Restrictive Opioid Prescribing after Surgery for Prolapse and Incontinence: A Randomized Controlled Trial

The **ST**andard versus No **O**pioid **P**rescription after **P**rolapse and **A**nti-**IN**continence Surgery (**STOP-PAIN**) Trial

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Background and Significance

Over the past two decades, there has been a dramatic rise in the use of prescription opioids worldwide. Opioid overdoses accounted for more than 47,000 deaths in the United States in 2017, more than any previous year on record[1]. **Overprescribing opioids is considered a major contributor to the opioid crisis**[2]. After pain medicine specialists, surgeons have the highest rate of opioid prescribing[3]. Hill et al. demonstrated that within a general surgery practice, over 70% of the prescribed opioid pills were never taken[4]. Disturbingly, 45% of patients who did not take opioids at all on their day of discharge were discharged with an opioid prescription[5]. Similar excess opioid prescribing practices have been described within gynecologic surgery[6-7].

The prescription of excess opioids, especially when none are needed to reasonably manage pain, is an alarming trend that demands attention. Lack of knowledge about patterns of postoperative opioid use, desire to minimize patient dissatisfaction during recovery, and avoiding the inconvenience of an office visit to obtain a prescription refill have all been cited as reasons for this practice[2]. Research has been conducted to improve knowledge of opioid usage after various operations. This has led to development of opioid prescribing guidelines by expert panel consensus; in one such guideline, the minimum recommended number of opioid tablets after 20 different surgeries was zero, based off actual patient usage patterns and stakeholder input[8].

Recent initiatives have attempted to utilize restrictive opioid prescribing protocols for postoperative pain management. In a prospective study of 190 patients undergoing minimally

invasive general surgery and urology operations, patients were advised to use non-opioid analgesics and provided with a small (4-10 pills) rescue opioid prescription for breakthrough pain[9]. Fifty-two percent of patients used no opioids after surgery, and 98% of patients used 10 pills or fewer. Patients still reported high satisfaction and pain control with this opioid-sparing pathway[9]. Another recently published large case-cohort study of over 1,200 gynecologic oncology surgery patients tested an opioid prescription protocol in which patients were not prescribed opioids at discharge unless they required more than 5 doses of opioids while in the hospital[10]. Investigators found a significant reduction in the number of dispensed opioids after implementation of this protocol, without any change in the number of refill requests, postoperative pain scores or complications[10]. These well-conducted studies show that **restrictive opioid prescribing policies achieve the goal of reducing excess opioid exposure without causing undue harm, inconvenience or dissatisfaction amongst patients**.

Over 375,000 women undergo surgery for pelvic organ prolapse and urinary incontinence annually in the United States[11]. These patients represent a large population that are likely exposed to opioids in the postoperative period. In an effort to decrease excess opioid prescribing in the urogynecologic population, our section conducted a trial led by Dr. Davidson in which women undergoing prolapse surgery were randomized to standard (28 pill) versus reduced (5 pill) opioid quantities, and found no difference in patient satisfaction[12]. Importantly, 37% of our study patients used no opioids at all after their operation. Similarly, Tolley et al. reported that 42% of benign gynecologic patients exposed to a multimodal pain control regimen used no opioids after surgery[13].

Data from these studies support our belief that a restrictive opioid prescribing protocol, wherein patients are not prescribed opioids unless they request them, may be both feasible and acceptable to the urogynecologic patient population. To date, there has been no randomized controlled trial examining restrictive opioid prescribing practices after urogynecologic surgery. Our section has already instituted an enhanced recovery after surgery (**ERAS**) protocol in which multimodal analgesia is used on all surgical patients to maximize pain control and decrease opioid use. Furthermore, based off the results of the aforementioned study by Davidson et al, patients are discharged with a reduced opioid quantity of no more than 10 tablets after prolapse surgery. **We believe that physicians can capitalize on the new ability to electronically prescribe opioids for patients who require them after discharge to further prevent over-prescribing without impacting patient care.**

Hence, the *objective* of this study is to determine if a restrictive opioid prescription protocol (in which patients are not prescribed postoperative opioids unless they request them) is acceptable to patients after ambulatory and major urogynecologic surgery, compared to standard opioid prescribing practices. We also intend to describe postoperative opioid use patterns in the urogynecologic population, including factors predictive of opioid use and non-use. The results of this research *will have a significant and timely impact* by helping to reduce opioid overprescribing and informing future prescribing guidelines in the field of urogynecology.

Specific Aims

Aim 1. To compare patient satisfaction and pain control using two different opioid prescribing protocols.

We hypothesize that postoperative pain control and satisfaction will be non-inferior between patients not routinely prescribed opioids after surgery and those prescribed a standard quantity. Participants will be asked to rate their pain control during the first 7 postoperative days with validated questionnaires. Participants' satisfaction with pain control will be evaluated at their postoperative visit.

Aim 2. To examine opioid use patterns after ambulatory and major urogynecologic surgery.

We hypothesize that most postoperative patients will use few or no opioids after urogynecologic surgery, regardless of prescribing protocol. All participants will receive thorough counseling with detailed instructions on non-opioid pain management, as well as multimodal analgesia via ERAS protocol during the perioperative period. Participants will be asked to log their opioid and non-opioid medication use in the first postoperative week. We will also assess the number of requests for opioid prescription (in those randomized to the restrictive protocol) and opioid refills (from patients in the standard protocol).

Aim 3. To determine patient and perioperative factors associated with opioid use after urogynecologic surgery.

We plan to collect and analyze demographic, clinical and psychometric data on all participants with the goal of predicting analgesic needs and opioid use after urogynecologic surgery. Results from this study will guide surgeons on how to tailor opioid prescriptions to the needs of each patient, based off individual patient and perioperative characteristics.

Research Plan

1. Study Design

This is a randomized controlled, non-inferiority trial evaluating pain control, satisfaction and opioid use after urogynecologic surgery under two opioid prescribing protocols.

Arms and Interventions

Control Arm: Standard postoperative medications (opioids and non-opioids) are prescribed upon discharge after surgery

Intervention Arm: Only non-opioid analgesics (i.e. ibuprofen and acetaminophen) are prescribed upon discharge after surgery. Patients are allowed to request an opioid prescription if they so desire (see *Study Intervention* below).

2. Outcome Measures

Primary Outcome: Patient satisfaction with pain control at 6 week postoperative visit

Secondary Outcomes:

- Pain level scores during first postoperative week
- Number of opioid pills used
- Number of requests for new opioid prescription or refills
- Predictive factors for opioid use after surgery

3. Study Population and Subject Identification

Eligibility Criteria

All patients of the Center for Urogynecology and Pelvic Reconstructive Surgery in the Department of Ob/Gyn and Women's Health Institute at the Cleveland Clinic (Main Campus, Fairview Hospital, Hillcrest Hospital and Medina Hospital) scheduled to undergo surgery for pelvic organ prolapse and/or urinary incontinence* (see list below).

Inclusion Criteria:

- Age >18 years old
- Access to ancillary care, including phone advice, nurse and outpatient clinic numbers
- Transportation to outpatient clinic or ability to access Virtual Care Visits
- Able to speak and read English
- Has decision-making capacity and able to provide consent for research participation

Exclusion Criteria:

- History of substance abuse disorder
- Chronic opioid use
- Score ≥ 30 on Pain Catastrophizing Scale[14] [See **Appendix 1**]
- Allergy (not intolerance) to ≥ 2 opioids
- Contraindications to both NSAIDs and acetaminophen
- Surgery scheduled before major federal holiday
- Patients undergoing concomitant colorectal procedures
- Patients with perioperative complication (e.g. iatrogenic bowel and bladder injury, hemorrhage, unanticipated laparotomy or ICU admission)

*** Surgical Procedures for pelvic organ prolapse and/or urinary incontinence included in this study:**

- **Ambulatory Surgery**: Isolated colporrhaphy (anterior, posterior) and perineorrhaphy; Placement of mid-urethral sling; Vaginal mesh removal or revision; Insertion of permanent neurostimulator for incontinence (InterStim)

- **Major Surgery**: Vaginal vault suspension, Minimally invasive (laparoscopic or robotic-assisted) sacrocolpopexy, Vaginal or minimally invasive hysteropexy (uterine suspension).

  Additional procedures accompanying the above major operations may include: hysterectomy (total or supracervical), trachelectomy, salpingectomy or salpingo-oophorectomy, anterior and/or posterior colporrhaphy with perineorrhaphy, enterocele repair, minimally invasive Burch colposuspension or paravaginal defect repair, vaginal mesh removal or revision, placement of vaginal graft, or placement of midurethral sling

4. Study Procedures

Randomization

Trial participants will be randomized to one of two arms: 1) Standard Opioid Prescription (Control) or 2) Restrictive Opioid Prescription (Intervention). The allocation sequence will be generated with random block sizes using computer software. The assignment will be distributed to the primary surgeon using a sealed, opaque envelope. The primary surgeon is expected to

open the envelope and disclose the assignment to the patient on the day of surgery. If patients are assigned to the intervention arm, the sealed envelope will contain the randomization assignment as well as a brightly-colored sheet of paper without identifiers that is to be placed on the patient's chart, indicating patient involvement in this research study, as well as a reminder to postoperative caregivers (i.e. nurses, residents).

Study Paradigm

Participant Screening and Consent

Participants will be prospectively identified by the primary surgeon when the decision is made to proceed with ambulatory or major urogynecologic surgery. A chart review by the study investigators will be performed to ensure eligibility criteria is met. Patients will be contacted by telephone to introduce the study, explain the purpose of the study, risks, benefits and alternatives to participation using a phone script [See **Appendix 6**]. Patients who agree to participate will be approached by a study investigator or research nurse at their preoperative visit to sign a consent form and complete three questionnaires (Pain Catastrophizing Scale [**PCS**], Preoperative Questionnaire and Modified Pain Scales [See **Appendices 1-3**]). Encounter notes in the electronic medical record will document the screening phone call and informed consent process. Documentation including signing the consent form will be obtained at the preoperative visit. Please refer to the attached consent document for IRB review.

Compensation will be provided to trial participants with a total of $50 in the form of two $20 stipends (one mailed after the first postoperative week, the second after the patient attends their postoperative visit) and a $10 parking voucher, with the goals of increasing compliance in completing their logs, attending their 6 week postoperative visit, off-setting the cost of parking for that visit and minimizing patient drop out. Approval for funding of this research study to cover participant compensation, as well as personnel support, was granted by the Research Program Committees (RPC) and Women's Health Institute on May 11, 2020 (RPC application #1785).

Preoperative Visit

Thorough preoperative surgical counseling will take place at the preoperative visit as per our standard protocol. The counseling will be performed by advanced practice providers or nursing staff, using a standardized template that includes discussion about normal postoperative symptoms and care, expected discharge pain medications and dosing regimen. Patients are instructed that they do not have to use an opioid prescription if it is not needed, per our usual practice.

Other than the postoperative medications that patients are discharged home with, the perioperative pain control regimen will be the same for both study arms. The pain control regimen utilized involves a multimodal protocol [See **Table 1**] established after a prior study conducted in our department by Drs. Hickman and Paraiso.

Day of Discharge

Per protocol, all patients undergoing surgery will be prescribed a non-opioid pain relief regimen consisting of a 7-day supply of ibuprofen and acetaminophen at hospital discharge. Patients will be instructed to take both acetaminophen and ibuprofen around the clock for 3 days, then as

needed thereafter. Patients are instructed to "stagger" these medications, such that the patient will take a dose of either acetaminophen or ibuprofen every 3-4 hours to permit continuous analgesia.

Study Intervention

Control Arm: In addition to the above non-opioid regimen, patients randomized to the Standard Opioid Prescription arm will receive an opioid prescription for breakthrough pain upon discharge. Currently, it is our practice to discharge patients with a small opioid prescription of 5-10 pills for major urogynecologic surgery and 2-5 pills for ambulatory surgery. Providers will be recommended to prescribe oxycodone 5 mg every 6 hours as needed, but substitutions for other opioids will be allowed based on surgeon discretion.

Intervention Arm: Patients randomized to the Restrictive Opioid Prescription arm will be discharged with non-opioid prescriptions only. If the patient requests an opioid prescription on the day of discharge, the patient will be provided with a 1-day supply (4 pills). **To ensure that postsurgical pain is well controlled after discharge, we will make clear that patients can request an opioid prescription or refill by telephone**. All study participants will receive a scheduled telephone call by a caregiver on the day after discharge from the hospital (see below), and patients in the intervention arm will be asked if an opioid prescription needs to be called in. If a prescription is requested over telephone, the patient will be triaged by a nurse and physician. The opioid prescription will be electronically prescribed by the triaging physician, and a maximum of 10 opioid pills will be provided, per physician judgment and the level of surgery. If the physician deems that the patient's pain is related to a postsurgical complication, the patient will be requested to come in for an urgent postoperative visit. Virtual Care Visits will be utilized if deemed appropriate.

Contact information and instructions for postoperative questions/concerns will be given to all patients at discharge.

Postoperative Period

At the time of discharge, patient will be reminded to complete logs of their pain medication use and pain levels for the first 7 days. They will be given the option to do this electronically through Research Electronic Data Capture (**REDCap**) or by using paper forms. They will indicate their preference on the preoperative questionnaire. If they prefer the latter, these forms will be provided to them at discharge.

All patients will be contacted by telephone on the day after discharge from the hospital by one of the study investigators. During the telephone call, the investigator will assess the patient's postoperative pain control and elicit any questions or concerns about their pain medications. Other postoperative concerns will be promptly relayed to the patient's surgical team. Study participants will be reminded to complete their pain medication and pain scale logs during their first telephone call and by text or email messages on postoperative days (**POD**) 3 and 7 [See **Appendix 7**]. Participants will be asked their preferred modality for reminder communications on the Preoperative Questionnaire. For patients who elect text message communication, the first text message will indicate that data rates may apply and the option to opt out of text messaging.

Subsequent text messages will contain a reminder and a link to their individualized REDCap logs. Similarly, email messages will contain a reminder and link to REDCap.

All postoperative telephone calls to the surgeon's office from study participants will be reviewed by individuals on the patient's surgical team. If a patient calls due to inadequate postoperative pain control, and the physician believes that an adjunctive non-opioid medication (e.g. gabapentin, cyclobenzaprine) would be better for pain relief than an opioid prescription, they may prescribe this instead. If any patients require a second opioid prescription, office evaluation is required.

The following postoperative assessments will be performed:

- **Pain Level**: Patients will be asked to report their pain level for the first 7 days postoperatively. Pain levels will be assessed using questions 1, 2 and 4 from the Modified Surgical Pain Scales (SPS)[15] [See **Appendix 3**], which measures pain at rest, during normal activities and quantifies unpleasantness of worst pain using an 11-point numeric rating score.
- **Medication Usage**: Patients will be asked to log their daily non-opioid and opioid medication usage for the first 7 days postoperatively [See **Appendix 4**].
  All patients will have a scheduled postoperative visit at 6 weeks. At this visit, any paper versions of the postoperative pain scales and medication logs will be collected.
- **Patient Satisfaction and Pain Expectations**: Patient satisfaction with postoperative pain control and how pain expectations were met will be assessed with a 5-point Likert scale [See **Appendix 5**] at the postoperative visit.

Table 2. Summary of Tasks for Study

	Preop	DOS	POD1	POD2	POD3	POD4	POD5	POD6	POD7	6 wks
Pain Catastr. Scale	X									
Informed Consent	X									
Demographic Data	X									
Surgical Pain Scales	X		X	X	X	X	X	X	X	
Randomization		X								
Pain Med Log			X	X	X	X	X	X	X	
Patient Satisfaction										X
Pain Expectations										X

5. Statistical Plan

Sample Size:

The primary outcome of this study is to compare patient satisfaction with postoperative pain control using two different opioid prescribing protocols. Power analysis is based on our prior study by Davidson et al. demonstrating 93% patient satisfaction with pain control with reduced (5 pills) opioid prescribing[13].

If there is truly no difference between the Standard and Restrictive Opioid Prescribing Protocols (93% patient satisfaction in both groups), a sample size of 122 is required to demonstrate with 90% power that the upper limit of a one-sided 97.5% confidence interval will exclude a difference in favor of the standard group of more than 15% (non-inferiority margin). To allow for an anticipated 5% dropout rate, **a total of 128 participants are required (64 per arm)**.

Statistical Analysis:
Continuous descriptive data will be reported as mean and standard deviation (±SD) or median with interquartile range (IQR), depending on distribution. Categorical data will be reported as frequencies, using percentages. Patient satisfaction, pain scores at each time point and overall opioid use will be compared between arms. The investigators also plan to perform two subgroup analyses, comparing these study outcome measures between ambulatory and major urogynecologic surgery patients, and secondly, comparing baseline and perioperative characteristics between opioid users and non-users.

Patient satisfaction will be compared as a dichotomized variable using the chi-squared test. Pain scores will be treated as continuous, non-normally distributed data and will be compared using the Mann-Whitney U test. Opioid usage as a dichotomized variable will be compared using chi-squared test. Opioid usage in MMEs will also be compared using student's t-test. Binary logistic regression will be used to assess the influence of various patient and perioperative factors on the probability of using opioids, and results will be reported as odds ratios with 95% confidence intervals. JMP 14.0 (SAS Institute Inc., Cary, NC) will be used for all statistical analyses. The primary investigators (ASY, CAF) will perform the statistical analysis.

All analyses will be conducted using an intention-to-treat principle. The investigators anticipate that some non-adherence to the assigned therapy (e.g. crossover to opioid use in the intervention arm) will occur, and as these protocol deviations will bias the results towards non-inferiority, a per-protocol sensitivity analysis has also been planned.

All analyses, with the exception of that for our primary outcome, will be conducted with an a priori alpha level of 0.05; results yielding $p < 0.05$ are deemed statistically significant. For our primary outcome of demonstrating non-inferiority in patient satisfaction between arms, a one-sided alpha of 0.025 will be used, as this is considered to be more robust for non-inferiority assessment; the confidence interval is wider and therefore more likely to cross the non-inferiority margin.

6. Data Collection

Preoperative data will include the following:

- Pain Catastrophizing Scale score
- Patient MRN, age, race, ethnicity, vaginal parity, menopausal state, current tobacco use, BMI, prior prolapse and anti-incontinence surgery, preoperative prolapse stage

- Preference for paper or electronic logs, Preference for text or email reminder communication and preferred mobile phone number or email address.
- Modified Surgical Pain Scale scores

Perioperative data will include the following:
- Surgery date
- Surgeon (de-identified)
- Surgery level (Ambulatory, Major), surgery type, concomittant procedures
- Operative time
- Estimated blood loss
- Intraoperative complications
- Hospital length of stay
- Voiding trial (Pass/Fail)
- No. of opioid doses (IV and oral) postoperatively during admission
- Total MMEs of opioids used postoperatively during admission
- Did patient receive scheduled ketorolac and acetaminophen during admission? (Y/N)
- Last pain score at time of discharge
- Postoperative prescriptions at discharge and adherence to randomized assignment

Postoperative data will include the following:
- Daily Surgical Pain Scales
- Daily pain medication logs for opioid and non-opioid medications
- Telephone calls, urgent office visits and virtual visits for pain
- Emergency department visits and hospital readmissions
- Requests for opioid prescription or refills, Additional prescriptions for non-opioid (adjunctive) medications
- Patient satisfaction and pain expectations
- Postoperative complications

7. Data Management Plan

Protection of each subject's personal health information will be a priority in this study. One master excel file containing subject personal information including name and medical record number will be kept in a password-protected file, on a designated protected research drive on a password-protected computer in a locked office at the Cleveland Clinic. In that file, each subject will be assigned a subject identification number that will be used for the purposes of data collection in order to de-identify subjects. All paper forms used for data collection will be kept in a research cabinet dedicated to this project which will be locked at all times, in a locked office at the Cleveland Clinic. All forms will contain de-identified information – identification numbers will correspond to the subjects listed in the master excel file. All study data will be transferred and managed electronically using REDCap. Each subject will be entered into REDCap using the assigned identification number from the master excel file.

8. Adverse Events and Data Monitoring:

Any adverse event or unanticipated events will be reported as soon as feasible to the IRB using IRB WebKit. Examples of adverse events include hospitalization or disability (substantial disruption of a person's ability to conduct normal life functions) due to inadequate pain control.

All events will be recorded and kept in a research binder assigned to this study in a locked office. Monthly reviews during the study period will be done by all involved study staff members to ensure that events are not occurring, and if they are, that they are being handled and reported properly. The study will be terminated if over 50% of patients in the Restrictive Opioid Prescribing arm request more or stronger medication during interim analysis or have >20% decreased satisfaction to the control group; this will be assessed monthly at the reviews mentioned above.

9. Timeline for Completion

The goal for this research study is for completion by the conclusion of the primary investigator's (ASY) three year fellowship at Cleveland Clinic (June 2022). After obtaining institutional review board approval, a discussion will be held at our section research meeting to educate all urogynecology staff, fellows, and nurse practitioners on the implementation of this project. An in-service will be given to familiarize outpatient nursing staff with the project. Additionally, an email will be sent to the OB/GYN residents outlining key components of the project, and an in-service will be given to the residents on our service.

Patient recruitment will begin thereafter with the goal of recruiting and complete data collection on all patients over an 8 month time period. At the end of this time, data analysis will be performed and manuscript preparation will be initiated. The manuscript will be submitted to a high impact gynecology journal at the end of the 12 month time period. This timeline ensures project completion well before the conclusion of the primary investigator's fellowship.

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Table 1. Multimodal Pain Control Regimen

Preoperative
• Acetaminophen: 1000 mg orally, once
• Celecoxib: 200 mg orally, once
• Gabapentin: 600 mg (or 300 mg if age > 65 years or <50 kg) orally, once
Intraoperative
• Use of intradermal analgesia at surgeon discretion
• Ketorolac 15 mg intravenously at the conclusion of the surgical procedure
Postoperative, in hospital
• Scheduled acetaminophen: 1000 mg orally every6 h
• Scheduled non-steroidal anti-inflammatory:
o Ketorolac 30 mg (or 15 mg if age > 65 years or <50 kg) intravenously every 6 h for 4 doses
o Ibuprofen 600 mg orally every 6 h (start 6 h after last dose of ketorolac)
• Oral opioids:
o Oxycodone
▪ 5 mg orally every 6 h as needed for moderate pain (pain 4–6/10)
▪ 10 mg orally every 6 h as needed for severe pain (pain 7–10/10)
o If oxycodone not tolerated, oral tramadol:
▪ 50 mg orally every 6 h as needed for moderate pain (pain 4–6/10)
▪ 100 mg orally every 6 h as needed for severe pain (pain 7–10/10)
• Ice pack or cold gel pack: Apply to vulva and perineum q 2 h for 20 mins around the clock until discharge
Postoperative, post-discharge
• Scheduled acetaminophen: 1000 mg orally every 6 h for 3 days, then as needed for pain, 21 pills
• Scheduled ibuprofen: 600 mg orally every 6 h for 3 days, then as needed for pain, 28 pills
• Oral opioids, if randomized to Standard Opioid Prescribing arm
o Oxycodone 5 mg (or tramadol 50 mg, if oxycodone not tolerated) every 6 hours as needed for breakthrough pain not controlled by non-opioid medications
▪ If major urogynecologic surgery: 5 to 10 pills
▪ If ambulatory urogynecologic surgery: 2 to 5 pills