Dexamethasone Administration To Improve Patient Recovery In Ambulatory Vaginal Reconstructive Surgery: Is There A Role?

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Introduction:

The lifetime risk of undergoing surgical intervention for pelvic organ prolapse (POP) is estimated to be 10% and it is projected that from 2010 to 2050, the number of surgeries for POP will rise by 47.2%, from 166,000 to 245,970.[1] In 1980, accounting for the rising costs of health care, congress approved Medicare to reimburse procedures performed at outpatient and ambulatory surgery centers. [2]This led to an increasing number of stress incontinence (SUI) procedures being performed in the ambulatory setting from 34,968 in 1996 to 105,656 in 2006.[3] However, the number of ambulatory POP surgeries decreased in the same time period. This was possibly due to the increase in the mean age of women undergoing ambulatory procedures for POP and SUI during that time periods.

Our institution has performed outpatient surgeries for POP and SUI for the past 3 years. Patients have tolerated same day surgery with minimal complications. In our previous prospective study assessing satisfaction after outpatient surgeries for POP and SUI, patients had a decreased quality of recovery at 48 hours compared to baseline.[4] We also recognized that nausea and pain control could have been better addressed. Unpleasant postoperative nausea and vomiting, pain control, return to normal voiding and return of bowel function can influence the quality of recovery (QOR) from surgery.[5] Postoperative nausea and vomiting (PONV) and pain management are particularly troubling for the patients. This might also delay discharge and prolong convalescence from the surgery.

Several safe interventions have been assessed in the literature for alleviating PONV, pain and recovery from laparoscopic gynecologic surgery.[6,7] Dexamethasone is a potent corticosteroid that has been widely used for chemotherapy induced nausea and vomiting. The mechanism of action is not completely understood. It has been proposed that a single dose may hamper the production and release of anti-inflammatory mediators, thereby decreasing postoperative nausea, emesis, pain perception and Dexamethasone also has a central antiemetic effect by inhibition of prostaglandin and/or release of endogenous opioids. A recent metanalysis concluded that Dexamethasone administration at induction is safe.[8]

Pauls et al[9] in their recent study randomized patients undergoing vaginal prolapse surgery to receive Dexamethasone and noted a decrease in PONV and reduced requirement of a rescue antiemetic. Their model involved patients with overnight stay and the results may not be applicable to our population. They also noted that women who received Dexamethasone preoperatively were more likely to pass the voiding trial.

To our knowledge there are no studies in the literature evaluating the effect of Dexamethasone administration on patients undergoing outpatient vaginal prolapse surgeries.

Specific Aim:

The primary aim is to evaluate whether standard administration of Dexamethasone at the time of anesthesia induction in patients undergoing vaginal reconstructive surgery would result in improved QoR.

Hypothesis:

We hypothesize that patients who receive Dexamethasone at the time of induction may have a better quality of recovery, satisfaction, reduced symptoms of PONV and requirement for pain medications. Secondary outcomes will include 1) patient pain status, 2) postoperative urinary retention, 3) Infections- UTIs, wound and pelvic, 4) Readmission, and 5) Complications- Hematoma.

Significance:

For the past 3 years our institution has performed POP and SUI surgeries in the ambulatory setting. As this trend is being expanded universally in the United States, it is important to identify interventions that would improve the QoR, satisfaction in this patient population and to speed postoperative recovery.

Selection:

Subjects will be selected to participate based on inclusion and exclusion criteria. All subjects meeting inclusion criteria will be scheduled for surgery with one of the urogynecologists. Consent will be done prior to the day of surgery, but subjects will be allowed to sign the consent form the day of surgery if they had a discussion about participating in the research prior and were given time to consider participation.

Inclusion Criteria:

1. Women over the age of 18
2. Women scheduled for vaginal POP reconstructive surgery with or without concomitant anti-incontinence procedure and with or without hysterectomy
3. ASA class 1-2

Exclusion Criteria:

1. Daily use of steroids, antiemetics in the month prior to surgery
2. Chronic pain requiring daily opioid treatment
3. History of allergy/intolerance to Dexamethasone
4. ASA class 3
5. Numerical Pain score of more than 4 at baseline
6. Renal/Liver disease
7. Diabetes mellitus

8. Pregnancy
9. Inability to answer questionnaires
10. Any systemic infections
11. Immuno compromised status
12. Patients with planned overnight stay

Randomization:

All subjects will be assigned a number at the time of enrollment. Patient will be randomized to receive either Dexamethasone 8 mg or Normal saline at the time of anesthesia induction. A computer generated table will assign these subjects into two groups. The patients will be blinded to the group assignment. The envelope containing the group allotment will be opened in the operating room at the time of induction. However, the Anesthesiologist and surgeon will not be blinded to the group allotment. Dexamethasone 8mg or normal saline will be mixed and administered at the time of induction.

Preoperatively:

Prior to the surgery, patients will be asked to complete a numerical pain scale (NPS) for pain from 0 to 10 cm and the QoR 40.

All subjects will undergo urodynamics prior to surgery to detect baseline voiding function and SUI.

Anesthesia:

Subjects undergoing general anesthesia and will receive propofol induction, in combination with a muscle relaxant and inhalational gas per anesthesia standard of care at our institution. A maximum of 200 mcg of Fentanyl will be used for each patient during the procedure and immediate postoperative period.

For patients undergoing spinal anesthesia, 0.75% Bupivacaine, 8-12 mg depending on the duration of the surgery and discretion of the anesthesiologist. Patients will also receive propofol infusion at sedation level.

Fluids will be administered by anesthesiology in the usual manner.

Prophylactic antibiotics and Preoperative drugs:

Prophylactic antibiotics such as Ancef, Flagyl and Gentamycin or Vancomycin if Penicillin allergic is to be given prior to incision. Participants will undergo surgery at the Cleveland Clinic Florida by the urogynecology faculty and 3 fellows.

Vaginal packing:

Vaginal packing will be placed after all surgeries as deemed necessary by the surgeon, using gauze. Vaginal packing will be removed at the time of the voiding trial on postoperative day (POD) 0.

Postoperative pain management:

Patients will be given IV Morphine (or alternative in case of sensitivities) at doses of 2-4 mg every 10 minutes for moderate to severe pain assessed by a nursing administered pain scale. The maximum dosage administered will be 16 mg. Other alternative medications include IV toradol (30 mg for patients < 60 and 15mg for patients > 60 yrs). Patients may receive oral medications prior to discharge from the PACU. The standard oral medications administered will be Norco, Dilaudid, Tylenol, Percocet and Ultram.

Postoperative antiemetics:

Patients will be given Ondansetron 4mg IV every 8 hours as first line, followed by prochlorperazine10 mg IV every 6 hours as second line.

Voiding trial:

A voiding trial will be performed on POD 0 once the subjects are able to stand and ambulate to the bathroom. Voiding trial will consist of removing the vaginal packing and back filling the bladder with 300cc of saline or less if the subject has urgency. A voiding trial is considered successful if the subject voids at least 200cc and has a bladder scan showing less than 33% remaining. If a subject is unable to void after an hour, an additional hour will be permitted. However, after 2 hours from when the bladder was backfilled the subject is still unable to void, the Foley will be replaced and the subjects will be discharged home with a Foley catheter, leg bag and leg bag teaching.

The office will call and schedule an office nurse visit to remove the Foley between post-operative day number 5 to 7.

Postoperatively:

The QoR-40 is validated in gynecology and in same day surgery patients. Subjects will be administered the QoR- 40 by phone, subjects will also be administered the PONV intensity scale and a numerical scale for pain from 0 to 10 cm.

Discharge:

All subjects will be discharged home the same day unless there are surgical or medical complications requiring an overnight stay or higher level of care.

Discharge medications will include Percocet and Motrin for pain, Zofran for nausea, Colace and Miralax or Lactulose. Macrobid or an alternative antibiotic will be provided to subjects going home with a Foley. Possible alternatives to pain medication for those allergic include Norco, Ultram or Tylenol. A copy of all the questionnaires will be given to the patient prior to discharge.

Follow Up:

Subjects will receive a phone call from either a nurse or fellow, between 24 to 72 hours post-operatively to make sure that they are doing well and are not having any complications. A telephone survey will be administered during this follow up phone call using a validated questionnaire, the QoR-40. Additional information such as the PONV scale and numerical pin scale will also be administered. They will have received a copy of this survey to refer to at the time of their hospital discharge.

Subjects who were admitted to the hospital will have the same follow up, including a phone call 24 to 72 hours after their surgery, including the validated questionnaire, the QoR-40.

In addition, subjects will have a 6 week follow up visit in the clinic and will be asked to complete the QoR-40 and Surgical Satisfaction Scale (SSQ-8).

Structure:

This will be a single-center, randomized single blinded prospective trial conducted by the Urogynecology department at the Cleveland Clinic Florida.

Data Collection:

Study subjects will be assigned a number to limit patient identifying information. The original medical record number and name with corresponding assigned study subject number will be stored in a locked file cabinet in the gynecology department. The subjects' questionnaires will be stored in the locked file cabinet. De-identified data will be entered into Redcap. Demographic data will be entered into redcap and will include age, gravida, para, medical problems, marital status, and prior pelvic surgery.

Sample Size:

There have been studies evaluating Dexamethasone on QoR in patients undergoing vaginal prolapse surgery.

QoR is a validated tool that has been used in gynecology surgery. Women in general have a lower QoR with a mean score of 162 postoperatively [10]. Based on 80% power to detect a mean difference of 22 points between the two groups in the overall QoR 40, 22 subjects in each group will be needed. Allowing for a dropout rate of 20%, sample size of 54 subjects will be recruited (5 in each group). Therefore each treatment arm will include 27 subjects.

Data Analysis:

Demographic statistics will be compared using student t-test for continuous variables, Wilcoxon Rank Sum test for ordinal or categorical data.

The primary endpoint of change in QoR from baseline will be analyzed through t- test.

Secondary endpoints will be analyzed using t-test for 1) change in QoR-40 score from baseline to POD 1 2) change in QoR-40 from baseline to 6 weeks post-operatively 3) change in QoR-40 from POD1 to 6 weeks post-operatively 3) time to discharge and 4) time to void.

Wilcoxon Rank Sum will be used to evaluate postoperative complications including hematoma formation, UTI's, reoperations, readmission, and reinsertion of Foley catheter after discharge.

Univariate and multivariate analysis will be performed to evaluate for confounding variables.

Budget:

No additional funding is required for this study outside of nursing and fellow resources already budgeted into Department of Urogynecology.

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