**Project title: Utilizing telemedicine for delivery of postoperative care following minimally-invasive gynecologic surgery: A randomized controlled trial**

**Principal Investigator:** Steven Radtke MD FACOG

**Co-Investigators**: Randle Umeh MD

**Research Associate:** Sheralyn Sanchez, MPH

**Biostatistician:** Zuber Mulla, Ph.D., Professor

**Affiliations:** Texas Tech University Health Science Center El Paso, Paul L. Foster School of Medicine

**Background:**

The wide-spread use of minimally invasive techniques in gynecologic surgery has brought several tangible benefits to patients including faster-recovery times, shorter hospital stays, decreased risk of long term complications, to name a few. [1-3] Technological advances such as the development of robotic assistance have allowed to further expand the number of cases that can be performed via a minimally invasive approach.[4] The shift has been such that the landscape regarding operative routes in gynecologic surgery has completely reversed, with now the majority of cases being performed laparoscopically. [5] Although much has changed intraoperatively, the surrounding structure of an operative has lagged. Specifically, preoperative and post-operative visits are still conducted in a similar way than how it was done 20 years ago. Despite leaps in technology, the field of gynecologic surgery has been slow to widely implement these advances into perioperative practice. One of the specific areas of opportunity is the postoperative visit. It is common practice in the majority of fields to have a visit with the patient approximately 2 weeks after surgery. The objective of this visit is to evaluate how the patient has been progressing, examine the wound site(s), and discuss pathology results from any specimens that were removed during the procedure.

The logistics of this visit involve blocking a time-slot in an established clinic day. Patient is required to transport herself to the clinic site. Once checked-in, there may be a waiting period before being placed in a room for the practitioner to conduct the visit. Once the visit is started, as long as there are no issues, the duration of the interaction may range on average between 3-7 minutes.

Despite these visits being short and usually straight-forward, the invested time that patients have to dedicate is substantially greater than the actual interaction with the clinician. Furthermore, because of the advantages of minimally invasive surgery, many patients have already returned to work by the time of the postoperative visit which may result in a disruption of their daily work schedule.

The ubiquitousness of high-speed internet and mobile phones have allowed for the field of tele-medicine to thrive in recent years.[6,7] Although wide-spread application of this modality has not been implemented in the field of gynecologic surgery, other areas such as urology and pediatrics have successfully implemented tele-medicine programs, specifically for postoperative patients, yielding promising results. [8,9]

We propose a pilot project in which enrolled patients undergoing major gynecologic surgery will be randomized to either a traditional office postoperative visit or a telemedicine postoperative visit. The two groups will then be compared on a variety of metrics including clinical outcomes, patient satisfaction and time.

**Objectives**

1. Determine if there are differences in patient satisfaction between traditional postoperative visits and telemedicine postoperative visits
2. Determine the difference in time invested from the patient's side and clinicians side in order to complete the postoperative visit interaction
3. Analyze if there is a difference between groups regarding visits to the emergency department related to the surgery, delayed postoperative complications, etc.

**Hypothesis**

Patient satisfaction will be greater in the tele-medicine group.

Total time invested will be decreased.

There will be no difference in visits to the emergency department or unrecognized postoperative complications

**Inclusion criteria**

Female patients between ages 18-60

Have access to smart-phone with video /audio and internet capabilities

Undergoing laparoscopic gynecologic surgery that requires a postoperative visit

-Total laparoscopic hysterectomy

-Laparoscopic removal of adnexal structures

-Laparoscopic excision of endometriosis

**Exclusion criteria**

Patient unwilling to participate

Patient unwilling to install and utilize the telemedicine app on their smart phone.

**Recruited participants will be deemed ineligible to continue the study if:**

- After recruitment, participant experiences surgical complications (bladder or bowel injury, etc) that require face-to-face postoperative care
- After recruitment, participant visits the emergency room (ER) for postoperative complaints between surgery and scheduled postoperative visit

**Materials and Methods**

Study design: Randomized controlled trial.

Once IRB approval is obtained, we will begin recruitment based on the stated inclusion and exclusion criteria. Invitation to participate will be extended to eligible patients by clinic staff with a direct care relationship to the patient during their pre-operative visit in the TTUHSC El Paso Ob-Gyn department. If the patient agrees to participate, research staff will be called in to explain the study in more detail. The patients will be advised that if they agree to enroll, there is a 50% chance their post-operative visit may be via tele-medicine and 50% chance it will be as a traditional visit in the office. They will be asked to fill out a short survey that verifies they have a compatible mobile phone, and will be asked to download the appropriate app. An instruction sheet on how to utilize the tele-medicine application will be given to all patients, to be used in case they are allocated to the tele-medicine group. Once enrolled, surgery will proceed as planned. After surgical stop-time, patients will be allocated to either a traditional postoperative visit group or a tele-medicine postoperative visit via block-randomization, utilizing block sizes of 4:6. This will be achieved by giving patients a sealed envelope that allocates them in a sequential fashion based on a previously generated random series. The envelope will contain information regarding group assignment, along with simple instructions as to how to schedule the post-operative visit within a window between one and three weeks from the surgery.

Both the tele-medicine and traditional visits will be carried out using the same structure.

1) Inquire about any concerns the patient has regarding recovery.

2) Review findings and procedures done during surgery and pathology results.

3) Visually examine abdominal laparoscopic port-sites.

4) The opportunity for the patient to ask any additional questions.

In the case of the telemedicine visits, they will open by asking the patient to state her full name, and her date of birth. Additionally, this will be correlated with the code in the instruction sheet in order to verify identity.

A video-call application that is HIPAA compliant and easily accessible from mobile phones or video-enabled PCs will be used (doxy.me). A Business Associate Agreement between TTUHSC and Doxy.me has been generated in order to comply with HIPAA requirements. Patients will be given a time when they will receive their virtual appointment link, which will be sent to their mobile phone via text. It is expected that patients will use their phone to establish the connection. Providers will utilize a computer station set up with a camera and audio equipment, with a professional appearing backdrop. As part of the consent form, patients will be made aware that they may incur in data charges if they are using a limited data plan, and they are responsible for this expense.

Data will be collected in a de-identified manner. Baseline variables that will be captured include age, ethnicity, BMI, parity, distance from home address to the clinic in miles (calculated using Google maps). Surgery performed and operating time will also be collected. Post-operative visits will be timed. In the case of telemedicine, recorded time will be from when connection is established until disconnection. In the case of the traditional visit, it will be time from when the provider enters the exam room until time the patient exits). Patients will be contacted by phone between 7 to 14 days after the postoperative visit and they will be subjected to a PSQ-18 (Patient satisfaction questionnaire) focused on their post-operative visit, which will be conducted by a member of the research staff blinded to allocation. We will also inspect their medical records to determine if there were any phone calls to the clinic/call-center or visits to the emergency department following the postoperative encounter (within the first 30 days after surgery). In addition to the PSQ-18 questions (after they are completed), patient's will be asked "If they had the opportunity to have switched groups, would they?" and then they will be asked to give an estimate of how much time they utilized in order to complete the postoperative visit including transportation, waiting time, etc. (rounded to the nearest 15 minute increment).

**Sample size:**

Our primary outcome is to detect a difference in patient satisfaction. If we expect a 20% relative increase in the experimental arm, assuming two-tailed testing with an alpha of 0.05, and power of 80%, we will need a total sample size of 64 patients. This is considering a base satisfaction score of 70, with a standard deviation of 20.

**Safety Procedures:**

-Confidentiality and Privacy: Data will be stored in a secure de-identified database. No personal/identifiable information will be collected in this database. A separate list that contains a list of enrolled patients, with information including patient name, phone number and internal research code will also be generated for the purpose of performing the follow-up surveys. The information from the surveys will then be uploaded into the de-identified database by using the internal research code.-Safety – A member of the research staff will be assigned as a safety monitor. Interval analysis will be performed for every 20 patients recruited. If the experimental arm demonstrates an increase of greater than 10% in visits to the emergency-room related to post-operative complaints, or an increase in unexpected complications (wound infection, wound dehiscence, etc.), the study will be halted. However, only patient's undergoing minimally invasive surgery will be included, which is known to have a lower wound-related complication rate than traditional surgery, so we do not expect any significant difference regarding complications.

**Data Management:**

All data will be collected in a de-identified fashion and stored on Redcap, which is approved TTUHSC IT software. Only approved members of the research team will be granted access. The data will be stored in a secured server. Data will not be linked by code to any identifying information.

**Data analysis:**

All data analysis will be carried out in SPSS version 24 (IBM, Armonk, NY, USA). We will use T-student to compare demographic variables that are continuous (age, BMI), as well as duration of the visit and number of readmissions or phone-calls. Pearson's Chi Square will be used when analyzing categorical binary variables.

**Strengths/limitations**

This is an innovative study that seeks to apply existing and well established technology to improve patient experience in regards to the postoperative portion of their care. If found to be effective, it could also have the potential of reducing costs for the patient and clinic. The study is strong given its randomized nature. Randomization will occur after the surgical procedure is completed to avoid bias that could affect intra-operative technique or decisions. We will also use validated instruments to assess patient satisfaction.

The main limitation of the study is that patients and providers who are doing the post-operative visit cannot be blinded. This may lead to some degree of subconscious bias in the way the visits (traditional or tele-medicine) are carried out, which could potentially impact duration and patient satisfaction. We will attempt to mitigate this by utilizing a standardized visit structure which is exemplified in the methods section. Additionally, the research staff that will conduct the survey will be blinded to allocation. Patients will be instructed during the consenting process to avoid revealing their group when the surveyor calls.

**Timeline**

Accrual will commence after IRB approval. We expect to enroll on average 4 patients per week.

**References**


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