Evaluating patient satisfaction with 2-week post-operative virtual visits compared to in-office visits: A randomized control trial.

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Background

Telemedicine is defined as "the use of computer-based technologies to manage a patient's health by exchanging medical information over a distance". (Harting, et al). As technologies like smartphones, tablets, and computers have become more integrated into everyday life, they have also been incorporated into medical practice. Telephone visits have been incorporated into a variety of surgical fields, including pediatric surgery, urology, and outpatient general surgery (Young, et al; Finklestein, et al; Soegaard Ballester, et al) and are associated with decreased overall visit times and shortened or eliminated travel times (Soegaard Ballester, et al.).

Virtual visits (visits conducted face-to-face using computers, tablets, or smartphones) have grown in popularity. A systematic review noted that the concerns of physicians conducting telephone-based care included potential risk of missing a serious condition, inability to use visual cues, and inability to conduct a physical exam. (Car, et al.) Virtual visits add back a visual component of an in-person visit, while preserving the above benefits of telephone visits. In the General Surgery literature, patients attending virtual visits after outpatient surgery reported higher levels of satisfaction than their in-person counterparts. (Healy, et al.)

Telemedicine has been introduced in obstetrics for prenatal care, monitoring of chronic conditions during pregnancy, genetic counseling, medical abortion, and colposcopy (Kohn, et al., Griener). A randomized control trial in urogynecology in 2019 demonstrated that telephone-based postoperative visits were non-inferior to in-person postoperative visits in terms of patient satisfaction. (Thompson, et al.) Although utilization of telemedicine in OB/GYN is expanding, there is still a dearth of literature, particularly regarding virtual visits in gynecology. The Cleveland Clinic has instituted telemedicine with the provision of virtual visits in all specialties. In benign gynecologic surgery, virtual visits have been offered in the last couple of years as an alternative to the in-person 2-week post-operative visit, but have not been evaluated systematically.

Our study aims to evaluate the safety and efficacy of virtual postoperative visits as compared to in-office postoperative visits for patients undergoing minimally invasive hysterectomy. We hypothesize that virtual visits will be non-inferior to in-person visits in terms of patient satisfaction. The primary objective for this study is to evaluate patient satisfaction of their postoperative visit experience, as measured by the Press Ganey Medical Practice Survey and Medical Practice Telemedicine Survey (Presson, et al). The secondary objectives include evaluating the incidence of a new diagnosis of a postoperative complication requiring medical treatment (e.g. calling in of a prescription), an office visit with CNP or MIGS surgeon, or an urgent care or ER visit. Post-operative complications include infection (urinary, pulmonary, wound, pelvic abscess, bloodstream), thromboembolic events, bleeding; and issues with wound healing, such as dehiscence. We will record no-show rates, visit times, and estimated travel distance as measured by distance of home to clinic site (Srikrishna, et al).

Study Methods:

This is a two arm, randomized non-inferiority clinical trial.

Setting

This study will take place within the Minimally Invasive Gynecologic Surgery division in the Women's Health Institute of the Cleveland Clinic, Cleveland, OH.

Population

We will recruit patients undergoing benign minimally invasive hysterectomy (laparoscopic, robotic, and vaginal). Inclusion criteria include patients >18 years of age who are able to provide informed consent without assistance, speak English, and who have access to a phone or device equipped for virtual visits. Patients will be excluded if the staff surgeon determines they are inappropriate for virtual follow-up, if there is suspicion of malignancy, if they are unable to provide consent, or if they do not have access to technology that enables virtual visits.

Inclusion criteria	Exclusion criteria
>18 years of age	Deemed ineligible by staff surgeon
Able to provide consent without assistance	Suspicion of malignancy
English-speaking	Unable to provide consent
Access to phone or device equipped for virtual visits	Do not have access to technology for virtual visits

Recruitment

Enrolled participants will be randomized to either a two-week virtual postoperative visit with a certified nurse practitioner (CNP) or a two-week in-office postoperative visit with a certified nurse practitioner (CNP) in a 1:1 allocation ratio. Block randomizations with block size of 4 will be assigned to nurse providers independently. Randomization schedules will be implemented by Redcap.

Data collection

The primary outcome of this study is patient satisfaction, as measured by the Press Ganey Medical Practice Survey and Medical Practice Telemedicine Survey. These questionnaires will be sent via RedCap on the day of their two-week postoperative appointment. We will provide verbal reminders about study participation and survey administration at the visit. If participants have not responded by their six-week visit, a scripted phone call will be made as a reminder. The secondary outcome is a new diagnosis of a postoperative complication requiring medical treatment (e.g. calling in of a prescription), an office visit with a CNP or MIGS surgeon, or an urgent care or ER visit. Complications include infection (urinary, pulmonary, wound, pelvic abscess, bloodstream); thromboembolic events; bleeding; and issues with wound healing, such as dehiscence. Calvien-Dindo classification system for postoperative complications will be used. We will also look at no-show rates, visit times, and travel distance.

We will collect basic demographic information from the EMR, including MRN, age, email address, BMI, race, insurance status, parity, and prior surgical history. Date of enrollment, date of surgery, date of admission, and date of discharge will be recorded. Surgical indication, procedure performed, length of hospital stay, and perioperative outcomes (reoperation, readmission, unscheduled office or virtual visits (i.e. earlier than the scheduled 2 week visit), ED/urgent care visits, infection rates) will also be obtained. No-show rates will be obtained through the EMR. We will also note if a planned virtual visit is unable to be completed due to

technical difficulties, or is converted to a telephone visit. We will collect date of their 6 week postoperative visit or date they withdrew from the study. We will collect zip code; travel distance from home to clinic site will be calculated using average travel time with minimal traffic based on participant's zip code using Google Maps.

We will collect the reason for ineligibility for all patients deemed such by staff surgeons.

All participants will be assigned a study number to facilitate de-identification of data. Data will be compiled in RedCap and securely stored on an encrypted server.

Statistical analysis

Power Calculation:

We hypothesized that patient satisfaction would be non-inferior for patients randomized to the postoperative virtual visit compared to those randomized to in-person virtual visit (Thompson, et al). Sample size of 70 patients in each arm is needed to achieve 90% power to detect a non-inferiority margin of -0.20. Allowing for a dropout rate of 20%, 88 patients will be recruited in each arm.

Analysis plan:

For the primary outcome, the Farrington-Manning score test for non-inferiority will be performed, for both intention-to-treat and per-protocol analyses. Approximately normally-distributed continuous measures will be summarized using means and standard deviations and will be compared using two-sample t-tests. Continuous measures that show departure from normality and ordinal measures will be summarized using medians and quartiles and will be compared using Wilcoxon rank sum tests. Categorical factors will be summarized using frequencies and percentages and will be compared using Pearson's chi-square tests or Fisher's Exact tests.

All analyses will be done using SAS (version 9.4, The SAS Institute, Cary, NC) and a $p < 0.05$ will be considered statistically significant.

Study Timeline:

The MIGS division performs at least 20-30 hysterectomies per month. We estimate to achieve our target recruitment in 7-8 months.

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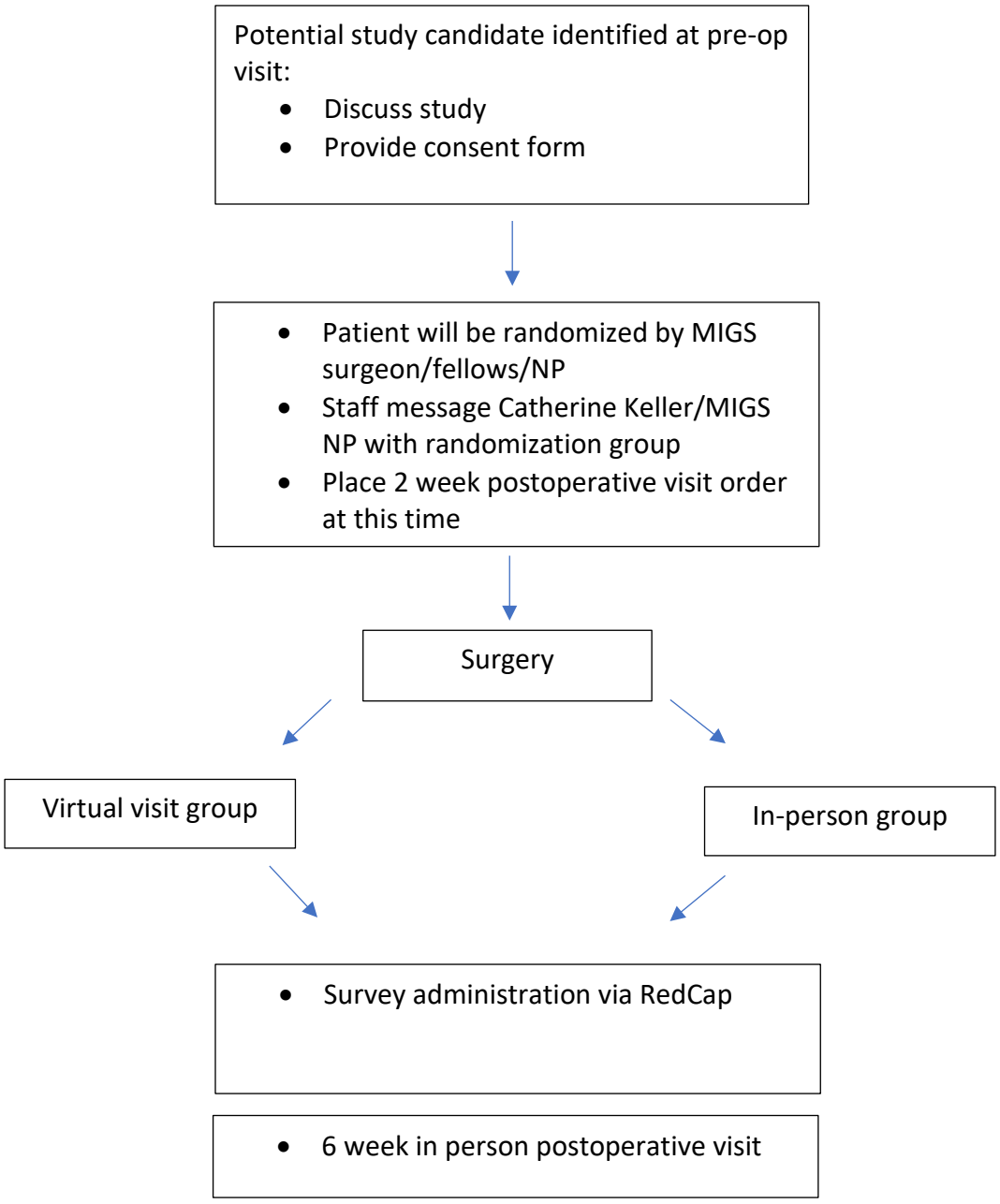

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