Telemedicine Based Remote Home Monitoring After Liver Transplantation

Results of a Randomized Prospective Trial

Tiffany C. Lee, MD, Tiffany E. Kaiser, PharmD, Rita Alloway, PharmD, Ervin Steve Woodle, MD, Michael J. Edwards, MD, and Shimul A. Shah, MD, MHCM✉

Objective: This study assesses the impact of a telemedicine-based home management program (THMP) on patient adherence, hospital readmissions, and quality of life (QOL) after liver transplantation (LT).

Summary of Background Data: Telemedicine interventions represent an opportunity to personalize care and can lead to improved adherence and patient satisfaction. However, there is limited data on impact of these interventions on outcomes after LT. Therefore, we conducted the first randomized controlled trial (RCT) of a THMP compared to standard of care (SOC) after LT.

Methods: One hundred six consecutive LT recipients were randomized (1:1) to 1 of 2 posttransplant care strategies: SOC or THMP. The THMP included an electronic tablet and bluetooth devices to support daily text messages, education videos, and video FaceTime capability; data was cyber-delivered into our electronic medical record daily. Endpoints were THMP participation, 90-day hospital readmission rate, and QOL.

Results: One hundred patients completed the study with 50 enrolled in each arm. Participation and adherence with telemedicine was 86% for basic health sessions (vital sign recording), but only 45% for using messaging or FaceTime. The THMP group had a lower 90-day readmission rate compared to SOC (28% vs 58%; $P = 0.004$). The THMP cohort also showed improved QOL in regards to physical function ($P = 0.02$) and general health ($P = 0.05$) at 90 days.

Conclusions: To our knowledge, this is the first RCT demonstrating the impact of THMP after LT. The magnitude of effect on LT outcomes, hospital readmissions, and QOL suggests that the adoption of telemedicine has great potential for other major operations.

Keywords: bluetooth, liver transplantation, readmissions, remote home monitoring, telemedicine

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Care after liver transplant (LT) and other major surgery needs to be more patient-centered. Postoperative care after discharge from the hospital remains provider and hospital-centered and not individualized to optimize patient outcomes and quality of life (QOL). Following LT, patients are discharged after their hospital stay and given care instructions with weekly follow-up visits. Providers expect patients to improve at home and have a complete understanding of how to manage their care once home. The traditional postoperative care paradigm is a ''one size fits all'' approach; it is not individualized to optimize outcomes. Current practice guidelines in LT do not incorporate patient preferences, needs, and expectations. Depression and anxiety are common after LT, leading to apprehension about the ability to successfully care for oneself and poor adherence with complex medication and health behavior regimens.[1–3] Although a patient's QOL improves following LT, when compared with the general population, the vast majority of LT recipients have significant deficiencies in most QOL domains.[4,5] Additionally, the reoperation and readmission rates in the first 90 days after LT are the highest of any surgery performed in the United States.[6]

By 2030, the total number of patients with end-stage liver disease is expected to be more than quadruple from the current number (14,000 patients), reaching total annual costs of $85 billion in the United States.[7] Despite the high burden on the health care system, the care of LT recipients does not significantly leverage information technology resources, personalized care, or use of patient-centered mechanisms to improve outcomes. Readmissions after LT remain high while patient satisfaction and adherence are suboptimal. We previously reported a national 90-day post-LT readmission rate of 47% with half of all readmissions occurring within the first 7 days.[6]

Through a stakeholder engagement process with the University of Cincinnati Liver Transplant Program that was designed to find ways to improve posttransplant care, we found that increasing care between visits was a top priority for patients to improve function, QOL, and independence.[8] The development of telemedicine programs and smart technology presents an opportunity to personalize care to meet the needs of individual patients. In a previous small pilot study, we demonstrated feasibility of developing a telemedicine-based home management program (THMP).[8,9] Participants in this study had lower 90-day hospital readmission rates than the institutional and national averages.[6,10] Additionally, participants reported high overall satisfaction, along with satisfaction with posttransplant preparation, quality of medical care, and access to medical care and specialists. In this follow-up randomized clinical trial, we aimed to assess the impact of this THMP in addition to standard of care on posttransplant THMP participation, hospital readmission rates, and quality of life.

METHODS

We performed a randomized controlled nonblinded pilot trial to test the clinical effectiveness of a THMP compared to the standard provider-centered care model after LT from Jan 2017 to July 2018. The LT procedure and postoperative protocols did not change over the course of the study at our center. All transplants were performed in a piggyback fashion with standard immunosuppression of

From the Cincinnati Research on Outcomes and Safety in Surgery (CROSS), Department of Surgery, University of Cincinnati College of Medicine, Cincinnati, OH.

✉ shahsu@ucmail.uc.edu.

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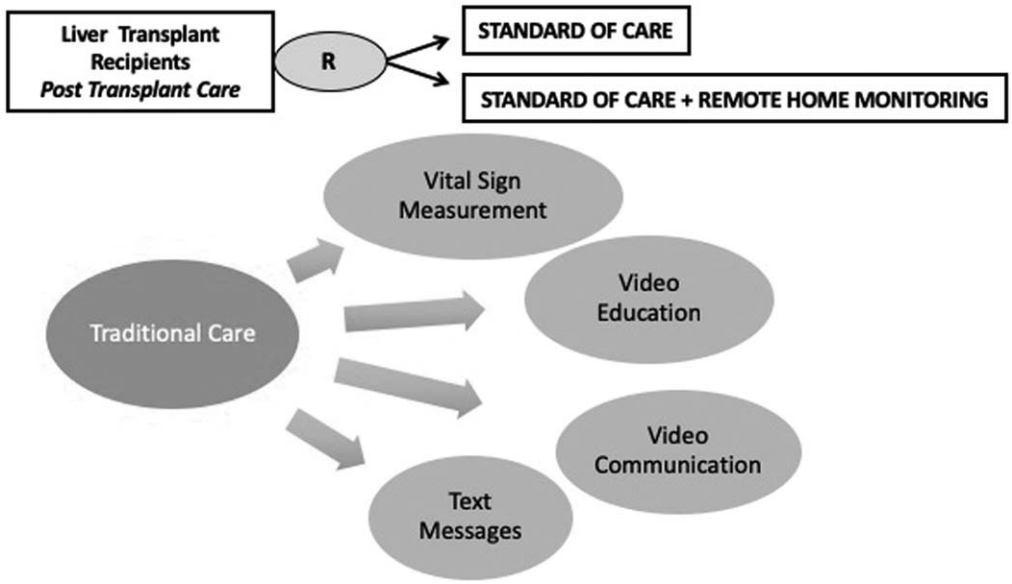

FIGURE 1. Schematic of randomized nonblinded controlled trial of 50 patients in each arm.

tacrolimus, mycophenalate mofetil, and steroids. All LT recipients were considered for participation including whole organ, split liver, and combined liver kidney recipients. Internal Review Board approval was obtained from the University of Cincinnati College of Medicine (UC-IRB 2015-0865). The ClinicalTrials.gov Identifier is NCT03878329.

Consecutive LT recipients were enrolled to 1 of 2 posttransplant care strategies: standard of care (SOC) or THMP (Fig. 1). Inclusion and exclusion criteria are shown in Table 1. After LT, patients were consented to participate in the study when they were transferred from intensive care unit to the transplant floor which usually occurred around postoperative day (POD) 2 or 3. Once enrolled, they were then randomized (1:1) to SOC or THMP using randomly permuted blocks of 2 to 8 subjects per block. The randomization list was created using R 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria). Consort diagram for study is shown in Figure 2.

Subjects enrolled into the SOC arm received the standard discharge education provided by our multidisciplinary team. According to our current SOC model, upon discharge home, patients are instructed to check their temperature, weight, blood pressure, pulse, and blood sugar values at varying times throughout the day during the first 90 days at home. Temperature, weight, blood pressure, and pulse were checked in the AM. Blood sugars were checked every 6 hours. They are provided with a *Home Monitoring Paper Log* to record the information they collect while at home. There were given instructions for when to call their coordinator or office. Prophylactic phone calls were not performed by our team. Study visits occur as part of the SOC clinic visits, initially weekly and then less frequently according to patients' recovery and clinical situation.

The THMP intervention added the telemedicine-based HMP to the SOC protocol. All smart technology and support was provided by Intel-GE Care Innovations, LLC (Roseville, CA). Subjects enrolled into the THMP arm received the standard discharge education provided by our multidisciplinary team members similar to the SOC arm. In addition to the typical *Home Monitoring Paper Log*, subjects enrolled into this arm also received a smart tablet and peripheral Bluetooth devices, free of charge (Fig. 3). The smart tablet and peripherals were used during the first 90 days at home to obtain and record vital signs measurements including temperature, blood pressure, blood sugar, and weight. The devices also supported daily text messages, education videos, and video FaceTime capability. Additionally, the tablet delivered daily questions and reminders based on postoperative day to assess clinical status including surgical wound, pain, gastrointestinal distress, medication adherence, and comfort level of using telehealth technology. This data was captured at varying frequencies throughout the day during the first 90 days at home. Answers to these questions provided insight into the transplant

TABLE 1. Inclusion and Exclusion Criteria for Participation in the Randomized Trial

Inclusion criteria:
1. Male and female subjects ($\geq$ 18 yrs old) who are liver transplant recipients.
2. Discharged home within 45 d of liver transplant.
3. Able and willing to provide informed consent.
Exclusion criteria:
1. Posttransplant admission and care provided by University of Cincinnati Medical Center or rehab facility $>$ 45 d after liver transplant.
2. Unable to have 4G wireless connectivity or wifi in their home.
3. Patient has any form of psychiatric disorder or a condition that, in the opinion of the investigator, may hinder communication with the investigator.
4. Inability to cooperate or communicate with the investigator.

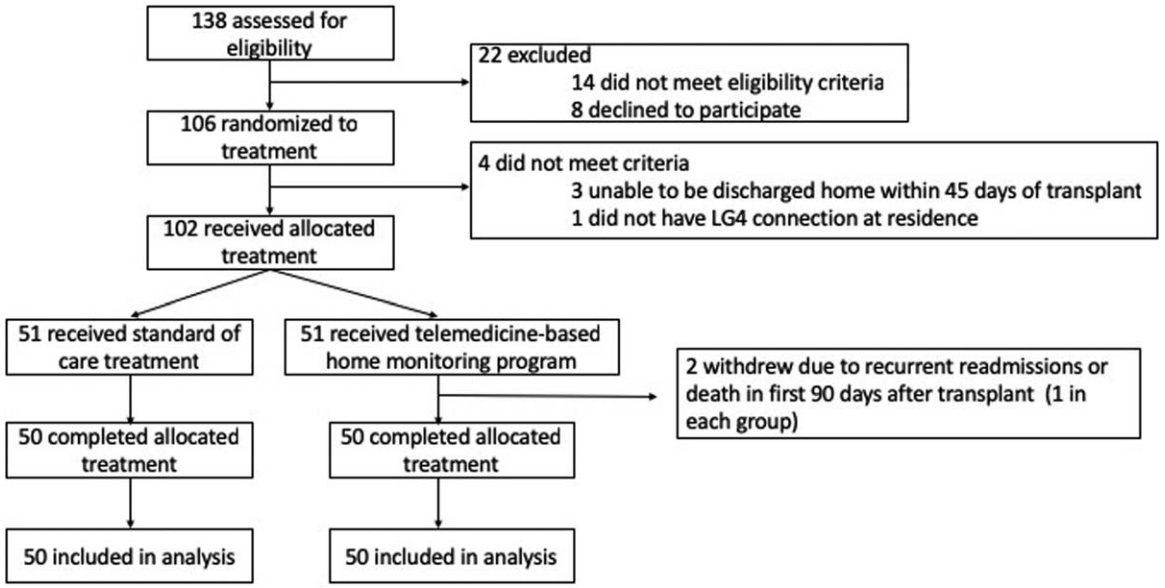

FIGURE 2. CONSORT diagram of study.

FIGURE 3. Tablet interface in THMP arm. A, Interface with pulse oximeter monitoring device. B, Interface with blood pressure monitoring device. C, Interface with blood glucose monitoring device.

team regarding the patients' general mood, recovery, and function that is not ascertainable from vital signs and other measurements. Education on each of these components of the technology was provided to the patient and their caregivers prior to discharge by a member of the study team. Additionally, within the first few days after discharge, a study team member contacted the patient to answer questions, ensure the e-health delivery is working, and assess patient comfort with the technology. When necessary, a home visit could occur. Data captured in the telehealth tablet was stored within the Health Harmony application of Care Innovations LLC. The research and clinical team had access to the secure site to allow for data review in real time. In addition, vital sign data was transmitted and organized in Epic, the patients electronic health record (EHR), to facilitate review for both patient and provider in a password protected interface. This was reviewed on a daily basis and alerts were responded to first by the nurse care coordinator and then escalated to the providers. Different algorithms for alerts were created and allowed the staff to address issues as they arose. Appropriate care was initiated if necessary usually with treatment or a clinic visit if needed.

Assessments of patient satisfaction and QOL (with the SF-36) were performed at 90 and 180 days posttransplant in both groups. We also assessed functional health literacy for patients and their primary caregivers using the Rapid Estimate of Adult Literacy in Medicine (REALM).[11,12] The REALM takes a short time to administer and results in a score between 0 and 66. Scores are categorized as follows: 0–18 (third grade and below), 19–44 (fourth to sixth grade), 45–60 (seventh to eighth grade), and 61–66 (ninth grade and above). Qualitative assessments of the study were performed during regular post-LT follow-up clinic visits by the study team either alone or within a group setting at various times points in the study (30 and 90 d).

Study data were collected and managed using REDCap electronic data capture tools hosted at University of Cincinnati.[13] All data transfers, management, and handling were in compliance with HIPAA regulations. We provide descriptive data for patient characteristics and primary outcomes (90-d readmission rates, THMP participation, and patient satisfaction) for both study arms. Continuous variables were described as estimates of central tendency

TABLE 2. Demographics of 100 Patients Enrolled in Randomized Trial Comparing Remote Home Monitoring With Standard of Care

Demographics	Standard of Care (n = 50) N (%) or Median (IQR)	Telemedicine Based Home Monitoring Program (n = 50) N (%) or Median (IQR)	*P* Value
Pre liver transplantation			
Age (yrs)	60 (56,65)	58.5 (51,65)	0.32
Male sex	26 (52%)	30 (60%)	0.42
Race/ethnicity			0.81
Caucasian	48 (96%)	46 (92%)	
African-American	1 (2%)	3 (6%)	
Other	1 (2%)	1 (2%)	
Type of transplant			0.06
Whole organ	47 (94%	44 (88%)	
Split	2 (4%)	0	
Liver-kidney	1 (2%)	6 (12%)	
MELD score	23	24	0.90
BMI	29 (26,36)	30.5 (26,35)	0.84
HgbA1c	5 (4.5,5.5)	5.2 (4.6,6.3)	0.23
History of abdominal surgery	10 (20%)	11 (22%)	0.81
Hemodialysis	2 (4%)	3 (6%)	1.00
Post liver transplantation			
Hemodialysis	5 (10%)	3 (6%)	0.72
Unplanned postoperative reoperation	8 (16%)	11 (22%)	0.44
Postoperative technical complication	15 (30%)	19 (38%)	0.40
Hospital length of stay	7 (6,9)	7 (6,9)	0.60
Hospital discharge location to home	39 (78%)	40 (80%)	0.81

BMI indicates body mass index; HgbA1c, hemoglobin A1c; MELD, model for end stage liver disease; Unplanned: some operation for any reason after transplant; Technical complication: hepatic artery thrombosis, bile leak or bile stricture.

(median) and interquartile range (IQR). Categorical variables were described as percentages (%). Categorical variables were analyzed using Pearson chi-squared test or Fisher exact test when appropriate, while continuous variables were compared through Wilcoxon rank-sum test. Variables with a P value of < 0.05 were determined to be statistically significant. We censored patients with missing data prior to the 6 month time point at the last date for which status can be determined. The status of the patient was set to ''failure'' at the date of the last contact with the patient.

RESULTS

Beginning in January 2017, 106 consecutive LT patients were enrolled, with 100 patients completing the study (50 per study arm). Only 6 patients were unable to participate after consenting due to unable to be discharged home within 45 days (n = 3), no LG4 connection at residence (n = 1), and inability to conduct study due to recurrent readmissions in the first 90 days (n = 2). Table 2 shows no difference in recipient demographics before LT, ensuring both groups were similar medically prior to enrollment. Donor characteristics and perioperative outcomes were also similar between groups.

We assessed the THMP participation as shown in Table 3. Patients randomized to the THMP group were receptive to the device, but assistance was needed at the home to ensure appropriate hookup and function of the remote device in nearly one-third of patients (32%). This was despite extensive teaching when in hospital with explanation of bluetooth technology. Vital sign monitoring and use of the devices to input the data was excellent with 86% frequency. Patients were sent text messages daily in the first month and then periodically after that to assess their general health. This was not very effective as only 60% of the patients would respond to text messages in the first month and this dropped to 25% after POD 30. A similar trend was seen with the vital sign monitoring but was not significant. Common explanations for this were returned to activity or work and not having remote device with them or not knowing they had to respond to the questions. In many instances, responses to the questions did not correlate with the patients complaints (eg, call about abdominal pain, but response to text message revealed no abdominal pain). Most patients used phone calls for their issues (70%), while very few used the FaceTime or messaging feature for complaints. This was consistent on both the patient and the provider sides as providers preferred to call the patient due to general comfort compared with text message or video discussion. Video educational sessions were all downloaded on the remote device and these were generally viewed and enjoyed by patients. These videos were made by our faculty, have been in place since 2015, and are available on line as well. Most patients preferred this form of education compared to a book or general text.

The primary endpoint was to examine the rate of 90-day hospital readmissions. The THMP arm showed a lower rate after discharge at 28% compared to 58% with SOC (Table 4A; $P = 0.004$). Further analysis showed that the largest difference with THMP

TABLE 3. Participation in Telemedicine Base Home Monitoring Program

Postdischarge Task	Frequency (%)
Vital sign monitoring	86%
Response to text messages 0–30 d	60%
Response to text messages 31–90 d	25%
Use of FaceTime or video messaging	6%
Use of phone calls for issues	70%
Educational video slides viewed	75%

TABLE 4. A Readmissions After Liver Transplant in 100 Patients Enrolled in Randomized Trial Comparing Telemedicine Based Home Monitoring With Standard of Care

Days After Transplant	Standard of Care (n = 50)	Telemedicine Based Home Monitoring Program (n = 50)	*P* Value
0–30	18 (36%)	12 (24%)	0.19
31–90	11 (22%)	2 (4%)	0.01
0–90	29 (58%)	14 (28%)	0.004

B Causes of Readmissions After Liver Transplant in 100 Patients Enrolled in Randomized Trial Comparing Telemedicine Based Home Monitoring With Standard of Care

Causes of Readmission	Standard of Care (n = 50)	Telemedicine Based Home Monitoring Program (n = 50)	*P* Value
Abdominal pain/ gastrointestinal issues	5	2	0.43
Acute kidney injury	2	2	1.00
Anemia	2	1	1.00
Biliary	4	3	1.00
Cardiac	1	0	1.00
Dehydration	2	1	1.00
Elevated liver function tests	1	0	1.00
Fever/Sepsis	3	1	0.62
Hyperglycemia	4	1	0.36
Pulmonary	1	0	1.00
Seizures/Neuro	1	0	1.00
Wound	3	3	1.00

TABLE 5. Short Form 36 Health-care Related Quality of Life Assessment at 90 D Posttransplant Comparing Standard of Care and Telemedicine Based Home Monitoring Program

Category	Standard of Care (n = 50)	Telemedicine Based Home Monitoring Program (n = 50)	*P* Value
Physical function	60	75	0.02
Role limitations—physical	61	70	0.05
Role limitations—emotional	60	60	0.72
Energy/fatigue	60	65	0.95
Emotional well being	62.5	70	0.12
Social functioning	60	71	0.05
Pain	63	64	0.90
General health	60	70	0.05

Values represent medians.

occurred between days 31 and 90 as the readmission rate was similar between groups in the first 30 days. Table 4B summarizes the different readmission causes and reveals that the THMP group was associated with fewer readmissions for complications that were able to be tracked by the tablet compared to SOC, such as abdominal pain, fever/sepsis, and blood sugar issues.

All patients received the SF-36 QOL questionnaire at discharge and at 90 days. We focused on physical function and general health components of the questionnaire since the goal of the THMP was to improve those aspects of care. At 90 days, compared to discharge, patients in the THMP arm had significantly improved QOL for physical function ($P = 0.02$) and general health ($P = 0.05$). We did not see significant differences in energy or social functioning on the SF-36 (Table 5). Patients have commented that in their view, the biggest determinant for QOL is time spent at home compared to the hospital. There was no difference in the REALM health literacy assessments between the 2 groups as 90% patients scored in the highest group at ninth grade or above.

DISCUSSION

Historical barriers to widespread adoption of telemedicine interventions include technological literacy and costs of implementation, limiting consumers to younger patients with higher socioeconomic statuses.[14] As part of our previous pilot study, we demonstrated that patients in our LT clinic, despite older age and socioeconomic barriers, had satisfactory exposure to and understanding of smart technology and software applications.[8] Indeed, a majority indicated that use of electronic monitoring and communication would be helpful for postoperative care. Participation in this current study was 94.3%, demonstrating feasibility of this THMP in the LT population. Additionally, health literacy was similar in both groups and in the highest category in the majority, showing that the LT population generally has adequate ability to understand most patient education materials. Although not a direct assessment of technological literacy, one can extrapolate that these patients are generally able to understand the education videos and should be able to navigate self-monitoring devices. This randomized controlled trial demonstrated the impact of a THMP after LT. The magnitude of the effect on outcomes, readmissions, and QOL suggests that the adoption of telemedicine has great potential for other major operations and conditions.

Given the complexity of posttransplant care involving management of polypharmacy, routine laboratory testing, and monitoring of clinical factors such as blood pressure and blood glucose, the importance of patient adherence is crucial to optimizing outcomes and preventing complications. The use of telemedicine interventions has been shown to increase adherence with medications, self-monitoring, and laboratory testing in adult kidney and lung transplant recipients, as well as adolescent liver transplant recipients.[15–18] We did not measure strict medication adherence in this study but future work with THMP is under way with new pill box technologies.

National readmission rates after LT range from 27 to 50% at 30 days and 46 to 48% at 90 days.[6,19] At our institution, historical readmission rates were 42% at 30 days and 69% at 1 year posttransplant.[10] Several reasons for readmissions which could be targeted using telemedicine interventions included immunosuppression complications, graft rejection, and medication toxicity. In this current study, 90-day readmission rates were significantly lower in the THMP group than the standard of care group, as well as compared to historical rates. A study by Kothari et al demonstrated that LT recipients who were readmitted to hospitals other than that at which they received their transplant had worse 30-day mortality as well as subsequent readmissions.[20] Although reasons for readmission to an outside hospital were unclear, the use of a THMP provides closer monitoring and more convenient access to the transplant care team, which may either prevent readmissions altogether, or help facilitate readmission to the transplant center hospital if necessary. In our center, almost all readmissions occur within our medical system so we are able to capture and be involved in the care of all the

readmissions in this study. It is difficult to measure the true impact of a THMP on readmissions but examination of the different reasons for readmissions suggests that some of the aspects of care addressed by the THMP, including abdominal pain, temperature elevations, and blood sugar control issues, may help to reduce those readmissions. Surgical complications and emergencies that occur after LT cannot and will not be prevented by a THMP and our data confirmed this.

There have been other interventions in the LT population aimed at improving post-LT care and reducing readmissions. Mahmud et al demonstrated that implementation of a nurse practitioner (NP)-based post-LT care program including increased NP clinic availability and in-house weekend care coordination was associated with significantly decreased rates of 30-day and 90-day readmission.[21] The authors attributed this improvement to earlier first follow-up clinic visits as well as earlier phone encounters. However, an increasing number of phone encounters was associated with increased readmissions at both 30 and 90 days, while increasing number of clinic visits was associated with fewer readmissions at 30 days. A limitation in our current pilot study is that number of clinic visits was not tracked and therefore we cannot comment on impact of the THMP on this metric. However, this will be addressed in a future study, with the hypothesis that the THMP would allow providers to address issues remotely without the need for increased clinic visits. Additional work has been done by Toledo et al[22] using Lean Six Sigma methods to systematically analyze their processes from transplant listing to hospital discharge after transplant. Through this process, they were able to implement multiple interventions, including a clinical pathway and enhanced communication, with a resultant decrease of median length of stay from 11 to 8 days. While readmission rates were not significantly changed throughout this study, the systematic approach to evaluating the LT processes represents another potential approach to identifying and decreasing risk factors for readmissions.

The use of any telemedicine intervention may be complicated by inefficiencies in handling the large amounts of data that can be transmitted from the patient to the provider. For example, McElroy et al[23] describe the use of digital health kits (including a tablet linked to vital sign monitors) to reduce readmissions after cardiac surgery. In this study, the authors found that there was a median of 54 alerts per patient during the 30-day study period, prompted by abnormal biometric measurements, triggered by responses to daily survey questions, patient requests for additional video sessions, or notifications of noncompliance with daily monitoring. However, only the alerts due to abnormal biometrics (64% of the total alerts) were significantly correlated with requiring an intervention such as medication adjustment, patient education, or further triaging. This demonstrates the potential inefficiencies in the alerts, with only a portion resulting in necessary interventions, and may also lead to alert fatigue in providers. Additionally, despite this high number of alerts, they found no difference in 30-day readmission rates using this digital health kit intervention. In our current study, we also had a significant number of alerts or abnormal values that were addressed and this will be analyzed in a future project. The main focus of ''alerts'' is for providers to address what to do with alerts in the middle of the night or on weekends. This could be a liability issue and one the community will need to address in the future.

Recognition of the importance of patient-centered outcomes has increased interest in optimizing not only clinical outcomes, but also patient satisfaction with their medical care. In a study by Le et al,[24] general patient satisfaction was similar between LT recipients utilizing a telemedicine follow-up care and those undergoing standard care. However, the telemedicine group had significantly less commute and waiting times. Similarly, in this study, we established patient satisfaction improvement in some areas with THMP compared to SOC because patients felt that they were being monitored more closely with the THMP devices. This was reassuring because some providers felt that patients may be annoyed by the amount of work and monitoring of results that would be needed but this turned out to be minimal. These results show that telemedicine-based programs may enhance patient satisfaction in medical care after transplant by optimizing efficiency and convenience in access to care, along with decreasing readmissions.

Although posttransplant QOL has been shown to be improved compared to pretransplant status, it still remains inferior to that of the general population.[4,25] Therefore, any intervention that has potential to result in incremental increase in QOL after LT is of significant interest. To our knowledge, this is the first study to assess the impact of a telemedicine program on QOL after LT. We demonstrated that physical function and general health was improved by 90 days. More work is needed to determine if this persists to 180 or 360 days when patients do not have the tablet and rely on improve health behaviors.

One of the remaining challenges in the implementation of telemedicine-based interventions is cost-effectiveness.[14] A cost analysis at a German center showed that a telemedicine-based case management after living donor kidney transplantation was less costly than standard of care.[26] However, similar studies have not been conducted in the United States or in the LT population. Variability in and insufficiency of reimbursements by Medicaid and Medicare may limit the feasibility of telemedicine implementation in underserved populations that may benefit the most.[27] We had previously shown that the cost of readmissions after liver transplant amounted to $45,000 per episode.[6] The cost of a telemedicine program up front would be cost-effective based on historical data for payers. Future studies should include a cost-effectiveness analysis of these interventions, with the understanding that it may vary from state to state.

There are several limitations to this study. As a single-center study, this trial does have limitations in regards to patient heterogeneity, race, and socioeconomic status. First, we did not track the total amount of data transmitted from the devices to Epic, the number of phone calls, or the number of clinic visits and therefore cannot comment on differences in the amount of time required by the staff to monitor patients within each group. This time cost will need to be addressed in future cost-effectiveness analyses. Second, we chose to use standard of care as our control group to demonstrate feasibility of our intervention. However, there may be other interventions which we did not utilize in this study, such as scheduled phone calls, that may also result in better monitoring and decreased readmission rates. Third, as we provided the home-monitoring devices free of charge, we cannot evaluate the cost of the intervention from the patient perspective, which may be a substantial barrier to utilization outside the study.

CONCLUSION

To our knowledge, this is the first RCT demonstrating the impact of THMP after LT. The magnitude of effect on LT outcomes, readmissions, and QOL suggests that the adoption of telemedicine has great potential for other major operations. Its role could be greater in planned elective operations where education and learning with the device could be planned preoperatively.

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DISCUSSANT

DR. Sherry M. Wren (Palo Alto, CA):

I have no disclosures. I compliment the authors on completing a randomized clinical trial to assess whether patients' participation in a home telemonitoring program could minimize admissions. The majority of telehealth papers have been done in lower risk procedures, not liver transplants where 30 to 50% of patients require readmission within the first 90 days. Post-transplant care is also much more complicated than standard general surgical follow-up. Post-transplant patients' are at risk for post surgical complications, rejection, changing medical regimens, and infections.

There have been other successful post-liver transplant follow-up interventions that have resulted in similar readmission reductions, as seen in this presentation Carolinas Medical Center improved their readmission rates from 53%–26% by developing a protocol to 1. Decrease the need to consider readmission. 2. Define readmission criteria. 3. Establish outpatient alternatives to readmission. The University of Pennsylvania expanded its nurse practitioners follow-up protocol to utilize phone calls post discharge, after lab draws, and after any medication change as well as provide expedient access to NP clinics as needed. They too saw significant decreases in readmission rates at 30 and 90 days post discharge. Neither one of these examples utilized a telehealth internet platform for communication and tracking of patient variables.

This trial by Dr. Shah and the University of Cincinnati group focused on home tablets equipped with Bluetooth-enabled vital signs, daily question reminders, and video education. They showed an impressive decrease in readmission rate in the readmission rate in the post operative day 31–90 time period.

Readmission causes were not reported as different between the two groups, but there were more admissions for abdominal pain, GI issues, fever and sepsis in the standard care group. The authors state the readmissions for issues that could be tracked by the device were less than in the control group.

A similar study was done at UCLA in post-cardiac surgery patients. They showed there is no difference in the rate of 30-day readmissions, but readmissions were different. CV and pulmonary causes were most common in the standard care group as compared to the telehealth group where issues that could not have been detected by monitoring vital signs, such as amiodarone toxicity, resulted in readmission. The telehealth platform generated approximately 55 real-time alerts per patient in this cardiac group, the vast majority of which were from abnormal vital sign measurements with an average of 14 alerts per one intervention observed.

All of the studies including the one presented by Dr. Shah's group show a high degree of patient and health team satisfaction, time saved on the part of the patient and their family, and clearly this will be incorporated in some way on future post operative care.

I have a few questions:

Did anyone in the health care team for the standard cohort make any calls to discuss symptoms or issues as was done in the telehealth group? Were the standard cohorts given access to the videos that the telehealth group used? If not, how do you know that this is really the telehealth platform but just not the number of touches from someone on the team after the transplant as well as information available to them that's driving the results? When you had to do the home visits to get the Bluetooth systems set up by your research group, did this also include a health assessment? Was patient education also done at this time?

It's also not clear from the paper how the biometric data was reviewed from the telehealth cohort. Was it in real-time? Who reviewed it? What action was taken? Did this result in more clinic visits in the telehealth cohort compared to the standard cohort?

After looking at all this, do you believe that the device itself was necessary, or could you have seen the same reductions by just doing more simple telephone follow-ups and close monitoring as was done in these other studies? Thank you.

Dr. Shimul A. Shah:

Thank you, Dr. Wren. The videos were made available by YouTube, and all patients are told about the videos. The difference is that if you're in the standard of care group, you actually have to get on a computer and log in and watch the videos versus the videos being readily available on the iPad. So everyone does have access to it. And the phone calls essentially are just normal standard of care. Patients are not getting phone calls asking if you're feeling well. Just like with typical care, you call the office if you're not feeling well, and that's the same aspect with the telemedicine arm.

There are a lot of outliers that occur with the vital sign measurement, and we're studying that. I didn't report that here today, but there's a lot of "noise," and consistent with abnormal blood pressures and things, and we're trying to understand how to interpret that, especially if it's at odd hours. But the care is essentially the same care. The main issue is when there is a problem, how is the provider dealing with the data they have at hand. They have more data at hand with the telemedicine information that they can just log into and look at.

The visits that are done to the home are done by the research staff, which are non-transplant clinicians, and so another visit wasn't performed at home.

The biometric data that we get two to three times a day was reviewed by a medical assistant or a transplant coordinator daily or as needed. It was my interpretation of dealing with this on the qualitative side that there was a lot of resistance to adopting this technology by my team primarily because of just old standards, ''This is the way we do it.''

So the ability to use video technology by my team was resisted more than just picking up the phone and calling the patient if there was an issue. The biometric data and examining it needs to be sorted out. One thing that we did not do in this study was track utilization. Clinic visits, phone calls, the touches, as you mentioned, and that's an important aspect we believe for the next study. Can we reduce utilization? Can we reduce the number of clinic visits if we have some technology that's taking care of the patients at home?

When we compare the use of telehealth to just phone calls, that's an interesting question, and my view of telemedicine is that the advantages are more than just picking up the phone and talking to the patient. The goal here is increase engagement and increase education to the patient so they care about how they're doing. They can look at charts on the iPad and see what their weight has been over the course of the last ten days. They can start to interpret what their health is postoperatively. To me, that's the advantage, that increased care in the first 90 days, which is when they get the tablet, does that lead to better care at the one-year mark and at the two-year mark in terms of blood pressure, blood sugar control, and weight gain, which are big issues post-transplant? Thank you.

Dr. Goran Klintmalm (Dallas, TX):

No disclosures. This was a very interesting presentation. New technology and something that is so inside our society today, but I have two questions. One different angle.

Number one, this actually implies significant additional workload on the team-coordinators, assistants, nurses, and physicians. Do we have the funding to increase the number of employees to actually deal with all of these, review the report, et cetera, and respond to all the stuff that comes in? That's my first question.

My second question is, I think, maybe even more important. Say that we, the team, missed something that was sent by one of these things because we didn't review that report on an hourly or three-times-a-day basis. What kind of legal liabilities are we creating for ourselves as a medical community? As we know, we are continuously running head on into the legal community in a very unpleasant way.

So those are my two questions: resources and legal implications.

Dr. Shimul A. Shah:

Certainly increased resources are required, I think, if we're going to do a higher monitoring system. The way to think about it is what kind of resources do we really need? You really need probably a medical assistant, college kids that can just monitor the data and look if there is a blip or look if there is a response out of the ordinary. It does not need a hepatologist, a surgeon, potentially even a nurse. It could be lower–level type FTEs that we're talking about.

The way to justify it is to talk about the decrease in readmissions, and the benefit to the medical center––all our hospitals are clogged, but the benefit to the medical center to reduce the readmissions and potentially reduce utilization by increasing one or two extra FTEs just to monitor this program. So I think it can be sold if framed in the right way in a pretty easy financial justification.

The liability issue is a big one across the country as other programs are adopting this model, and there are numerous avenues to do 24/7 monitoring through paid companies and things like that. We didn't do that here. I agree, that's an issue, and that's something that needs to be taken very seriously. We advise patients that if it was after hours and it was an emergency, obviously they have to call our emergency line in our office to get a human on the phone, and there is a lot of education about that. I agree, that is a big issue we need to think long and hard about as we adopt other programs.

Dr. Fabrizio Michelassi (New York, NY):

Dr. Shah, congratulations. This was a great presentation and a clear example of innovation, minutes after President Ellison talked about innovation and just minutes before the panel on innovation. I congratulate you. I think this technology will become even more used in the future, and I think it's going to be important for us to embrace it and figure out its limitations and advantages.

We have been involved in creating apps for post-discharge patients after gastrointestinal procedures. One of our challenges has been sometimes the lack of app literacy with the patients that we treat. You mentioned that to solve this challenge you occasionally send your collaborators to the homes of the patients to instruct them. Can you please elaborate on this and how you approach this issue.

I noticed that the measured decrease in readmission rate was after 30 days. I also noticed that the compliance with this new technology decreased substantially after 30 days. I think that only a fourth of your patients continued to use this app after other initial month. Were there other reasons, maybe stimulated by the use of the app or for that matter telemedicine, that contributed to the drop in readmission rate?

Finally, one last comment and maybe a question. Did this contribute to patient satisfaction? Are you thinking potentially of including patient-reported outcomes in this technology? Patient reported outcomes will play an even more important role in the future. Could this technology achieve both the goal of post-discharge monitoring of patients and the collection of patient reported outcomes into the same technology. Again, congratulations.

Dr. Shimul A. Shah:

Thank you, Dr. Michelassi. I did not show the iPad in a live video, but although it's an iPad, it's not really an iPad. It's big writing. You can't surf the net, you can't get on other sites. It's written in big block lettering, and you just click boxes. It's very user friendly for those that are not smart technology avid.

We did a lot of qualitative work in 2014-15 to understand patients, at least patients in Ohio, what their literacy was. 80% of patients said that they were comfortable using smart phones, and about 75% said they used e-mail and smart phones daily. What we found in our 20-patient pilot, though, was that was not the case. So we're still working and trying to understand how to improve compliance. I agree, the apps are difficult to use, so that's what made this product a little bit better in the sense that it was easy to use and just had health care stuff related to our project.

I would say one-third to one-half of the patients required some help once they got home with how to get on the WiFi, how to log in or how to use the LG interface and how to turn it on.

In terms of what happens after 30 days, the common feedback that we got were two things. One, "This is redundant; I don't need it anymore." Secondly, a bunch of patients actually went back to work. They said, "How am I supposed to answer all these questions? I'm done with it." Those are the patients that obviously did very well. So I think part of having enhanced care and increased care we as providers have to realize, when is it getting redundant, and maybe we can peel back. That was the feedback we got just qualitatively.

I agree with you that the patient reported outcomes is going to be the next step. Patients loved having the technology, and the primary feedback that we got was they felt that we were just watching them more, and that the care was more comprehensive. Was it more just a placebo effect? Maybe. But they certainly responded very well in terms of their satisfaction with the project.

Dr. Keith Lillemoe (Boston, MA):

Shimul, this is a great technology, a lot of work and a nicely done study and presentation. I'd like to get your thoughts as to taking it to the next level. Our medical physicians have been working on home hospital status for patients with heart failure, pneumonia, some of the common conditions that lead to readmission and the penalties associated with readmission. We're now starting a pilot with patients with complications after colorectal surgery where we have teams with the ability to go into the patient's home to assess and deliver care; they can administer IV fluids, place NG tubes, draw labs, administer IV antibiotics, all this can be done. Do you see your technology leading the ability to keep people out of the hospital even when they have conditions that might now still be bringing them into the emergency room or even requiring readmission.

Clearly, we haven't had a lot of experience yet. We have just had few patients that have been successfully managed in the last few weeks. Your technology would be a nice adjunct to continue to maintain close communication with the patients in the home hospital setting.

Dr. Shimul A. Shah

That is a great point. I think this would alert you when you need to go to their home. The only caveat, I'm sure at your center and what we're seeing at our center, is patients are traveling a lot farther for their care. If the patient lives 200 miles away and comes for their transplant, it's not as easy to go to their home. But it is a way to communicate with them from far away. I think that is an excellent adjunct.

Dr. Dennis Lund (Palo Alto, CA):

Great study. I congratulate you on doing a randomized trial on this. I also want to take this to the next step, and that is in the realm of wearables. We are making quite a bit of use of wearables in children. We developed a single ventricle interstage program as well as a type 1 diabetes home monitoring program for children. And in this case, the data actually goes into the electronic health record in real time. And now we're working on AI, machine learning interfaces that will assess this data and really monitor, do the medical assistant work that you're talking about. Are you thinking about wearables as a way to maybe enhance the home monitoring? Again, what we found is the nurses spend less time on the phone transcribing data because the data is all in the electronic health record already for them to see.

Then the second thing is, have you considered maybe doing this as a pre-transplant interaction with the patient to help train them when they get their transplant to better comply with treatment afterwards? You could even possibly incorporate the use of smart pills to make sure that they are actually taking their medications on schedule. Thanks again, and congratulations.

Dr. Shimul A. Shah:

Thank you for the questions. The wearables is the future of medicine, and we did separate projects looking at wearing a Fitbit after transplant and found you have to really collaborate with your mathematicians at the medical center because the amount of noise that you get with the number of steps each day was hard to interpret. But I think wearing a Fitbit gives you an idea, whether it's pre-op or post-op in terms of activity level versus what any patient tells you. We also did a separate study looking at a electronic pillbox, so we know when the patients are opening their pillbox and when they are closing it to make sure that we have compliance.

Nowadays, we have Bluetooth pills, so you can actually make sure that they are also taking the pills. So that's the future of medicine. The third aspect of it which we haven't done is using sweat technology. Someone we're collaborating with at our center who is putting wearables on and understanding sweat technology to get your electrolyte lab values just through the sweat.

We've done some work with oral glucose monitoring as well to eliminate finger sticks to improve patient compliance. But I do agree that wearables are the future. We've done some work with it. It's hard to put all of it together in one huge study given just information overload, especially because we're doing our aspect in the post-transplant setting. So I think that addresses your first question.

The second question, which was can we look at them pre-transplant and start the education? It's hard because, as many people in transplant are in the room, we don't know who we're transplanting. It's hard to do it preoperatively. But that's the caveat, I think, for many people in the room.

If you do complex GI surgery, complex thoracic surgery, I think this is really a great way to improve post-op care, where when you see the patient one week before the operation, when you get the consent, you're doing your H&P, the educational process can be performed right then and there by the research team, by your nurse, and they go home with the electronic devices, and they spend the week at home pre-op understanding how to use the tablet, how to use the devices. That way, post-op they are ready to go. For instance, if you're doing a pancreaticoduodenectomy, the length of stay is similar to a liver transplant but their care post-op is almost as complex, but now they know how to use the machine. After transplant or after major surgery, there are so many things going on, it was hard sometimes to educate them. So educating them in the clinic, I think, is the next step.

Thank you very much for the podium.