Telehealth Electronic Monitoring to reduce Post Discharge Complications and Surgical Site Infections Following Arterial Revascularization with Groin Incision

Registered on ClinicalTrials.gov NCT02767011.

This study is funded by West Virginia Clinical and Translational Science Institute (WVCTSI) grant U54GM104942 and Charleston Area Medical Center Research Institute. The study design, data collection, analysis, interpretation of data, manuscript writing; or decision to submit the manuscript for publication was solely the responsibilities of the authors.

The study protocol was approved by CAMC/WVU Charleston Division governing Institutional Review Board (IRB).

Document Date: 9/28/2016

Surgical Site Infections Following Arterial Revascularization with Groin Incision

Albeir Y. Mousa, MD*
Associate Professor
Mike Broce, BA**
Research Assistant
Elaine Davis, ED**
Care Manager
Barbara McKee, RN***
Care Manager
*Department of Surgery
Robert C. Byrd Health Sciences Center/West Virginia University
Charleston Area Medical Center, Vascular Center of Excellence
3110 MacCorkle Ave., SE, Charleston, WV 25304
**Center for Health Services and Outcomes Research
Charleston Area Medical Center Health Education and Research Institute
Charleston, WV
***Partners in Health Network Charleston, WV

Corresponding author:
Albeir Y. Mousa, MD
Robert C. Byrd Health Sciences Center/West Virginia University
Charleston Area Medical Center, Vascular Center of Excellence
3110 MacCorkle Ave., SE, Charleston, WV 25304
Phone: 304-388-4875; Fax: 304-3884876; email: amousa@hsc.wvu.edu

This study is funded by West Virginia Clinical and Translational Science Institute (WVCTSI) grant U54GM104942 and Charleston Area Medical Center Research Institute. The study design, data collection, analysis, interpretation of data, manuscript writing; or decision to submit the manuscript for publication was solely the responsibilities of the authors.

The study is registered on ClinicalTrials.gov NCT02767011.

The authors have no other conflicts to report.

Tele-Health Electronic Monitoring to reduce Post Discharge Complications and Surgical Site Infections Following Arterial Revascularization with Groin Incision

Abstract:

It is intuitive that post discharge surgical complications are associated with increased patient dissatisfaction, and directly associated with an increase in medical expenditures. It is also easy to make the connection that many post hospital discharge surgical complications including surgical site infections could be influenced or exacerbated by patient co-morbidities. The authors of a recent study reported that female gender, obesity, diabetes, smoking, hypertension, coronary artery disease, critical limb ischemia, chronic obstructive pulmonary disease, dyspnea, and neurologic disease were all of among significant predictors of surgical site infections after vascular reconstruction was performed. The main concern for optimal patient care especially in geographically isolated areas of West Virginia is to have early, expeditious, and prompt diagnosis of early surgical site infection with subsequent indicated interventions. This theme will lead to patient satisfaction, minimizing third party interventions and decrease the total cost associated with these complications. Nevertheless, it seems reasonable to believe that monitoring using telehealth technology and managing the general health care patients receive after a hospital vascular intervention will improve overall health and reduce post-operative complications.

Aims/Objectives:

1. The primary objective of the current project is to compare early and late outcomes for patients who receive post discharge health care monitoring (which includes using **T**ele**h**ealth **e**lectronic **m**onitoring; THEM) to patients who receive **s**tandard **o**f **c**are (SOC) and routine discharge instructions and no monitoring.

Methods:

1. Randomize patients who are scheduled to have revascularization interventions with groin incisions to receive either telehealth electronic health care monitoring or normal standard of follow-up care.
2. Follow patients for 4 weeks, record any 30-day hospital readmissions or complications. In addition, have participants complete the follow-up survey questionnaires.

Background:

Postoperative hospital readmissions present significant challenges for patients and health care systems as well. There is significant Medicare expenditure devoted to this issue. Although it is intuitive to assume that these issues can be prevented to minimize cost, but the problem continues to escalate in many aspects. A recent report indicated that Medicare expenditures were associated with a readmission rate estimated to be $12 billion per year.[1] Another report[2] has indicated that about 24% of the entire Medicare expenditure is consumed by readmissions. Ironically, those reports were based on data gathered between1974 to 1977, and definitely would be much higher in today calculations according to current inflation index in GDP. As health care professionals, we should be aware of all ongoing ramifications associated with readmissions, as the integral scope of proper patient care is under scrutiny with all its related issues such as, hospital reimbursement, physician credentialing process and regulation, referral pattern and eventually educational enterprises.[3]

Surgical Site Infections Following Arterial Revascularization with Groin Incision

Vascular surgery especially arterial revascularizations with groin incisions (ARGI) has always been associated with the potential of higher rates of readmission pertaining to high-risk patients with multiple co-morbidities such as diabetes, cardiac issues and poor general nutrition. These types of issues are more demanding in geographical areas such as rural West Virginia where easy access to medical attention is not available. In most cases, 30 day-readmissions are considered to be in-hospital complications. However, some authorities have suggested that readmissions after vascular interventions are really measures of post discharge complications rather than in-hospital complications.[3-8] Most U.S hospitals are currently in full compliance with the Surgical Care Improvement Project (SCIP). Unfortunately, compliance with these processes has not yet directly been associated with reduced SSI rates.[9, 10] In addition, reports of 30-day readmission rates for vascular surgery patients are very high and it may vary from 11 to 25%.[1, 8]

Identifying patients with higher rates of readmission after discharge is of essence in order to pay more attention or even to deploy a system to monitor them closely. In one study,[11] patients with a positive clinical culture obtained more than 48 hours after hospital admission had an increased hazard of readmission (HR, 1.40; 95% CI, 1.33-1.46) after adjusting for other co-morbidities. Another review indicated that SSIs may develop in 10% of the 3,663 patients who underwent an inpatient general surgical procedure. It has been reported that diagnosis of SSI after discharge was also associated with a high readmission rate despite occurring in healthier patients. It has been proposed that discharge specific instructions related to wound infections along with a wound surveillance in-clinic visit within the first week may result in a decreased readmission rate.[7] Gohil et al assessed 30-day readmission rates from 323 hospitals and reported that infection-related readmissions accounted for 28% of all readmissions. The same study reported that academic hospitals had higher all-cause and infection-related readmission

rates.[12]

The thought of reducing readmission and infection rates has been energized by the recent policy proposals suggested by the Medicare Payment Advisory Commission to lower average per-case reimbursements to hospitals with high (risk-adjusted) rates of re-hospitalizations. It is important to identify high-risk patients in order to be more focused and to incorporate procedures to identify early signs of infection. This approach of increased outpatient support has been proven to be cost effective.[2] Some researchers have developed a scoring system to accurately identify patients at high risk for 30-day unplanned readmissions and suggested this could help direct discharge and home health care resources to patients, which ultimately could be used to reduce readmissions and improving efficiency.[8] Gibson et al reported that diagnosis of surgical site infection (SSI) after discharge is associated with a high readmission rate despite occurring in healthier patients.[7] The authors of a recent study reported that female gender, obesity, diabetes, smoking, hypertension, coronary artery disease, critical limb ischemia, chronic obstructive pulmonary disease, dyspnea, and neurologic disease were all of among significant predictors of SSI after vascular reconstruction was performed.[13] Another important potential impact of telehealth technology is that it may minimize the burden and cost of 3rd party home visits to evaluate wounds or provide treatment. Currently, many interventions of vascular surgery require postoperative visiting nursing service (VNS) to evaluate wound or treatment at home. The home visit approach utilizes significant resources to achieve its target. As part of the main objectives of telehealth technology, we believe that our suggested approach will limit not only the number but also the frequency of VNS. In addition it may even supersede VNS as it provides to some extent more continuous and more objectives measures to provide a better follow up to our patients after discharge.

In conclusion, it seems reasonable to believe that monitoring using telehealth technology and managing the general health care patients receive after a hospital vascular ARGI intervention will improve overall health, patient care and will reduce post operative complications. Our project will be conducted to directly give more and continuous attention to postoperative period after hospital discharge. We believe that early readmission is a "failed discharge" as has suggested by others. This matter is of great interest particularly to our specialty.

Objectives

The primary objective of the current project is to compare outcomes for patients who receive post discharge health care monitoring (which includes using **T**ele**h**ealth **e**lectonic **m**onitoring; THEM) to patients who receive **s**tandard **o**f **c**are (SOC) and routine discharge instructions and no monitoring.

Outcomes

The primary outcomes include 30-day readmissions, post-operative complications and access site/wound infections. Secondary outcomes will include a pre and post surgery quality of life measures (SF-8) and patient satisfaction (>30-day) along with an occurrence of any 30-day stroke, MI or death.

Study hypotheses:

1. A smaller percentage of THEM patients will require a 30-day unplanned readmission.
2. A smaller percentage of THEM patients will develop a SSI.
3. THEM patients will report greater post discharge satisfaction and higher quality of life measures.

Significance:

1. Information and results obtained from this study may suggest additional post discharge treatment approaches which in turn could lower 30-day readmissions and complications for patients undergoing surgery.

2. Likewise, information and results obtained from this study could be used to help promote greater patient satisfaction and quality of life measures.

3. This approach may impact some direct cost pertaining to post-discharge follow-up as visiting nurse services. THEM approach will provide a direct, measurable, specific tool to provide therapy related information to the treating physician during post-discharge period.

Study Design:

The current study is designed to be a **p**rospective, **r**andomized, **o**pen-label, single-center with **b**linded **e**ndpoints (PROBE) study.[14] More specifically, it is designed to test the hypothesis that Tele-health monitoring will decrease 30-day readmission and complication rates. Patients with planned vascular ARGIs will be consented for possible inclusion. Patients who give their consent will be enrolled and randomly assigned to one of the two treatment arms: 1) standard of care (SOC) or 2) Tele-health electronic monitoring (THEM) using TeleMed 2020 home health monitoring system.
The primary endpoints will be measured as simply the occurrence or not of any unplanned 30-day readmission and/or complication (0/1). Patients in the intervention group (THEM) will receive a tablet computer and home monitoring medical devices with sensors to transmit the information to a central website that will be monitored by care managers. Medical devices will include weight scales, blood pressure cuffs and oxygen saturation monitors. Clinical care mangers will remotely monitor the patients and all electronic readings. Clinical care managers will call or send electronic messages to the patients based on alerts generated by the tele-health monitoring system.

Sample:

The population for this study will be patients with any planned vascular procedures with cut-down access to the groin and will be treated by one of the Vascular Surgeons in the Vascular Center of Excellence (VCOE).

Sample Size:
The sample size was estimated based on the readmission rates from a previous research study. An overall sample size of 200 subjects will have 80% power to detect a reduction in the 30-day infection/readmission rate from ~12 in the SOC group to ~2% in the THEM group using a 2-sided α of 0.05. We expect a 10% drop-out rate and thus plan to enroll 110 patients in each group (N=220 overall).

Inclusion/exclusion criteria:
Patients meeting the inclusion criteria, which is any planned vascular procedures with cut-down access to the groin and treated by one of the Vascular Surgeons in the Vascular Center (VCOE) will be consented and enrolled. Patients will be excluded for any of the following reasons (1) do not plan to do follow-up visit at the VCOE; (2) inability to sign or understand the consent form; (3) do not have home internet service with WIFI or live outside of the provided cell coverage area (cell coverage will be provided for patients without internet WIFI). Informed consent will be obtained research coordinator; eligible patients will be randomly assigned to either the treatment group (THEM) or the control group (SOC).

Randomization:
The randomization will be done centrally using a computer containing a SPSS algorithm. The randomized list will be placed in 220 envelopes and labeled 1 through 220. After randomization and necessary medical procedures, but before discharge each patient depending on treatment assignment will receive either the home monitoring equipment with instruction for those in the treatment group (THEM) or normal discharge instructions for the control group (SOC).

Patients in the intervention group will receive a tablet computer and home monitoring medical devices with sensors to transmit the information to a central website that will be monitored by care managers. The TeleMed 2020 electronic home health monitoring system will be used to provide constant surveillance of THEM patients. In addition, the tablets will have the ability to send a high resolution photograph of wound if needed. Medical devices will include weight scales, blood pressure cuffs, thermometers and oxygen saturation monitors.. Clinical care mangers will remotely monitor the health of patients by viewing all electronic readings. Study care managers will call or send electronic messages to the patients based on alerts generated by the tele-monitoring system. The main focus of this approach is to have a direct, specific, objective and measurable assessment of any early wound infection after lower extremity revascularization. The care manager will make direct electronic communication as to the

appearance of the access wound and if needed request that a picture be sent for observation.

TeleMed 2020

Bloomberg Business Company Overview of TeleMed 2020, Inc.

Company Overview
TeleMed 2020, Inc. owns and operates a cloud-based SaaS solution for remote patient monitoring. The company allows clinician scheduling and ongoing patient capture and sharing of critical information yielding earlier and more active care plan management. The company is based in Indianapolis, Indiana.

http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapid=310873357

For the THEM group, the care manager will:

1. Monitor patient vital signs: daily weight, blood pressure, pulse, , oxygen saturation and temperature
2. Ask about the description of the postoperative wound site: including any surrounding erythema, discharge, wound dehiscence and healing. If necessary, ask for a picture of the wound site to be sent. A transmitted photograph of the wound condition may augment amount of knowledge available to clinical care management team.
3. Complete a target organ evaluation: which means to evaluate the bypass and this will include general feeling, pain (location, degree, type and relieving elements).
4. Assess compliance with the discharge medications.

Early signs of infection would include, but not be limited to fever, tachycardia, discharge, erythema, wound dehiscence, and pain. All of these will be evaluated via telecommunication tools by the care manager and if needed immediately discussed with supervising physician. In addition, the patient, if needed, will be scheduled for an early office visit and/or re-hospitalization.

For the SOC group, the care manager will follow the current standard of care.

Procedure:

PRE-TREATMENT:

- Patients will be identified by the Vascular Surgeon and scheduled for the procedure.
- Study coordinator will review patient scheduling records to identify potential study participants.

- The study coordinator will explain the research study and the informed consent with the patient prior to the surgical intervention.
- The patient upon appropriate consent signs and dates the consent form and the HIPPA authorization form, which is attached to the consent form.
- Patient upon informed consent is randomized to either receive the treatment (THEM) or to the SOC control group (SOC).
- Complete a pre-treatment SF-8 and baseline history form.

Quality of life measure

The SF-8™ Health Survey is a brief and comprehensive quality of life population survey. It has only eight questionnaire items, and by design according to the company's website "was constructed to replace the SF-36® and SF-12® in population health surveys in the U.S. and internationally. Accordingly, it has been translated and linguistically validated for use in more than 30 countries and languages using IQOLA Project methods. It has been adopted by federal agencies (e.g., the DOD), leading polling organizations (e.g., the Roper-Starch Worldwide Health Report), and industry sponsors of clinical trials and effectiveness research (e.g., Glaxo Smith Kline, Johnson & Johnson, and Searle)." In addition, the validation and norming measures of the SF-8™ Health included the general population as well as many subgroups of subjects with co-morbidities such as depression and diabetes. The SF-8™ is a very sensitive test that has both test/retest reliability as well as the ability to detect change of time. The scoring of the SF-8™ produces two summary scores. One for the physical (PCS) and one for the mental dimension (MCS). It also provides the same 8 subscale scores for each dimension as the SF-36.

Vascular Intervention:

All patients will receive their planned and scheduled procedures.

Follow-Up Protocol:

After 2-4 weeks, all patients will have a follow-up visit scheduled at the VCOE clinic. Follow-up will include physical exam including a routine visual inspection of access site wound and comments will be collected. All patients will complete a second SF-8 survey form and a patient satisfaction survey. If follow-up visit is less than 30 days, then a member of the study team will call patients and obtain SF-8, satisfaction survey and follow-up form.

Data Collection:

Will include (see appendix):

1) Signed consent forms
2) Enrollment and demographics form
3) SF-8 survey
4) Patient satisfaction survey
5) 4 week follow-up form

Schedule of Events

Information:	**SOC**	**THEM**
Sign Informed Consent	Pre-Intervention	Pre-Intervention
Randomization	Pre-Intervention	Pre-Intervention
Pre-treatment	SF-8 survey	SF-8 survey
Equipment & instructions	At discharge	At discharge
Follow Up:		
Special issue follow-up	**Patient initiated**	**Patient or monitor initiated**
Routine follow-up exam	**2-4 weeks**	**2-4 weeks**
	SF-8 survey	SF-8 survey
	Satisfaction survey Follow-up form **Debriefing**	Satisfaction survey Follow-up form **Debriefing**

SOC = Standard of Care
THEM = Tele-Health Electronic Monitoring

Statistical Analysis:

All analyses will be based on intention-to-treat (ITT) analyses. However, if possible we will sub-analyze the data on a per-protocol basis as well. Descriptive statistics will be expressed in terms of frequencies, percentages, or means $\pm$ standard deviation (SD). Categorical variables will be tested by chi-square or Fisher exact tests and continuous variables will be tested by student t-test or paired t-test for pre/post measures, where deemed appropriate. Survival and freedom from event curves such as freedom from re-admission will be created using the Kaplan Meier method, compared by the Log Rank test, and graphically presented using life tables. All probability values will be 2 sided and 'p' values <0.05 will be considered significant. Statistical analyses will be performed using SPSS version 19.0 for Windows. This study will be registered at ClinicalTrials.gov.

End Points:

The primary outcomes include 30-day readmissions, post-operative complications and access site/wound infections.

Secondary outcomes will include a pre and post-surgery quality of life measures (SF-8), patient satisfaction (>30-day) and number of VNS visits along with an occurrence of any 30-day stroke, MI or death.

Definitions:

Event-free survival will be defined as the freedom from unplanned 30-day readmission and/or 30-day access site wound infection.

Human Subjects
Recruitment Method(s)

The current study protocol received approval from our local institutional review board. The study group participants will sign consent papers on admission to the vascular lab when the patient presents for pre-procedure evaluation. The study care manger will identify potential study participants, and provide information about the study. Study staff will be trained and knowledgeable on the research protocol. This study will not offer any direct benefit for the study participants. Staff will not begin consenting patients until they have completed this training and are in compliance with any pertinent trainings offered by Research and Grants.

Payment/Costs of Testing:

Patients enrolled in both study comparison groups (THEM and SOC) will not incur additional expenses as a due to their participation in this study. Normal standard of care will be provided to the participants in the SOC group, while the members of THEM group will receive enhanced care management. The patient's insurance or the patient will not be billed for any of the care management or Tele-health monitoring.

Risk and Benefits:

There are no known risks or benefits to the study patients. Data collection takes place utilizing existing data that has been acquired during the delivery of routine medical care

SIDE EFFECTS

To date there are no know or expected side effects. Should other unknown risks become available to the researchers; patients will be informed as soon as possible.

Adverse reactions

To date there are no know or expected side effects. Should other unknown risks become available to the researchers; patients will be informed as soon as possible.

Confidentiality of Records:

Records will be kept on all study participants according to standard routine procedures. However, additional study variables will be collected. Electronic and data collection sheets will be kept in strict confidence. Data collection sheets will be kept in a

locked area. Electronic data will reside on a secure CHERI server and will only be accessible by appropriate research staff members.

Compensation:
Participation in this research study is strictly voluntary and participants will not be reimbursed or paid for their participation.

Debriefing:
Participants will be treated with the same standard of care as all other patients.

Interventions:

Participants will follow the same standard of care as other patients requiring treatment. If a study participant has any side effects, the patient will be evaluated by their physician and a decision to continue or stop treatment will be made.

Investigator Qualifications:

Albeir Mousa, MD., FACS, RPVI, MPH, MBA
Associate Professor, Department of Surgery
Vascular and Endovascular Surgery Division
West Virginia University
3110 MacCorkle Ave SE
Charleston, WV 25304
Office: 304-388-4886
Pager: 304-330-7177
Fax: 304-388-4876

Other Participants:
Mike Broce BA will provide data analysis and interpretation support; he is an employee of the CAMC Health Education and Research Institute.

A .5 FTE nurse will serve as study coordinator/clinical care manager.

References:

1. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. 2009;360(14):1418-28.
2. Anderson GF, Steinberg EP. Hospital readmissions in the Medicare population. N Engl J Med. 1984;311(21):1349-53.
3. Brown RE, Qadan M, Martin RC, 2nd, Polk HC, Jr. The evolving importance of readmission data to the practicing surgeon. J Am Coll Surg. 2010;211(4):558-60.
4. Adamuz J, Viasus D, Camprecios-Rodriguez P, Canavate-Jurado O, Jimenez-Martinez E, Isla P, et al. A prospective cohort study of healthcare visits and rehospitalizations after discharge of patients with community-acquired pneumonia. Respirology. 2011;16(7):1119-26.
5. Al-Khazaali A, Arora R, Helu HK. Effective Strategies in Reducing Rehospitalizations in Patients With Heart Failure. Am J Ther. 2014.
6. Araujo da Silva AR, de Souza CV, Viana ME, Sargentelli G, de Andrada Serpa MJ, Gomes MZ. Health care-associated infection and hospital readmission in a home care service for children. Am J Infect Control. 2012;40(3):282-3.
7. Gibson A, Tevis S, Kennedy G. Readmission after delayed diagnosis of surgical site infection: a focus on prevention using the American College of Surgeons National Surgical Quality Improvement Program. Am J Surg. 2014;207(6):832-9.
8. Iannuzzi JC, Chandra A, Kelly KN, Rickles AS, Monson JR, Fleming FJ. Risk score for unplanned vascular readmissions. J Vasc Surg. 2014;59(5):1340-7 e1.
9. Babayan RK. Re: Underlying Reasons Associated with Hospital Readmission following Surgery in the United States. J Urol. 2015;194(2):448.
10. Merkow RP, Ju MH, Chung JW, Hall BL, Cohen ME, Williams MV, et al. Underlying reasons associated with hospital readmission following surgery in the United States. JAMA. 2015;313(5):483-95.
11. Emerson CB, Eyzaguirre LM, Albrecht JS, Comer AC, Harris AD, Furuno JP. Healthcare-associated infection and hospital readmission. Infect Control Hosp Epidemiol. 2012;33(6):539-44.
12. Gohil SK, Datta R, Cao C, Phelan MJ, Nguyen V, Rowther AA, et al. Impact of Hospital Population Case-Mix, Including Poverty, on Hospital All-Cause and Infection-Related 30-Day Readmission Rates. Clin Infect Dis. 2015.

13. Wiseman JT, Fernandes-Taylor S, Barnes ML, Saunders RS, Saha S, Havlena J, et al. Predictors of surgical site infection after hospital discharge in patients undergoing major vascular surgery. J Vasc Surg. 2015.
14. Cryer B, Li C, Simon LS, Singh G, Stillman MJ, Berger MF. GI-REASONS: a novel 6-month, prospective, randomized, open-label, blinded endpoint (PROBE) trial. Am J Gastroenterol. 2013;108(3):392-400.