Evaluating safety, cost, and patient satisfaction with same-day discharge after minimally invasive sacrocolpopexy

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Background & Significance

Enhanced recovery after surgery **(ERAS)** pathways play a critical role in the delivery of high-quality surgical care. These protocols incorporate multiple perioperative patient interventions including preemptive analgesia, measures to reduce postoperative nausea and emesis, fluid balance aimed at euvolemia, and both early ambulation and oral intake. ERAS pathways are significant because they have been shown to shorten recovery, decrease hospital stay, reduce complications/nosocomial infections, and conserve resources.[1-20] Same-day discharge **(SDD)** is a central aspect of enhanced recovery pathways.

SDD and ERAS protocols are part of a new initiative within the Women's Health Institute, and their application for gynecologic surgery is of increasing interest across the country.[1-19] To date, the focus of studies has largely been on laparoscopic and robotic hysterectomy in the benign and gynecologic oncology literature. Studies have consistently demonstrated both feasibility and safety of SDD after laparoscopic and robotic hysterectomy, with no significant increase in complications or readmissions as compared to discharge on postoperative day **(POD)** 1. In fact, a recent systematic review by Korsholm et al of 15 observational studies with nearly 12,000 patients revealed SDD is feasible, at a rate of nearly 80%, when patients are properly selected and careful surgical planning is performed.[3] Studies have also demonstrated high patient satisfaction[10,12] and less cost[18] with SDD after minimally invasive hysterectomy. SDD has been applied in other minimally invasive gynecologic procedures, such as minimally invasive myomectomy, with low readmission rates (0.6% within 48 hours, 1.4% over 3 months).[20]

ERAS pathways can have an important role in other areas of gynecologic surgery. In the field of urogynecology, quality of life reconstructive surgery is often performed to address symptoms of pelvic organ prolapse, urinary incontinence, and/or fecal incontinence. A prospective study by Kalogera et al evaluated the impact of an ERAS pathway for patients undergoing vaginal reconstructive surgeries for pelvic organ prolapse versus historical controls.[21] In this cohort, patient satisfaction with perioperative care was high, mean duration of hospital stay was significantly reduced, and there were no differences in 30 day outcomes. In a case series by Zakaria and Levy, an ERAS pathway was utilized after vaginal hysterectomy, which permitted SDD in 96% of patients.[19] Notably, only 5 of the 1071 patients required readmission or emergency room evaluation within 30 days of surgery. Taken together, these studies provide support for the application of ERAS pathways in urogynecology, where well-selected surgical candidates are undergoing surgeries appropriate for SDD.

Yet, to date, **only one research study has investigated the role of SDD after minimally invasive sacrocolpopexy.** A sacrocolpopexy is a surgery for pelvic organ prolapse in which a bridging piece of mesh is utilized to suspend the vaginal cuff to the anterior longitudinal ligament overlying the sacral promontory. This is an extensively studied and highly effective surgical technique to correct pelvic organ prolapse and is a mainstay in the field of urogynecology. A study by Faucheron et al evaluated SDD for robotic and laparoscopic ventral rectopexy, a similar mesh-augmented procedure that is performed for rectal prolapse, and concluded that SDD is feasible and safe.[22] A preliminary study by Lloyd et al performed at the Cleveland Clinic within the Female Urology division investigated SDD after minimally invasive sacrocolpopexy (*article in press*). In this study, SDD was achieved in 10 of 12 patients (83.3%). The two patients who did not have SDD were due to case completion after 6PM, a preset case completion requirement. Outcomes were also retrospectively compared between patients who underwent SDD (N= 10) and patients who stayed overnight (N=30). Only one

patient had an emergency department visit on POD 20, due to an unrelated mechanical fall. Importantly, there were no major complications in either group requiring procedural interventions, new prescriptions, or additional interventions. Recently, a study by Kisby et al was published examining SDD after robotic-assisted sacrocolpopexy. In this retrospective study, 80 women underwent SDD compared to 192 who were discharged on >/=POD 1.[23] This study found no difference in unplanned provider visits, emergency department visits or readmissions between the groups.

We hypothesize that an ERAS protocol utilizing SDD for minimally invasive sacrocolpopexy is as safe as those that utilize discharge on POD 1 while incurring less total procedure-related costs and being acceptable as a post-op management plan for patients. The *objective of this study* is to provide data which are necessary to widely implement SDD after a minimally invasive sacrocolpopexy. The results of this research *will have a significant impact* on increasing patient satisfaction, minimizing resource utilization, and improving clinical practice patterns in the field of urogynecology, both for this procedure and potentially other surgeries within our subspecialty.

Specific Aims

Aim 1. To compare the incidence of adverse events in patients following a SDD protocol for minimally invasive sacrocolpopexy compared to those patients discharged on POD 1.

We hypothesize that there is no difference in the incidence of adverse events between SDD compared to discharge on POD 1 after minimally invasive sacrocolpopexy. Using the *Epic* electronic medical record **(EMR),** we will evaluate 1) the number of unscheduled office visits, patient-initiated calls for a surgery-related complication, emergency department visits, and readmissions/reoperations of patients who had a SDD protocol and 2) the severity of any adverse events using the Clavien Dindo Scale. We will utilize patient phone calls to inquire about any of the aforementioned events outside of our institution. We will compare incidence of postoperative adverse events between patients undergoing SDD versus a historical control group who were discharged on POD 1.

Aim 2. To compare the total procedure-related costs associated with SDD compared to discharge on POD 1 for minimally invasive sacrocolpopexy.

We hypothesize that the total costs associated with SDD following minimally invasive sacrocolpopexy is less than the same procedure with discharge on POD 1. We will utilize data from the billing function of *Epic* EMR to compare total procedure-related costs for each approach to minimally invasive sacrocolpopexy.

Aim 3. To determine patient satisfaction with SDD after minimally invasive sacrocolpopexy.

We hypothesize that patients will be satisfied with SDD after minimally invasive sacrocolpopexy. We plan to address this aim using a series of validated measures.

Research Plan

1. Study Design

This is a prospective cohort study evaluating safety, cost and patient satisfaction with SDD for patients undergoing minimally invasive sacrocolpopexy for pelvic organ prolapse. A prospectively collected, historical control group who underwent the same surgical procedure will be utilized to compare these outcomes when applicable. SDD will be facilitated in part by a utilizing novel patient education video created for this study and implementing an ERAS pathway. All patients meeting eligibility criteria will be approached for study participation. Outcomes will be assessed on POD 0/1 and at the routine post-operative follow up visit, generally at 6 weeks after surgery.

Primary outcomes: The primary outcome of this study is serious adverse events.

Secondary outcomes:

- Patient-initiated phone calls for a surgery-related complication

- Unscheduled office visits, including voiding trials
- Emergency department visits
- Cost of surgery/post-operative hospitalization
- Quality of Recovery (QoR-15), a validated questionnaire created to measure a patient's early post-operative status[24]
- Visual analog scale (VAS) pain scores
- Minimally invasive sacrocolpopexy survey

Paradigm

Preoperative Visit

Participants will be prospectively identified by the primary surgeon when the decision is made to proceed with a minimally invasive sacrocolpopexy. A chart review by the primary investigator will be performed to ensure eligibility criteria is met, after which all patients will be called explaining the purpose of the study, risks, benefits and alternatives to participation. A telephone encounter in the EMR will document this informed consent process. Documentation including signing the consent form will be obtained at the preoperative visit or on the day of surgery.

Thorough preoperative surgical counseling will then take place at the preoperative visit as per our standard protocol. A patient education video, approximately 10.5 minutes in length, developed by the primary investigator will be administered to all patients either during preoperative visit or prior to her scheduled surgery and will address:

- The expectation that eligible patients will be discharged home the same day following surgery
- Normal postoperative symptoms and care
- Warning signs (e.g. pain, vaginal bleeding, nausea/vomiting, fever, urinary retention) and restrictions
- The possibility of being discharged home with an indwelling catheter if unable to void after surgery
- The importance of the presence of a caregiver postoperatively

Contact information and instructions for postoperative questions/concerns will be given to the patient.

Prescriptions will also be provided for analgesia, a bowel regimen, and postoperative nausea and vomiting prophylaxis, so that all medications will be immediately available upon discharge after surgery.

Day of Surgery

An ERAS protocol for preemptive analgesia, postoperative nausea and vomiting, fluid balance, and postoperative oral intake will be used on the day of surgery to help facilitate SDD.

Fasting: Patients will be instructed to take no food by mouth starting at midnight the day of surgery. Clear liquids will be allowed up to 3 hours before surgery. This protocol is in accordance with Cleveland Clinic Anesthesia protocols.

Preemptive Analgesia: Prophylactic medications (if no contraindications) will be given upon arrival to the hospital on the day of surgery for increased postoperative pain relief, decreased narcotic consumption, and patient satisfaction. These orders will be placed as part of the pre-operative order set and will include: celecoxib 400 mg PO, acetaminophen 1,000 mg PO and gabapentin 600 mg PO. For patients 65 years old or <50 kg, a reduced, 200mg dose of gabapentin will be provided. One dose of ketorolac (30 mg IV or 15 mg IV in patients 65 years old or <50 kg) will be given at incision closure if no contraindications exist. Use of intradermal analgesia will be at the discretion of the primary surgeon. Sparing use of IV opioids intra-operatively and in the post anesthesia care unit (PACU) will be at the discretion of anesthesiology.

Postoperative Nausea and Vomiting: Prescription for scopolamine transdermal patch and instructions for use will be provided at the preoperative visit for any patients with a history of postoperative nausea and vomiting if no contraindications exist (e.g. angle closure glaucoma).[25]

- Dexamethasone 4mg IV once prior to incision (± 30 min) if no contraindications exist.
- Ondansetron 4 mg IV once prior to incision closure (± 30 min) if no contraindications exist.
- Antiemetic medications may be given in the PACU at the discretion of anesthesiology.

Fluid balance: The goal will be to maintain intraoperative euvolemia. After surgery, the peripheral IV will be saline locked when tolerating PO intake in the PACU.

Postoperative Oral Intake: Early feeding will be encouraged, and a regular diet may be resumed immediately following surgery. Amount and type of food consumed may be determined by the patient.

Vaginal Packing: Avoidance of vaginal packing will be encouraged, however, if packing is placed, it will be removed in the PACU by a staff, fellow, or resident prior to the voiding trial.

Voiding Trial: Our standard voiding protocol will be performed in the PACU when the patient is able to stand and ambulate to the restroom. The bladder will be retrograde filled with 300 ml of sterile fluid. The Foley catheter is then removed and the patient must void 200 ml (or 2/3 of the instilled volume if the patient is not able to tolerate the full amount). If the patient is unable to void then the Foley catheter will be replaced and she will be given Foley teaching or, alternatively, the patient may be taught intermittent self-catheterization. A repeat voiding trial will be scheduled within 2-5 days in the outpatient clinic.

Post-operative Assessment and Disposition: All patients will be assessed by the primary surgical team prior to discharge home. Post-operative requirements include: Ability to tolerate oral fluids and medications, adequate pain control and ability to walk with assistance. Patients <u>not</u> meeting criteria for discharge home at the conclusion of the recovery period will be kept for observation overnight as an extended recovery.

<u>Post-operative Follow-up</u>

- POD 0: All patients will be contacted by an individual on their surgical team to see how the patient is doing. If patients have a late discharge from the hospital, after 1700, a POD0 call will not be initiated. This call will last approximately 5 minutes in length (or as dictated by patient questions or concerns), to occur between 1500 and 1900 on day of surgery.
- POD 1: All patients will be contacted within 24 hours of their surgical completion time by a registered nurse or a physician. This call will last approximately 10 minutes in length.
- All patients will have a scheduled post-operative visit at ~6 weeks, as per our standard protocol.

2. Study Population and Subject Identification

Eligibility Criteria

Patients of the Center of Urogynecology and Pelvic Reconstructive Surgery in the Department of Ob/Gyn and Women's Health Institute or the Female Urology division in the Department of Urology at the Cleveland Clinic scheduled to undergo a minimally invasive (robotic-assisted or laparoscopic) sacrocolpopexy for pelvic organ prolapse with a board-certified female pelvic medicine and reconstructive surgery specialist will be approached for participation in this study.

Additional surgical procedures may include: hysterectomy (either total or supracervical), trachelectomy, anterior and/or posterior colporrhaphy, enterocele repair, minimally invasive Burch colposuspension or paravaginal defect repair, vaginal mesh removal or revision, vaginal graft placement, midurethral sling, or perineal rectal prolapse repair (Delorme or Altemeier).

<u>Inclusion Criteria</u>:

Preoperative requirements include:

- Age <80 years old
- Preoperative American Society of Anesthesiologists grade I (normal healthy patient) or II (mild systemic disease)
- Access to ancillary care, including phone advice, nurse and outpatient clinic numbers
- Caretaker at home for at least 24 hours post-operatively
- Able to speak and read English
- Has decision-making capacity and able to provide consent for research participation

Exclusion Criteria:

- Laparoscopic, robotic, or open abdominal surgical procedures that require an overnight admission. This may be due to unanticipated additional intraoperative procedures or surgical complications such as unintentional cystotomy or enterotomy, hemorrhage, or anesthetic complication.
- Patients undergoing concomitant laparoscopic colorectal procedures or anal sphincteroplasty
- Surgery start time after 1:00PM, as previous studies have determined this is associated with a decreased likelihood of SDD[3,14]
- Pregnancy or positive hCG testing, which is standard of care preoperative testing.

3. Data Collection

The EMR will be reviewed to collect preoperative, intraoperative, and POD 0 data points. We will use the following method to identify the occurrence of a procedure-related adverse event: The EMR will be reviewed for patient phone calls for a procedure-related complication, unscheduled office visits, emergency department visits, hospital readmissions or reoperations within 30 days, and adverse events occurring up to 6 weeks post-operatively. The adverse events of interest will include the following:

- Wound infection
- Hematoma
- Transfusion
- Pelvic abscess
- Osteomyelitis
- Venous thromboembolism (deep vein thrombosis or pulmonary embolism)
- Delayed bowel or urinary tract injury
- Bowel obstruction or ileus
- Cardiac or pulmonary complication
- Neurologic injury

We will also employ an approach that will allow us to capture events that may have been handled outside of the CCHS or in institutions that do not utilize *Epic*. To capture these data points if they exist, we will contact participants by telephone on POD 1 (within 24 hours of surgical completion time) to determine if they received any care from a facility outside of the CCHS and then again at the post-operative follow up visit, which generally occurs at 6 weeks. We will then use these data with the Clavien Dindo Scale to determine the severity of the adverse event, with a grade 3 or higher considered to be a serious adverse event, and we will compare this proportion to the reference proportion of 26.3%. A proportion of patients with grade 3 or higher less than 45.1% will be considered non-inferior to the reference.

As part of the effort to characterize the patient population, we will extract data regarding total procedure-related costs using the EMR. We will assess satisfaction using the quality of recovery questionnaire, visual analog scores for postoperative pain, and a patient satisfaction survey described by Fountain et al[4] at thepostoperative visit, which uses a Press Ganey scale for responses (See Appendix A). Please see data collection sheet for a comprehensive list of planned data points.

4. Statistical Plan

Statistical analysis: Categorical variables will be presented as n/N (%) with 95% confidence intervals. Continuous variables will be presented as mean +/-SD or median [range]. A Pearson's chi-square test or Fisher exact test will be used for frequencies and proportions of categorical values and t test or the non-parametric Wilcoxon rank sum test for mean values of continuously measured variables. P values ≤ 0.05 will be considered statistically significant and we will use SAS (version 9.4, The SAS Institute, Cary NC) as our statistical package to perform these analyses. The primary investigator will perform the statistical analysis with assistance from the WHI statistician.

We will use data from a historical control group discharged on POD 1 after minimally invasive sacrocolpopexy to examine Aim 1 and Aim 2. This is a cohort of 60 women matching our eligibility criteria from a prospective randomized trial of two different types of lightweight polypropylene mesh (IRB #14-354). This study completed recruitment 2017. It consists of a group of women who underwent minimally invasive sacrocolpopexy using the same surgical approaches, at the same institutions (main campus, Fairview and Hillcrest), and performed by the same surgeons as our study. The primary difference is that participants in that study and the cohort proposed here is that all participants were discharged home on POD 1. We will utilize this cohort to compare the incidence and severity of procedure-related adverse events and costs between SDD and POD 1. Comparisons on outcome measures will be done using either an ANOVA analysis or a student's t test for parametric continuous outcomes, a Kruskal-Wallis or Mann Whitney U test for non-parametric outcomes and a Chi-square test for all categorical outcomes. Logistic regression will be performed to control for confounding variables.

Sample size: We estimate that approximately 80 minimally invasive sacrocolpopexy surgeries will be performed per year. Of these, we anticipate that ~3/4 will meet eligibility criteria and of these patients, ~3/4 will consent to participate. Based upon data by Unger et al, a Clavien Dindo grade 3 adverse event (defined as requiring surgical, endoscopic, or radiologic imaging/intervention) was identified in 26.3% of patients after a minimally invasive sacrocolpopexy.[26] A meta-analysis of laparoscopic versus open sacrocolpopexy combined results of 9 randomized control-trials and found a post-operative complication rate of 5.4% after minimally invasive sacrocolpopexy (robotic and laparoscopic).[27] We suspect that 26.3% may be an overestimation of adverse events as the Unger et al study included any imaging required in the postoperative period even if the result was normal. However, we also suspect that a 5.4% adverse event incidence may be low. As such, we feel that an adverse event incidence of 12% may be more representative of that expected after this surgical procedure.

We used a one-sided exact test for non-inferiority of binomial proportion to determine the degree of difference between the proportion of 26.3% and an incidence proportion greater than the reference which could be detected and deemed inferior (significantly greater) to the reference with a power of 80%. With a sample size of 45 patients, the proportion of patients with a Clavien Dindo grade of 3 will need to be 45.1% or greater. We will account for a 3% drop out rate (based on 2016 post-operative visit "no-show" rates for the Urogynecology division) by recruiting an additional 2 patients, making the sample size planned for this study a total of 47 patients.

5. 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 will be kept in 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 an identification number that will be used to de-identify subjects. All paper forms, including the informed consent, will be kept in a research cabinet dedicated to this project which will be locked at all times, in the locked Women's Health Institute urogynecology research office on A81. All survey 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 (Research Electronic Data Capture). REDCap is a secure, web-based application designed to support data capture for research studies. The system is protected by a login and Secure Sockets Layers (SSL) encryption.

6. Research Environment

SDD and ERAS protocols are part of a new initiative within the Women's Health Institute directed by our chair, Dr. Ridgeway. The co-investigator and senior mentor on this project, Dr. Paraiso, is the division director and is also committed to the success of this project. Lastly, this project has been discussed at multiple research

meetings and has the support of the other surgeons in the division, some of whom have successfully discharged patients same day after this surgery.

Regarding surgical volume, a chart review determined that ~60 minimally invasive sacrocolpopexies without concomitant rectopexy were performed within our division in 2016. Our Female Urology collaborator, who will be participating in this study, performs ~20 minimally invasive sacrocolpopexies per year. In 2017, we also had two new staff join the urogynecology division, who also perform this surgery and will be participating in subject recruitment. As such, we feel that our target recruitment is an achievable goal. Lastly, there are no current or planned clinical trials that could compete for subject recruitment for this study. Together, we feel that this environment is conducive to the implementation and successful execution of this research study.

Timeline for Completion

The goal for this research study is for completion by the conclusion of the primary investigator's three year fellowship at Cleveland Clinic (June 2020). After obtaining institutional review board approval, a discussion will be held at our division research meeting to educate all urogynecology and urology staff physicians, fellows, physicians assistants, and nurse practitioners on the implementation of this project. An in-service will be given to familiarize the PACU and outpatient nursing staff with the project. Additionally, an email will be sent to the Ob/Gyn and Urology residents outlining key components of the project, and an in-service will be given to the residents on our service. The anesthesiology staff will also be re-informed regarding this project.

Patient recruitment will begin thereafter with the goal of recruiting all patients over a 12 to 14 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 18 month time period. This timeline ensures project completion well before the conclusion of the primary investigator's fellowship.

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Appendix A

Minimally Invasive Sacrocolpopexy Survey

The following questions are asking about your recent prolapse surgery.

Check the box that applies:

1. When did you go home from the hospital? (check one box)
   [ ] The day of surgery [ ] 2 or more days after surgery
   [ ] 1 day after surgery

2. How many weeks has it been since your surgery? (check one box)

[ ] 4 weeks
[ ] 5 weeks
[ ] 6 weeks
[ ] more than 6 weeks

3. Please rate the education that you received in this clinic before surgery that prepared you for your surgery and recovery after surgery.
   [ ] Very poor
   [ ] Poor
   [ ] Fair
   [ ] Good
   [ ] Very good

4. Please rate the care that you received in this clinic before your surgery.
   [ ] Very poor
   [ ] Poor
   [ ] Fair
   [ ] Good
   [ ] Very good

5. Please rate the care that you received in the hospital after your surgery (before going home).
   [ ] Very poor
   [ ] Poor
   [ ] Fair
   [ ] Good
   [ ] Very good

6. Please rate your postoperative recovery after surgery through today.
   [ ] Very poor
   [ ] Poor
   [ ] Fair
   [ ] Good
   [ ] Very good

7. Overall how satisfied are you with your entire surgical experience at Cleveland Clinic for this most recent surgery?
   [ ] Very satisfied
   [ ] Somewhat satisfied
   [ ] Neither satisfied or dissatisfied
   [ ] Somewhat dissatisfied
   [ ] Very dissatisfied

8. Overall how satisfied are you with the pre-operative video education you received?
   [ ] Very satisfied
   [ ] Somewhat satisfied
   [ ] Neither satisfied or dissatisfied
   [ ] Somewhat dissatisfied
   [ ] Very dissatisfied

Please agree or disagree…

9. The pre-operative video education was helpful in preparing me for surgery and recovery after surgery.
   [ ] Strongly agree
   [ ] Agree
   [ ] Neither agree or disagree
   [ ] Disagree
   [ ] Strongly disagree

10. I would recommend my friends/family to go home on the day of their surgery.
    [ ] Strongly agree
    [ ] Agree
    [ ] Neither agree or disagree
    [ ] Disagree
    [ ] Strongly disagree