RESEARCH PROTOCOL

Date	11-28-16
Title	Predictors of Postoperative Pain in Urogynecologic Surgery
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Hatton #	**16-093**

Purpose of Study

- Postoperative pain remains the most important consideration for both patients and surgeons. A previous qualitative systematic review has identified preoperative pain, anxiety, age, and type of surgery as significant predictors of postoperative pain (Ip, Abrishami, Peng, Wong, & Chung, 2009).
- The purpose of this study is to determine the predictors of postoperative pain specific to the urogynecologic patient population. Such information would allow urogynecologists to tailor their preoperative counseling to provide more accurate expectations regarding postoperative pain.
    - **Primary Aim:** To determine if there is any relationship between preoperative factors (such as demographic information, medical history, disease burden), perioperative factors (such as length of surgery, blood loss) and postoperative pain scores with patients who have undergone urogynecologic surgery, specifically vaginal reconstruction for pelvic organ prolapse.

Hypothesis or Research Question

- We hypothesize that several perioperative factors (specifically age, BMI, medical and psychiatric history, prolapse stage, length of case, etc.) will be correlated with increased postoperative pain in the urogynecologic patient population.

Background

Prescription opioid use has become a growing epidemic in recent years, especially here in Ohio (Prevention). From 1990 to 2010, drug overdose death rates in the United States have increased four-fold (3.4 to 12.4 per 100000 population). Sadly, in 2009 the drug overdose death rate surpassed motor vehicle death rates for the first time in history (Center for Disease Control and Prevention). This opioid epidemic has been partly attributed to changes in medical professionals' prescribing of opioids in an effort to treat noncancer pain more effectively (Maxwell, 2011). While the rampant opioid problem is obviously multifactorial, we as medical providers would be remiss if we did not take some responsibility.

Patients are prescribed opioids and other related narcotic medications for a myriad of reasons. However, in the sphere of urogynecology and pelvic floor dysfunction, opioids are primarily reserved for postoperative pain management. Postoperative pain is one of the most frequently reported postoperative symptoms (Chung, Un, & Su, 1996). Given this fact, there has been much attention brought toward investigating predictive factors of postoperative pain. A systematic review of 48 eligible studies with 23,037 patients showed preexisting pain, anxiety, age, and type of surgery are the four most significant predictive factors for the intensity of postoperative pain (Ip et al., 2009). However this paper evaluated all types of surgical approaches. More recently, a prospective observational study showed that preoperative State Trait Anxiety Inventory (STAI) and Numerical Rating Scales (NRS) for anxiety and pain expectations are independent predictors of pain and morphine consumption following abdominal hysterectomy (Aouad et al., 2016).

To date, little is known about the predictive factors of postoperative pain in the urogynecologic patient population. We aim to investigate the relationship between perioperative factors (such as demographics and medical history) and patient-reported pain scores on postoperative day 1. This information would not only fill a gap in knowledge, but would also allow us to counsel our patients more accurately in regards to postoperative expectations. Furthermore, if we find any positive correlation between modifiable perioperative factors and postoperative pain scores, we may be able to minimize these effects in future surgical cases. In an era when the United States is declaring a national week of observation for Prescription Opioid and Heroin Epidemic Awareness (Obama, 2016), we as medical providers must continue our efforts to minimize one of the many culprits—postoperative pain.

Research Plan

- **Study Design**
  - Retrospective chart review

- **Setting for the study**
  - The retrospective chart review will be performed on TriHealth EPIC and database platforms at one of the various clinical locations.

- **Participants**
  - Study population: All participants of previous IRB-approved research studies within the Division of Urogynecology and Reconstructive Pelvic Surgery that incorporated assessment of postoperative pain as part of the data collection.
    - Participants from the following studies: Hatton #13090, #13072, #12136, #12132, #10072, and #09001
    - Previously developed databases from each of the above mentioned studies will be used to identify participants.
  - Inclusion criteria
    - Adults 18 years of age or older

        - Participant in one of six research studies previously performed by the Division of Urogynecology and Pelvic Reconstructive Surgery (Hatton #13090, #13072, #12136, #12132, #10072, or #09001)
        - Postoperative pain scoring data complete and available
        - Vaginal reconstructive surgery as primary treatment
        - General anesthesia
    - Exclusion criteria
        - Incomplete or unavailable postoperative pain scoring
        - Robotic sacrocolpopexy patients will be excluded
    - Sample size
        - Given the number of participants in each of the previously performed studies, we estimate that there will be approximately 374 participants in this study.
        - A sample size calculation is not applicable given the retrospective nature of this study design.

- **Data Collection**
    - Independent variables: Age, BMI, race, gravidity/parity, past medical history, past surgical history, home medications, menopausal status, tobacco use, sexual activity, stage of pelvic organ prolapse, type of surgery, length of case, estimated blood loss, type of anesthesia, length of hospital stay, surgical complications and perioperative hemoglobin level. All of these variables will be obtained either from previous data records or from chart review.
    - Dependent variables: Visual analog scale (VAS) pain score on postoperative day 1 (POD1), Nursing verbal pain score, and narcotic use (morphine equivalents) in the first 24 hours and entire hospital stay.

- **Intervention or experimental aspect of the study**
    - No intervention will occur as part of this study.
    - There are no potential risks to the study population by any aspect of the study.

- **Statistical Analysis**
    - The primary outcome of this study is the VAS pain scores on POD1 and the association with various perioperative factors. Pearson product moment correlation coefficient will be employed to measure the association between VAS pain score and a continuous factor such as age, blood loss, or length of surgery. If a factor is dichotomous (two categories, i.e. gender), point-biserial correlation coefficient will be used for investigating the association, and independent samples t test or Mann-Whitney U test will be also considered as well. For a factor having more than three categories, ANOVA or Kruskal-Wallis H test will be used to compare VAS scores among categories.

Ethical Considerations

- **Informed consent**
  - Since this is a retrospective chart review, waivers of Informed Consent and Authorization will be requested.
- **Privacy information**
  - Extensive efforts will be made to ensure and maintain participant confidentiality. All identifying information will be maintained in a secure area at all times. All communication between staff members regarding participant data will occur via the Hatton Study # and Subject ID number only. However, identifying information will be retained in the original/source documents.
  - The Excel spreadsheet will be stored on a password protected, encrypted TriHealth computer for ten years following study closure, and then purged.

Cost/Budget

- This study will incur no cost to the institution, the participants, or the investigators.

Estimated Period of Time to Complete Study	
When will study begin?	January 2017
Protocol Development Completed	2 weeks
Admin Review Time	2 weeks
IRB Approval	3 weeks
Data collection	4 weeks
Data analysis	4 weeks
Presentation development (if applicable)	2 weeks
Manuscript Development (if applicable)	4 weeks
Journal submission process (if applicable)	4 weeks
Study closure	2 weeks

- **When and how will results be disseminated?**
  - The results will be disseminated by way of an oral or poster presentation at a national meeting, and with publication in a high-impact journal.

References

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