statacorp, College Station, TX).