ASSESSMENT OF VIDEO-CONFERENCE TECHNOLOGY FOR POST-OPERATIVE FOLLOW UP IN A UROGYNECOLOGIC POPULATION

NCT04138810

Daniel Lee, MD

July 16, 2018

Background

Telemedicine is being utilized at much higher rates than in the past by medical professionals across all specialties. Telemedicine includes traditional telephone calls, virtual office visits with video conferencing and even virtual rounding with robots. Its adoption into medical practice has been well received by both patients and medical staff and has become widespread throughout the United States. Many studies have documented that post-operative telephone calls made by nurses, advanced practice providers or the providers themselves decrease patient anxiety, decrease unnecessary emergency room visits and increase patient education and satisfaction with the surgery and the surgical team.[1-9] These telephone calls also provide an opportunity to triage patients who may warrant an earlier post-operative office visit for myriad of concerns.[10-12] With the ever expanding capabilities of technology and increased access and adoption of mobile technology we now have the opportunity to expand beyond the traditional phone call to interact with patients on a more interactive and personal level.[13-15] The majority of the literature on hospital discharge follow up focuses on chronic disease conditions such as diabetes and congestive heart failure as these patients historically have multiple hospital re-admissions as their disease state progresses. The goals of close follow up of these patients were to ensure that patients were taking their medications and maximizing their health status as an outpatient to prevent costly inpatient management and admissions.[4,16-20]

There is currently a paucity of literature surrounding the use of post-operative videoconferencing technology to supplement or replace the traditional post-operative office visit. Patients have routine post-operative office visits approximately thirty and ninety days after their surgical procedure. Often, the first post-operative visit consists mainly of reassurance and counseling, rarely does this visit have any major effect on clinical decision making. Replacement of the thirty day office visit with a virtual clinical encounter (VCE) can help alleviate travel and caretaker burden while still addressing post-operative needs and possibly increasing patient satisfaction.[21] From the provider side, a VCE can help open up their office schedules to see more new patient consultations.[22] An opportunity exists to improve the quality and efficiency of post-operative care and increase patient satisfaction by utilizing videoconferencing technology to conduct VCEs.

1. Czarnecki MLG, M. M.; Weisman, S. J. Advanced practice nurse-directed telephone management of acute pain following pediatric spinal fusion surgery. J Spec Pediatr Nurs. 2007;12(3):159-169.
2. Turner D. Can telephone follow-up improve post-discharge outcomes? Br J Nurs. 1996;5(22):1361-1365.
3. Gunter RL, Chouinard S, Fernandes-Taylor S, et al. Current Use of Telemedicine for Post-Discharge Surgical Care: A Systematic Review. Journal of the American College of Surgeons. 2016;222 (5):915-927.
4. Soong CK, B.; Wells, D.; Caines, L.; Morgan, M. W.; Ramsden, R.; Bell, C. M. Do post discharge phone calls improve care transitions? A cluster-randomized trial. PLoS ONE. 2014;9 (11):e112230.
5. Emerson CG, L.; Harper, S.; Woodruff, C. Effect of telephone followups on post vasectomy office visits. Urol Nurs. 2000;20(2):125-127, 131.
6. Yang CC, C. M. Effects of post- discharge telephone calls on the rate of emergency department visits in paediatric patients. J Paediatr Child Health. 2012;48(10):931-935.
7. Kleinpell RM. Improving telephone follow-up after ambulatory surgery. J Perianesth Nurs. 1997;12(5):336-340.
8. Weisman DSB, L.; Mehta, A.; Bhatia, L.; Levine, S. M.; Mete, M.; Padmore, J. S. A medical resident post-discharge phone call study. Hosp Pract (Minneap). 2012;40(2):138-146.
9. Gray RTS, M. K.; Badger, S. A.; Harvey, C. F. Post-operative telephone review is cost-effective and acceptable to patients. Ulster Med J. 2010;79(2):76-79.
10. Alemi AS, Seth R, Heaton C, Wang SJ, Knott PD. Comparison of Video and In-person Free Flap Assessment following Head and Neck Free Tissue Transfer. Otolaryngology--head and neck surgery: official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2017;156(6):1035-1040.
11. Brough RJP, H.; O'Flynn, K. J.; Payne, S. R. Identification of patients requiring out-patient follow-up after transurethral prostatectomy: is there a role for nurse-led screening of post-operative outcomes by telephone? Br J Urol. 1996;78(3):401-404.
12. Forster AJB, L.; Shojania, K. G.; Feasby, T. E.; van Walraven, C. Identifying patients with post-discharge care problems using an interactive voice response system. J Gen Intern Med. 2009;24(4):520-525.
13. Burke D, Menachemi N, Brooks RG. Diffusion of information technology supporting the Institute of Medicine's quality chasm care aims. Journal for healthcare quality : official publication of the National Association for Healthcare Quality. 2005;27 (1):24-32, 39.
14. Mishra A, Kapoor L, Mishra SK. Post-operative care through tele-follow up visits in patients undergoing thyroidectomy and parathyroidectomy in a resource-constrained environment. Journal of telemedicine and telecare. 2009;15(2):73-76.

15. Reider-Demer M, Raja P, Martin N, Schwinger M, Babayan D. Prospective and retrospective study of videoconference telemedicine follow- up after elective neurosurgery: results of a pilot program. Neurosurgical review. 2017.
16. Bours GJK, C. A.; Frederiks, C. M.; Abu-Saad, H. H.; Wouters, E. F. The effects of aftercare on chronic patients and frail elderly patients when discharged from hospital: a systematic review. Journal of Advanced Nursing. 1998;27(5):1076-1086.
17. Altfeld SJS, G. E.; Rooney, M.; Johnson, T. J.; Golden, R. L.; Karavolos, K.; Avery, E.; Nandi, V.; Perry, A. J. Effects of an enhanced discharge planning intervention for hospitalized older adults: a randomized trial. Gerontologist. 2013;53(3):430-440.
18. Tang NF, J.; Karliner, L. Evaluation of a primary care-based post-discharge phone call program: keeping the primary care practice at the center of post-hospitalization care transition. J Gen Intern Med. 2014;29(11):1513-1518.
19. Morgan GJ, Craig B, Grant B, Sands A, Doherty N, Casey F. Home videoconferencing for patients with severe congential heart disease following discharge. Congenital heart disease. 2008;3(5):317-324.
20. Bowman GSH, J.; Allen, S.; Webster, R. A.; Thompson, D. R. A telephone survey of medical patients 1 week after discharge from hospital. J Clin Nurs. 1994;3(6):369-373.
21. Greiner AL. Telemedicine Applications in Obstetrics and Gynecology. Clinical obstetrics and gynecology. 2017;60 (4):853-866.
22. Jefferis H, Muriithi F, White B, Price N, Jackson S. Telephone follow-up after day case tension-free vaginal tape insertion. International urogynecology journal. 2016;27(5):787-790.

Abstract

Postoperative follow up is necessary following any surgical procedure and has been conducted in the same manner since the field of surgery began. We will determine feasibility and patient satisfaction of innovative postoperative virtual clinical encounters utilizing mobile video conference technology for women undergoing pelvic reconstructive surgery through a randomized controlled trial. The primary outcome will be patient satisfaction after their 4 to 6 week (30 day) postoperative visit. We will also study 30-day and 90-day re-admission rates, unplanned visits to the emergency room and clinic.

Overall objectives

The primary objective of the study is to determine if postoperative virtual clinical encounters via mobile video conference technology are non-inferior to traditional postoperative office visits at 30-days following surgery in terms of patient satisfaction. Secondary objectives include utilization of emergency room visits, readmissions, postoperative complications, unscheduled office visits and telephone encounters with the provider's office at 30- and 90-days following surgery.

Primary outcome variable

Patient satisfaction as determined by the Patient Satisfaction Questionnaire-18 (PSQ-18).

Secondary outcome variable(s)

1. Emergency room utilization in the 30- and 90-day postoperative period
2. Hospital readmissions in the 30- and 90-day postoperative period
3. Unscheduled office visits in the 30- and 90-day postoperative period
4. Telephone encounters with medical providers in the 30- and 90-day postoperative period
5. Postoperative complications
6. Efficiency: measured by time spent by patient on clinical encounter (time in waiting room, time in exam room and time with provider)

Study Design

Design

This will be a prospective randomized control study comparing postoperative virtual clinical encounters versus traditional in-office postoperative visits in women undergoing pelvic reconstructive surgery. The postoperative experiences of both groups will be assessed via surveys.

Virtual Clinical Encounter Group:

- Receive video-conference call from office nurse 48-72 hours post discharge from hospital

- Receive video-conference call from fellow and/or attending physician approximately 30 days after surgery
- Complete telephone survey within 24 hours of 30-day videoconference visit
- Have in-office postoperative visit with fellow and/or attending physician approximately 90 days from surgery

Traditional Office Group:
- Receive telephone call from office nurse 48-72 hours post discharge from hospital
- Have in-office postoperative visit with fellow and/or attending physician approximately 30 days from surgery
- Complete telephone survey within 24 hours of 30-day office visit
- Have in-office postoperative visit with fellow and/or attending physician approximately 90 days from surgery

Study duration
In the division of urogynecology there are approximately 30-40 pelvic reconstructive surgical procedures a month (approximately 500 surgical cases across all clinical sites in the past year). We aim to start recruiting patients as soon as possible and estimate that we will need approximately 4 months to recruit the 50 patients for the study (25 in the virtual clinical encounter group and 25 in the traditional office group). Once the last patient is enrolled, data collection on the study would be completed after 3 months (a total of 7 months to complete data collection on the study). A subject's participation in the study will conclude 90-days after the date of their completed surgical procedure.

Accrual
Our primary outcome is patient satisfaction as determined by the validated PSQ-18. The minimum important difference has not been previously reported for the PSQ-18 but prior studies utilizing this questionnaire have shown that the standard deviation for total PSQ-18 scores range between 5 and 8 with a mean total score range between 67 and 72.24. With a non-inferiority margin of 5 points on the PSQ-18, a type I error rate of 0.05 and a power of 0.80, we estimated a sample size of 25 women per group.

Last year, the combined surgical volume of these cases at our clinical sites was approximately 500 subjects; thus, we anticipate we will be able to easily recruit the proposed sample size in 4 months. We plan to recruit women from 2 clinical sites in the University of Pennsylvania Health System: 1) Urogynecology at Hospital of University of Pennsylvania (HUP) and 2) Urogynecology at Pennsylvania Hospital (PAH). Physician investigators are present at all three sites, and will have opportunities to screen patients planning for surgery for pelvic organ prolapse for participation.

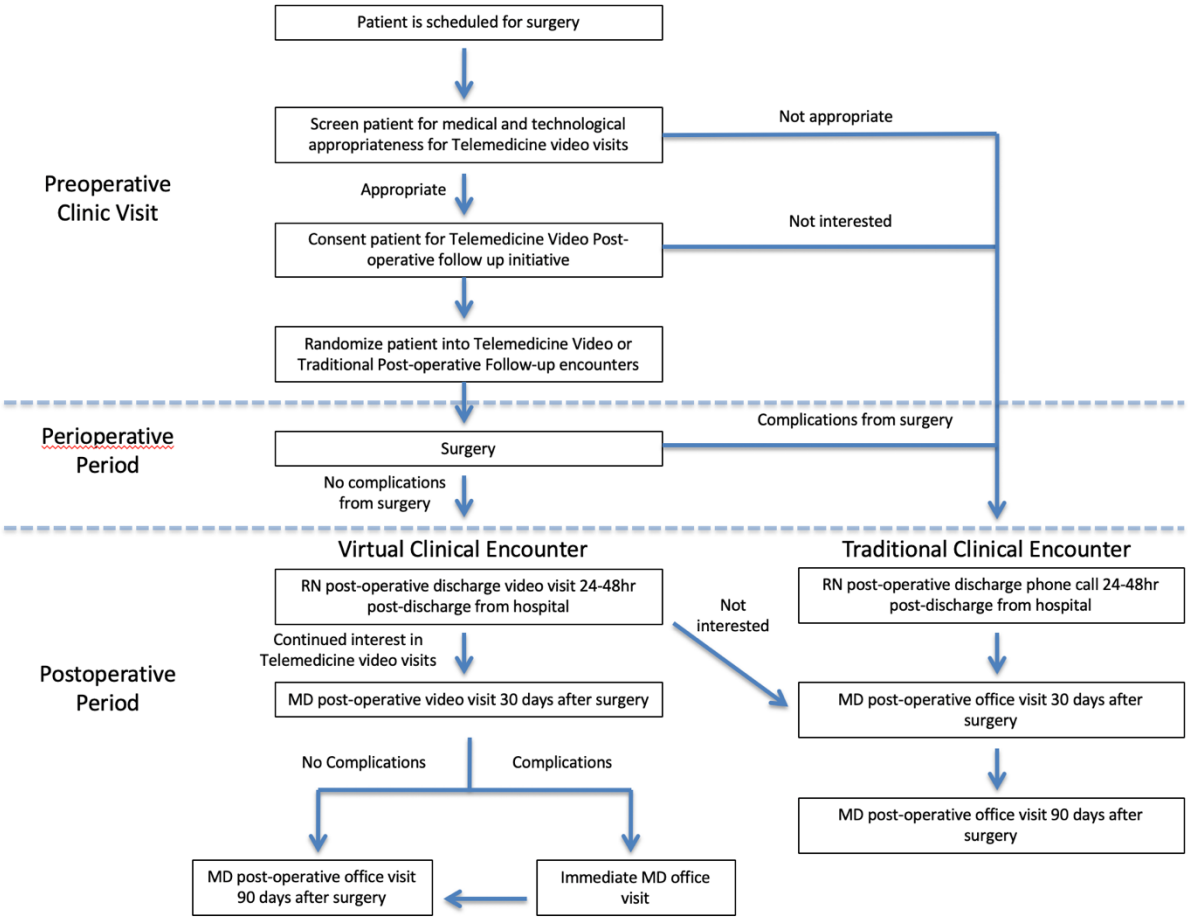
Key inclusion criteria
- Undergoing surgery for pelvic organ prolapse
- Age greater than 18
- Access to a smartphone
- Access to high speed internet access (via 4G or 3G on their smartphone or high speed Wi-Fi)
- Signed up for MyPennMedicine web portal
- Ability to download MyChart mobile application
- Pennsylvania Hospital Subject: NJ or PA resident, HUP & Presbyterian Hospital Subject: PA resident

Key exclusion criteria
- Pregnancy
- Inability to read, speak or understand English
- Isolated midurethral sling procedure
- Extraperitoneal vaginal colpopexy with Uphold mesh

Procedures
RECRUITMENT AND PREOPERATIVE PERIOD: We plan to recruit women from 2 clinical sites associated with the University of Pennsylvania Health System: 1) Urogynecology at Hospital of University of Pennsylvania (HUP) and 2) Urogynecology at Pennsylvania Hospital (PAH). All patients will fill out the Patient Technical Qualifying Checklist to verify that they meet the technical requirements needed for participation in the study. If the patient is not currently enrolled in My Penn Medicine or does not currently have the MyChart mobile application downloaded onto their smartphone, then the trained office staff at the clinical sites will assist the patient in obtaining these requirements for participation. Physician investigators, who are present at all sites, will screen patients planning for

surgery for pelvic organ prolapse for participation. Following confirmation of eligibility, the physicians will obtain informed consent prior to surgery at the planned preoperative visit. The combined annual surgical volume at our two clinical sites (four surgeons) is approximately 500 subjects; thus, we anticipate we will be able to easily recruit the proposed sample size in seven months.

ENROLLMENT AND PERIOPERATIVE PERIOD: After informed consent has been signed, the patients will be randomized to either postoperative virtual clinical encounters (VCE) via videoconference technology or traditional in-office post-operative visits using sealed, opaque, sequentially numbered envelopes following a blocked randomization schedule. The patient will undergo their planned surgery, if there are any surgical complications from surgery that warrant in-office visits, those patients randomized to virtual clinical encounters will be removed from the study and undergo the current standard of care with in-office postoperative visits. If there are no complications from surgery then the following follow up encounters will occur for the two groups.



POSTOPERATIVE PERIOD: As per standard of care, all subjects will be scheduled for a nursing clinical encounter 48-72 hours following discharge from the hospital from their surgery. The VCE group will conduct their encounter via the videoconference section of the MyChart mobile applications. The traditional follow up group will receive a telephone call from the office nurse as is current standard of care. Both of these encounters will be conducted according to a standard script which reviews the following key aspects of postoperative care: bowel functions, voiding functions, presence of vaginal bleeding, pain control, diet status, ambulatory status and any additional concerns. Standard postoperative instructions and precautions are reviewed as well. At the end of this nursing encounter, the office nurse will schedule the patient for a 30-day postoperative visit. This will either be a VCE or an in-office visit, depending on the subject's randomization. These encounters are documented in the electronic

medical system. If at any time the patient who is randomized to VCEs no longer desires to be in the VCE group, an in-office appointment will be scheduled for them by the office nurse.

On the scheduled day of the 30-day postoperative visit the VCE group will conduct their visit via the videoconference section of the MyChart mobile applications with the clinical fellow and/or their surgeon. The traditional group will have their in-office visit with the clinical fellow and/or their surgeon. Both encounters will be conducted according to a standardized script. Subjects will all be offered a physical exam if desired. If a subject in the VCE group desires a pelvic exam, then they will be offered to come into the clinic on the next following business day. These encounters are documented in the electronic medical system.

Demographic information will be collected from the patient's medical record (age, ethnicity, level of education, medical comorbidities, and duration of hospitalization). Data regarding the patient's surgical intervention (procedure type, surgical complications, operative time) will be collected from the operative record. Within 24 hours of completion of the 30-day visit, the subject will receive a telephone call from the research staff and a phone survey of the study questionnaires will be conducted.

All patients will be scheduled for an in-office visit for their 90-day postoperative visit. On the scheduled day of the 90-day postoperative visit the visit will be conducted by the clinical fellow and/or their surgeon. This will be conducted according to a standardized script. All subjects will receive a physical exam. This encounter is documented in the electronic medical system.

Analysis Plan
All analyses will be conducted using an intent-to-treat principle. Data between groups will be analyzed using two-sample t-tests, Wilcoxon rank-sum tests, Pearson chi-square and Fisher's exact tests, as appropriate. Non-inferiority will be determined by the PSQ-18 after the 30-day postoperative visit with a non-inferiority margin of 5 points.

Consent
Informed consent will be obtained by the investigator in the clinical office during the subject's preoperative office visit. The patient may choose to withdraw from the study at any time. Investigators will emphasize that participation (or lack of participation) in the study: 1) will not influence their evaluation, care, or treatment 2) is completely voluntary 3) does not involve any financial compensation 4) may be terminated at any time. Layman terms will be used by those obtaining the consent. The consent will be written at a 6th grade reading level. All questions will be answered to the patient's satisfaction and understanding before informed consent is obtained.