Project Title: Preferred Method of Postoperative Follow Up After Pelvic Reconstructive Surgery. (Phone Call versus Clinic Visit): A Non-Inferiority Randomized Clinical Trial

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I. Introduction:

Post-operative visits two weeks following reconstructive pelvic surgery is standard practice for our FPMRS division. With a growing number of new patients, scheduled procedures, and established patients, we, like most academic practices, struggle with maintaining an efficient workflow. To provide the best care, it is necessary to evaluate how we can improve patient satisfaction without seeing an increase in complications. Telephone consultations are increasingly being used as a novel approach to supplement or replace traditional outpatient care for various acute or chronic conditions. [1]. A review article published by Car, J and Sheikh, A found that telephone consultations are associated with increased patient satisfaction, less waiting time, and reduced travel costs. They also reviewed studies that both clinicians and patients value the convenience and flexibility offered by telephone consultations. However, amongst physicians dissatisfied with telephone -based care, the concerns cited included inability to confirm diagnosis with an examination and absence of visual cues [2]. Telephone follow up has been favorably evaluated following laparoscopic cholecystectomy, hernia repair, cardiovascular surgery, and

in oncology [2].

In the setting of urogynecological procedures, the use of telephone follow up is an area that needs to be studied. There is no known standardization about how postoperative follow up visits are conducted after pelvic reconstructive surgery. There is much variation amongst providers concerning when and how postoperative follow up visits are completed. With the advances in robotic and laparoscopic procedures, hospital length of stay has decreased significantly. We now must examine the benefits of minimally invasive surgery as it relates to postoperative follow up. If in person postoperative visits can be replaced with telephone visits, we can possibly increase patient satisfaction. By allowing the patient to have a postoperative visit in the comfort of her own home, we can save her travel costs and travel time. Additionally, in our practice, the in person postoperative visits can ultimately be replaced with procedures and established patient visits, ultimately allowing for more availability for new patient consultations. By evaluating the use of telephone follow up, versus clinic follow up we will show that patient satisfaction with telephone follow up will be unchanged or improved compared to our standard practices.

II. Objective:

A. Primary Aim(s):

- To determine if patient satisfaction with postoperative care with telephone follow up is non-inferior to clinic follow up.

B. Secondary Aim(s):

- To determine if telephone postoperative follow up is a safe alternative to clinic postoperative follow up visits
- To determine if telephone or clinic follow up visits are preferred based on differing demographics (i.e. age, race, distance traveled, outpatient versus inpatient surgery).
- To determine length of visit differences between telephone and clinic follow up.

III. Hypothesis:

For the standard two-week postoperative visit, follow up telephone calls will be non-inferior to traditional office visits. The telephone visit is a safe and efficient alternative to the in person visit following urogynecological procedures.

a. H_0 Traditional office visits are superior to follow up via telephone calls for two-week postoperative visits.

IV. Interventions:

Scheduled telephone call at the two-week postoperative visit completed by the urogynecology clinic nurse.

V. Study Design:

This is a two group, parallel randomized non-inferiority clinical trial at one institution evaluating telephone postoperative visits as non-inferior in patient satisfaction, patient preference, and patient safety, when compared with clinic postoperative visits. This protocol was written in accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines 2011.

VI: Methods:

A. Study Setting:

Patient recruitment will come from women presenting for their follow up clinic visit at the University of South Florida's (USF) Female Pelvic Medicine and Reconstructive Surgery (FPMRS) Clinic. Women who present to this follow up clinic visit have already been seen and evaluated within USF's FPMRS clinic by one of the FPMRS faculty, have undergone appropriate testing and are now receiving detailed, focused counseling in order to decide upon preferred surgical management. At this point a letter is sent to schedule the desired procedure. Once the physician and patient have agreed upon the surgical management plan it is the routine practice, at our institution, to submit a letter to the surgical scheduler. The letter details the type of surgery, medical clearance requests, and postoperative follow up. The patient is informed that she will be contacted, by our office, in the next two weeks and provided with all necessary information and documentation, including date of surgery and follow up appointments. It will be at this follow up clinic visit that patients will be told about our study and consented if applicable.

B. Eligibility:

The women that present to the USF FPMRS follow up visit and have decided to undergo surgical management of prolapse or incontinence, will be assessed to determine if they meet eligibility requirements. Eligibility requirements are as follows:

1. Inclusion Criteria:
    - Women >18 desiring surgical management of prolapse or incontinence
    - English speaking
    - Willing and able to provide written and informed consent without assistance from medical surrogate or interpreter

- Immediate access to telephone services (landline, mobile phone, office phone)

2. Exclusion Criteria:

- Women <18
- Non-English speaking
- Unwilling and unable to provide written and informed consent without assistance from surrogate or interpreter
- Hearing impairment
- No access to telephone services (landline, mobile phone, office phone)
- Grade 3 complication- a complication requiring surgical, endoscopic, or radiological intervention. [3]
- Patient who did not attend any postoperative follow up visit

C. Interventions and Recruitment:

The recruitment and consenting process will be performed by an FPMRS fellow or an attending physician and will occur in a private patient exam room at the time of the surgical consultation follow up visit. After obtaining informed consent, the women will be randomized to either a two-week postoperative telephone visit or two- week postoperative clinic visit. The preferred contact phone number and mailing address will be confirmed. The patient will also receive a brief outline summarizing the study and what to expect in laymen terms. These visits typically occur during each of the three attending physicians' clinics. The provider will include that the patient is a study patient in the surgery letter. Once the surgical scheduler confirms that the patient has been enrolled and consented, she will open the next sealed randomization envelope revealing the patient's allocated intervention and schedule the patient's two- week postoperative visit accordingly (telephone follow up or clinic follow up). If the patient is randomized to telephone follow up, the surgical scheduler will again confirm the preferred contact number and mailing address.

Concerning the two-week postoperative follow up visit, if the patient is randomized into the telephone follow up group, she will be contacted, at the pre-scheduled date and time, by the urogynecology clinic nurse. The nurse will utilize a scripted series of postoperative questions, which are consistent with questions asked during our standard postoperative clinic visits. The same nurse will conduct the telephone follow up visits in an effort to maintain consistency. An example of the script is attached.

Any patient responses that are not consistent with a usual postoperative course will be escalated to an in person visit. However, these patients will remain in the group, to which they were originally randomized, for research analysis purposes. If a patient cannot be reached at the time of her scheduled telephone visit, a second

telephone call will be attempted during the same week. If there is still no answer, the patient will be scheduled for an in person visit, the time and date of this visit will be left on the patients voicemail. Patient will be excluded from study. Patients who were found to have recovered satisfactorily based on telephone follow up, will have six -week clinic visit.
Vital signs and physical examination will be deferred for the patients in the telephone follow up group. The clinic visit will entail questions about common postoperative complications (including fever, nausea/vomiting, pain, urinary symptoms, constipation, etc.). As per usual, vital signs and a focused physical examination will be completed at the clinic visit. All clinic visits will be performed by an FPRMS fellow and/or attending physician. At the end of each visit (telephone and clinic) patient will be reminded about postoperative restrictions as outlined in discharge instructions. The length of duration of both the telephone and clinic visits will be recorded by documenting the start and end time. For the clinic visit the start time will be the time patient is documented as "arrived" status in waiting area and finish time when the physician leaves the room. For the telephone visit, the start time will be at the time the patient answers the phone and finish time when phone call ends. Both clinic and telehealth visits will be documented with progress notes in EMR.

D. Randomization

Eligible patients will be randomized to Arm1 or Arm2 (Telephone follow up or clinic follow up). Permuted block randomization with randomly varying block sizes will be used. Generation of allocation sequences will be performed using a random-number table.

E. Concealment of Treatment Allocation:

The allocation sequence will be generated by our statistician who is neither responsible for patient recruitment or outcome assessment. Sequentially numbered opaque sealed envelopes will be used for concealment of treatment allocation.

F. Blinding:

It is not possible to mask clinical staff or participants, as they will be aware of the follow-up care that is being delivered over the telephone or in clinic. As such this is not a blinded study. The surgical scheduler will open the sealed randomization envelope revealing the patient's allocated intervention and document this in the patients' chart. The PI will keep the master link matching the patient to the allocated intervention. The PI is also responsible for entering all collected data into a de-identified excel spreadsheet.

VII. Outcomes

A. Primary:

- Comparison of patient satisfaction as determined by completion of a non-validated, treatment non-specific satisfaction questionnaire between the two groups. Survey will be provided at the six-week follow up visit.

B. Secondary:

- Comparison of adverse events and Emergency Department (ED) visits between the two groups. Will be determined by reviewing the patient's record to identify adverse events as defined below. Informed consent will include consent to obtain outside ED records; as this is standard practice for patients seen in ED during perioperative/postoperative period.
- Actual time spent on phone call during postoperative telephone follow up compared to time spent in clinic follow up measured in minutes.
- Correlation, between groups, of overall patient's satisfaction with subjective measures, complications, demographics, and travel distance.

VIII. Data Collection:

At the initial visit, once eligibility status is determined and consent is obtained, data collection form will include demographics, distance traveled, complications, and number of ED visits, type of surgery performed etc. Also patients will complete three postoperative patient satisfaction questionnaires at the six-week postoperative clinic visit. This will include the Patient Satisfaction Questionnaire (PSQ) 18 Short Form, a validated questionnaire. Also will include the Patient Global Impression of Improvement (PGII), a validated questionnaire. And a three-question survey about patient satisfaction with the postoperative experience, not validated. All six -week visits will be in person. The questionnaires will be completed before the physician interviews the patient. These questionnaires will be stored in a locked filing cabinet and later transferred by the PI to an excel spreadsheet stored on a password-protected computer. Additionally, pertinent medical information will be extracted from the patient's medical chart, de-identified, and transferred to the an excel spreadsheet after surgery by a member of the study team, including socio-demographic data, perioperative and postoperative details, adverse events, and ED visits.

Adverse events are defined based on previous studies [4, 5,]

- bladder injury
- ureteral injury
- bowel injury

- operative estimated blood loss >500mL
- reoperation < 30 days
- hematoma
- pelvic abscess
- vaginal cuff cellulitis
- ileus
- small bowel injury
- transfusion
- pulmonary
- cardiac
- neurological injury
- urinary tract infection (culture proven, urinalysis with presence of leukocyte esterase, nitrites, or blood, symptoms of infection)
- pyelonephritis
- urinary retention (more than 6 week postoperative)
- mesh erosion
- incisional hernia
- wound complication
- reoperation for complication of surgery
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IX. Sample Size:

Sample sizes of 71 in Group 1 and 71 in Group 2 achieve 80% power to detect a non-inferiority margin difference between the group proportions of -0.12. The traditional office visit group proportion is 0.87. The Telehealth group proportion is assumed to be 0.75 under the null hypothesis of inferiority. The power was computed for the case when the actual Telehealth group proportion is 0.90. The test statistic used is the one-sided Z test (unpooled). The significance level of the test is 0.025.

X: Proposed Analyses:

Data analyses will be performed at the University of South Florida in Tampa, Fl. Data management and analyses will be conducted using SAS version 9.4 (SAS Institute, Inc, Cary,NorthCarolina). Subject demographic characteristics such as age, distance traveled, surgical procedures, ED visits will be summarized by standard descriptive statistics (e.g. means and standard deviations or median (range) for continuous variables and percentages for categorical variables. The difference between groups will be compared using the chi-square test or t–test, as appropriate. Logistic linear regression will be used to evaluate independent predictors for patient satisfaction. A p-value <0.05 will be considered statistically significant.

VIII. Confidentiality

At all times, appropriate measures will be taken to protect the confidentiality of all study participants in accordance with HIPAA guidelines. Patients will be approached for recruitment in private patient exam rooms. Once enrolled, all patients will be administered a study ID number starting with 1 and proceeding numerically. A master link between the individual subjects and their study ID number will be stored in a secure location (on a password-protected computer in the Urogynecology Fellows' office). All data collection forms (DCF) and stored patient information will only contain the study ID number. Charts will be reviewed in a secure location at all times. Upon completion of the data collection period, all information will be entered into an excel spreadsheet on a password-protected computer for data analysis.

IX Safety

This a voluntary study. Patients have the right to refuse to participate.

Data and Safety Monitoring
The study PI will be reviewing the data for completeness and any safety issues on an ongoing basis. An independent urologist will also review the data and safety after the enrollment of the first 10 patients, after ~50% recruitment and at the completion of the study. A summary of these reviews will be submitted to the IRB as part of the continuing review process.

After providing informed consent, the participants will proceed with the normal surgery scheduling process. If the patient is excluded from the study, due to meeting the exclusion criteria postoperatively, she will be notified and scheduled for clinic visit if she was randomized to the telephone group. At this point the patient will be a part of excluded patient population as documented in the CONSORT flow diagram. Patient may elect to be removed from the study at anytime.

References:

1- Connie H. Carr, Helen McNeal, Elaine Regalado, Richard A. Nelesen, and Linda S. Lloyd. Journal of Palliative Medicine. February 2013, 16(3): 263-267

2- Car, Josip, and Aziz Sheikh. "Telephone Consultations." *BMJ : British Medical Journal* 326.7396 (2003): 966–969

3- Clavien PA, Barkun J, de Oliveira ML, et al. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg*. 2009;250:187-196.

4- Unger CA, Hickman LC, Mitchell-Handley B, Barber MD, Ridgeway B. The incidence of

perioperative adverse events in the very elderly undergoing urogynecologic surgery. Female Pelvic Med Reconstr Surg 2016;22:425-429.

5- Brubaker, Linda et al. "Two-Year Outcomes After Sacrocolpopexy With and Without Burch to Prevent Stress Urinary Incontinence." *Obstetrics and gynecology* 112.1 (2008): 49–55. *PMC*. Web. 1 Feb. 2018.

6- 6- Beaver K, Williamson S, Sutton C, Hollingworth W, Gardner A, Allton B, Abdel-Aty M, Blackwood K, Burns S, Curwen D, Ghani R, Keating P, Murray S, Tomlinson A, Walker B, Willett M, Wood N, Martin-Hirsch P. Comparing hospital and telephone follow-up for patients treated for stage–I endometrial cancer (ENDCAT trial): a randomised, multicentre, non-inferiority trial. BJOG2017;124:150–160.

7- Bunn F, Byrne G, Kendall S. Telephone consultation and triage: effects on health care use and patient satisfaction. Cochrane Database of Systematic Reviews 2004, Issue 3.

8- Gray, RT et al. "Post-Operative Telephone Review Is Cost-Effective and Acceptable to Patients." *The Ulster Medical Journal* 79.2 (2010): 76–79.

9- Hwa K, Wren SM. Telehealth Follow-up in Lieu of Postoperative Clinic Visit for Ambulatory SurgeryResults of a Pilot Program. *JAMA Surg.* 2013;148(9):823-827.

10- Anderson ME Jr, Brancazio B, Mehta DK, Georg M, Choi SS, Jabbour N. Preferred parental method of postoperative tonsillectomy and adenoidectomy follow up (phonecall vs clinic visit). Int J Pediatr Otorhinolaryngol 2017 Jan: 92: 181-185

11- Gunter, Rebecca L et al. "Current Use of Telemedicine for Post-Discharge Surgical Care: A Systematic Review." *Journal of the American College of Surgeons* 222.5 (2016): 915–927. *PMC*. Web. 23 Mar. 2018.