Original Research

A Randomized Controlled Trial Comparing Health and Quality of Life of Lung Transplant Recipients Following Nurse and Computer-Based Triage Utilizing Home Spirometry Monitoring

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Abstract

Background: *Lung transplantation is now a standard intervention for patients with advanced lung disease. Home monitoring of pulmonary function and symptoms has been used to follow the progress of lung transplant recipients in an effort to improve care and clinical status. The study objective was to determine the relative performance of a computer-based Bayesian algorithm compared with a manual nurse decision process for triaging clinical intervention in lung transplant recipients participating in a home monitoring program.* ***Materials and Methods:*** *This randomized controlled trial had 65 lung transplant recipients assigned to either the Bayesian or nurse triage study arm. Subjects monitored and transmitted spirometry and respiratory symptoms daily to the data center using an electronic spirometer/diary device. Subjects completed the Short Form-36 (SF-36) survey at baseline and after 1 year. End points were change from baseline after 1 year in forced expiratory volume at 1 s (FEV_1) and quality of life (SF-36 scales) within and between each study arm.* ***Results:*** *There were no statistically significant differences between groups in FEV_1 or SF-36 scales at baseline or after 1 year.: Results were comparable between nurse and Bayesian system for detecting changes in spirometry and symptoms, providing support for using computer-based triage support systems as remote monitoring triage programs become more widely available.* ***Conclusions:*** *The feasibility of monitoring critical patient data with a computer-based decision system is especially important given the likely economic constraints on the growth in the nurse workforce capable of providing these early detection triage services.*

Key words: *home health monitoring, telehealth, telemedicine, m-health, transplantation*

Introduction

Lung transplantation has been a clinical option for patients with advanced lung disease for more than 20 years.[1–4] Clinical indications for transplantation include pulmonary and pulmonary vascular disorders such as α-1-antitrypsin deficiency, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, Eisenmenger's complex, and cystic fibrosis.[5–7] Timely identification and intervention are critical for treating bronchopulmonary infection and rejection, key problems in post-transplant care. Frequent monitoring of pulmonary function and respiratory symptoms allows for early detection and treatment of problems.[8–13] Home monitoring (HM) has been used in a range of clinical contexts, including chronic diseases like hypertension[14,15] and diabetes.[16,17]

HM of pulmonary function and symptoms is feasible to follow lung recipients to improve transplant care and clinical status.[18] Previous studies demonstrated home spirometry measures were equivalent to clinic spirometry in terms of validity, reliability, and repeatability, particularly when used to monitor changes in pulmonary function from "baseline" values.[19] The electronic datastream allows for timely interpretation of both spirometry and symptoms by clinical teams, rather than relying on patients recognizing emerging problems from the monitored data. In addition to clinical benefits, cost savings result from decreased hospital admissions (although some costs are offset by increased outpatient visits).[20] The potentially large HM datasets that require clinical interpretation are often overseen by a clinical transplant nurse. However, the scale of the data flow can overwhelm clinical teams stretched thin by increasing clinical demands and decreased staffing. A technological approach uses computerized decision support systems to perform the first level of triage to discriminate between patients who are functioning well from those who may need further review by clinical teams. Computerized systems to detect early clinical changes are based on timely review (e.g., daily or weekly) of HM reports.

This randomized controlled trial (RCT) was designed to determine the relative performance of a computer-based Bayesian triage algorithm compared with a manual nurse-based triage system in terms of patient health and health-related quality of life (QOL) in lung transplant recipients participating in the Home Spirometry

Research Program (HSRP) at the University of Minnesota Medical Center, Fairview.

Materials and Methods

The University of Minnesota Medical Center lung transplant program has performed approximately 700 lung transplants since 1986 and now performs 20–50 annually. Transplant recipients were eligible for the HSRP study if they were at least 14 years of age and were able to return home after hospital discharge to begin postsurgical care. All eligible lung transplant recipients from October 2006 to April 2009 were invited to participate in the HSRP. Volunteers provided informed consent approved by the University of Minnesota Institutional Review Board. The investigation compared clinical and QOL outcomes between subjects in a manual nurse triage (control) arm with those in a computer-based clinical decision system triage (intervention) arm.[21] HSRP subjects were instructed to perform daily HM of pulmonary function and symptoms using an electronic home spirometer/diary device designed to study specifications (TV 2004; Transviva, St. Paul, MN). The device combined a spirometer meeting American Thoracic Society standards and a patient interface that stored and automatically transmitted data on a daily preset schedule (generally between 12:00 a.m. and 4:00 a.m.) to a data center for review.[22]

Sample size calculation was based on HM experience with a subset of subjects in a previous study who had been followed up for a minimum of 1 year post-transplant. We estimated that forced expiratory volume at 1 s (FEV_1) would likely decrease by 12.9% in the control group, with a standard deviation of 9.5%. Using calculations for a two-sample test at a significance level of 0.1, we determined that 32 subjects per arm would provide 80% power to detect roughly 50% improvement in FEV_1 (i.e., a smaller decrease of just 6.9%) in the intervention arm compared with the control group after 1 year of HM. New transplant patients in the HSRP were randomly assigned to one of two study arms. Randomization was stratified by age ($\leq$50, >50 years) and functional capacity at enrollment based on the Karnofsky Index.[23]

The HSRP protocol included transmitting home spirometry data and self-reported respiratory symptoms daily. Subjects were instructed to perform three "blows" (forced expiratory maneuvers) to derive forced vital capacity, FEV_1, mid-flow, and peak flow. Following the forced vital capacity maneuver, subjects responded to a routine set of symptom questions that were stored in the device, providing a standardized record of daily symptoms (i.e., frequency of coughing and wheezing, sputum production and color, and shortness of breath at rest and after exercise). All subjects were instructed to perform daily HM. They were considered adherent if they transmitted at least one set of daily measurements per week. Subjects were excused for missing this adherence goal if too ill, hospitalized, or on vacation or had device or telecommunication problems for a specific week. Data were date- and time-stamped by the device software and stored in the monitoring device until each session was automatically downloaded to the data center during the subsequent nighttime transmission period. An electronic report summarizing spirometry and symptom values and descriptive statistics (means, standard deviations) was prepared weekly using a standard template by a study research assistant for clinical review to assess each subject's current status. Subjects were determined to be either stable (unchanged or improving spirometry and/or symptoms) or needing follow-up review (declining spirometry metrics or increasing symptoms) by the manual nurse review or by the computer algorithm.

Weekly HM reports for the control arm (manual nurse triage) were reviewed by two masters-prepared research nurses to assess the current status of each subject and the need for follow-up clinical review, based on the magnitude of changes in pulmonary function and symptom HM reports, the nurses' knowledge of each subject, and clinical judgment. Similar weekly HM reports were generated for the intervention arm (computer-based triage).

Weekly HM data for the intervention arm were reviewed by a Bayesian decision support algorithm that was informed by our previous HM studies[24,25] to assess current status and need for clinical follow-up. The statistical algorithm models each patient's symptom score (determined by the total reported severity of six different symptoms) and the log of his or her FEV_1 ratio (i.e., FEV_1 divided by the maximum predicted FEV_1 for the patient's age and gender) as a function of time. Patients with statistically meaningful increases in symptoms and/or drops in log(FEV_1) ratio are inferred to have had an event. The Bayesian statistical outlook means the algorithm produces a posterior probability that each patient has had an event during the previous 2 weeks; patients for whom this probability is high are contacted to set up physician visits. Troiani and Carlin[25] provided a full technical description of the algorithm and evidence of its superior sensitivity, specificity, and predictive performance relative to an older, purely heuristic event classification algorithm. The current research seeks to investigate whether the Bayesian algorithm is also superior to a manual nurse-based system.

To maintain the blinding of the clinical team to subjects' study arm, identical forms were used to generate status reports for subjects in either study arm who were considered to need follow-up review with the clinical (i.e., not the HSRP) team. Status reports, along with weekly HM reports, were sent to each subject's clinical transplant nurse coordinator for review and consultation with the subject's pulmonary physician. The clinical team (i.e., transplant nurse coordinator and pulmonary physician) and subjects were blinded to study arm assignment.

In addition to HM weekly data, routine pulmonary function tests (PFTs), including the FEV_1, were obtained in the clinic PFT laboratory at every scheduled clinic visit. PFT laboratory-measured FEV_1 collected at the scheduled annual visit was used for the outcome analysis instead of HM spirometry because these values were measured by the clinical team and were not dependent on adherence to the HM program. Subject attendance at these annual clinic visits was excellent, from 100% at baseline to 86% at year 2, confirming that clinic PFT missing data were not an issue.

Primary study end point was the percentage decline from baseline in clinic FEV_1 readings after 1 year; decline after 2 years was a secondary outcome. The start date was either the date of first data

transmission or the randomization date for the few subjects who had begun transmitting HM data on a pilot basis prior to randomization as part of system testing for the RCT. All subjects with clinic PFT values were considered for the intent-to-treat analysis, including those who withdrew from the HM program prior to study completion ($n = 16$). Subjects who died during the study ($n = 8$) were included in the analysis up to their date of death. Consented subjects who never transmitted data were not randomized and were excluded from analyses. The PFT laboratory FEV_1 value closest to the time point of interest was selected. If there were no PFT laboratory readings within ± 2 months, the end point was considered missing.

The percentage changes in FEV_1 between baseline and years 1 and 2 were summarized. Summary statistics for study arms were compared at years 1 and 2 using two-sample *t* tests. In addition, multiple regression analyses evaluated relationships between the decline in FEV_1 and group assignment after adjusting for subject characteristics (e.g., age, gender, education, and time since transplant).

Secondary outcomes included health-related QOL as measured by the Medical Outcomes Study Short Form-36 (SF-36)[26,27] (i.e., physical and mental health components and eight subscales). This 36-item instrument has been used widely to measure health status of persons with chronic health conditions. Earlier research established its psychometric properties.[28] The SF-36 is sensitive to differences in disease severity and has been demonstrated to predict use of healthcare services.

Subjects were mailed SF-36 questionnaires following a predetermined schedule, as close as possible to their individual randomization date and then annually thereafter. They were instructed to complete and return SF-36 questionnaires by mail or when returning to the clinic. Some individuals delayed returning it so a window of ±6 months was allowed for each time point. SF-36 data were separately collected for transplant patients by the Transplant Center's Transplant Information System. We used those surveys for 23 individuals who did not return the original HSRP form or when forms were returned outside specified time windows. Each of the eight subscales was analyzed separately and reported as the transformed scores (ranging from 0 to 100). Subscales were compared between study arms at baseline and for the difference between baseline and 1-year follow-up within each arm using two-sample *t* tests. Too few SF-36 questionnaires were returned at the end of year 2 to undertake statistical analysis. Statistical analyses were conducted using SAS version 9.2 software (SAS Institute, Inc., Cary, NC).

Results

REGIMEN ADHERENCE

During study recruitment, 111 patients received lung transplants at the University of Minnesota Medical Center. Of these, 78 (70%) consented to participate, and 65 (59%) followed through with recording and transmitting HM data (*Fig. 1*). Participants were randomly assigned to study arms after their first test data transmission. Those not submitting data lost interest, officially withdrew, or died before beginning the RCT. The control arm (nurse triage) comprised 35 subjects (21 men, 14 women; age range, 23–71 years). The intervention arm (computer triage) had 30 subjects (18 men, 12 women; age range, 37–69 years). Randomized subjects had a range of pulmonary conditions meeting transplant eligibility requirements (*Table 1*).

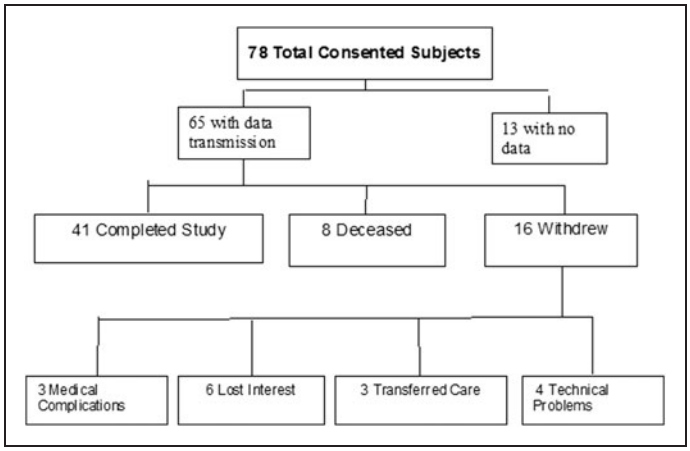

Fig. 1. Subject recruitment flow diagram.

Of the 65 participants, 8 (12%) died during the study, and 16 (25%; 10 nurse-triage, 6 computer-triage) withdrew before reaching the end point. Six of the eight deaths were in the control arm, and two were in the intervention arm; the difference was not statistically significant. One control subject died prior to starting the RCT. Three control subjects stopped submitting HM data 3–10 months prior to death. Another control subject transmitted a last HM report 6 months prior to death and withdrew from the study 2 months prior to death. The sixth control subject sent in HM data during only 1 week in the 7 weeks prior to death. One intervention subject transmitted HM data until being hospitalized 7 weeks prior to death. Another intervention subject received HM alerts for 2 weeks prior to being hospitalized 1 week prior to death. There were various reasons for withdrawal among the 16 subjects who withdrew, including medical complications ($n = 3$), transfer of care to another institution ($n = 3$), persistent device/transmission problems ($n = 4$), and lost interest ($n = 6$).

Table 1. Underlying Diagnoses for Lung Transplant

DIAGNOSIS	FREQUENCY	%
COPD and α-1-antitrypsin deficiency	29	47.5
Pulmonary hypertension (primary and secondary)	5	8.2
Cystic fibrosis	9	14.8
Pulmonary fibrosis	16	26.2
Other	2	3.3

Pretransplant diagnoses were missing for 4 subjects.
COPD, chronic obstructive pulmonary disease.

Overall adherence for all participants during data collection was 83% (from 100% weekly maximum to 58% weekly minimum). Adherence was 88% during the first year. There were means of 5.4 medical excused cases (hospitalization/illness), 1.5 vacation excused cases, and 1.9 technical (device or transmission problems) excused cases each week.

COMPARISON OF NURSE VERSUS COMPUTER TRIAGE

Changes from baseline for the primary study outcome (1-year FEV_1) and the secondary study outcomes (2-year FEV_1; 1-year QOL) were determined for each subject. Of the 65 randomized subjects, 64 had baseline, 58 had 1-year, and 49 had 2-year PFT laboratory data. For those who completed the SF-36, 56 (29 controls, 27 intervention) provided baseline QOL, and 45 (24 controls, 21 intervention) provided 1-year QOL data.

There were no significant differences between groups in FEV_1 (*Table 2*) and SF-36 scores (*Table 3*) at baseline, indicating the groups were comparable. A comparison of annual pulmonary function (FEV_1) changes from baseline within each arm showed no significant differences in percentage FEV_1 decline between groups after year 1 and year 2 (*Table 2*). Both groups combined showed slight changes over 2 years, including a 3.2% FEV_1 increase ($p=0.162$) at year 1 and a 2.6% decrease at year 2 ($p=0.408$).

Similarly, a comparison of annual changes in functional status (SF-36) from baseline within each arm revealed no significant differences for any of eight subscales (e.g., for physical functioning, general health, social functioning, and mental health) between groups (*Table 3*) or in changes in these subscales after 1 year (*Table 4*). There were too few SF-36 respondents at year 2 to determine the impact of the second year on QOL scales.

Multiple regression analyses showed that neither subject characteristics (e.g., age, gender, education, time since transplant) nor study arm was a significant factor affecting the changes in FEV_1 over time.

Discussion

This RCT compared the relative performance of a computer-based Bayesian triage system with a manually derived nurse-based triage system to determine effects on health and health-related QOL outcomes of lung transplant recipients over a 2-year post-transplant period. There were no significant differences in physical (FEV_1) or quality of life (SF-36) measures from baseline after HM triage follow-up for subjects in the two arms. These findings suggest that subjects' physiological and functional outcomes were similar regardless of the triage method used to monitor HM data. SF-36 responses were comparable to those reported from transplant centers worldwide[29–31] and were consistently lower than for healthy populations.[31]

These findings provide support for utilizing computer-based triage decision support systems as remote monitoring triage programs become more widely available and sophisticated. Such systems have the potential to safely supplement or possibly replace aspects of nurse-mediated monitoring and expand the capacity of clinical programs at transplant centers. A recent report estimated that 3,943 lung transplants were performed worldwide in 2010, a 123% increase compared with a decade earlier.[32] These estimates confirm trends in lung transplant services and the need to address related workforce issues to provide quality care for recipients following transplant. This is important because there likely will not be corresponding growth in the nurse workforce to provide early detection and triage for larger patient groups.

As advances in clinical care allow transplant teams to perform more lung transplants and provide acute and chronic care for larger populations of transplant recipients with complex health circumstances, it is vital to establish best practices for monitoring patients and managing care. We believe this was the first RCT to assess whether a computer-based algorithm could reasonably approximate the ability of nurses to detect early changes in pulmonary function or related symptoms based on transmitted HM data.

Clinical decision support systems have been developed in a range of medical applications, including nurse-supported triage management in cardiology, asthma, emergency medicine, and disaster management.[24,33–36] For example, in an emergency department a clinical decision support system had higher triage agreement than traditional nurse triage when compared with triage decisions by a blinded expert panel serving as a consensus standard.[34] Another emergency department triage study using retrospective chart review showed that a Bayesian triage clinical decision support system had higher sensitivity and lower specificity compared with an emergency department specialist for patients requiring hospitalization.[35] A recent review of emerging technologies for pediatric and adult trauma care concluded that the next generation of trauma triage monitors will constantly monitor physiological waveforms and care data for early detection of changes to alert providers to intervene before a patient's status deteriorates, creating a more complex situation in which response to therapy may become more complicated and urgent and have lower likelihood for success.[36] Such studies with diverse patient populations and across settings are based on the same rationale using HM and automated triage reported in the current lung transplant study.

Table 2. Baseline Clinic Forced Expiratory Volume at 1 S (FEV_1) and Percentage Change in FEV_1 from Baseline at Year 1 and Year 2 Between Study Arms

FEV_1	COMPUTER	NURSE	*P* VALUE
Baseline (L)	2.11 (0.66) ($n=30$)	2.01 (0.80) ($n=34$)[a]	0.584
% FEV_1 change			
Baseline to 1 year	2.4 (20.2) ($n=28$)	4.0 (14.6) ($n=30$)	0.721
Baseline to 2 years	−2.2 (23.2) ($n=24$)	−3.0 (20.9) ($n=25$)	0.861

Data are mean (standard deviation) values. A negative change indicates a decline in FEV_1 over time.

[a]One subject in the nurse triage arm who transmitted test data died before the start of the randomized controlled trial.

Table 3. Comparing the Baseline Short Form-36 Subscale Scores Between the Two Study Arms

SUBSCALE, ARM (*N*)	MEAN (SD)	*P* VALUE
Physical Functioning		
Computer (27)	60.2 (28.6)	0.897
Nurse (28)	61.1 (21.2)	
Role—Physical		
Computer (27)	47.2 (46.2)	0.706
Nurse (28)	42.9 (39.0)	
Body Pain		
Computer (27)	62.7 (22.5)	0.437
Nurse (29)	67.8 (25.8)	
General Health		
Computer (26)	56.5 (22.9)	0.335
Nurse (28)	61.7 (15.9)	
Vitality		
Computer (27)	54.1 (23.9)	0.192
Nurse (29)	61.7 (19.3)	
Social Functioning		
Computer (27)	74.5 (29.7)	0.713
Nurse (28)	71.9 (23.5)	
Role—Emotional		
Computer (27)	80.2 (38.4)	0.701
Nurse (28)	76.2 (39.4)	
Mental Health		
Computer (27)	78.1 (15.9)	0.746
Nurse (29)	76.7 (15.9)	

A higher score means a more positive response. The values shown are transformed scores. Not all subjects responded to all Short Form-36 scale items.

SD, standard deviation.

Table 4. Change in Short Form-36 Subscales from Baseline to the 1-Year Follow-Up

SUBSCALE, ARM (*N*)	MEAN (SD)	*P* VALUE
Physical Functioning		
Computer (20)	1.3 (17.1)	0.544
Nurse (21)	−3.1 (27.0)	
Role—Physical		
Computer (20)	−10.0 (39.2)	0.122
Nurse (20)	11.3 (45.5)	
Body Pain		
Computer (20)	−2.5 (28.5)	0.608
Nurse (21)	2.0 (26.7)	
General Health		
Computer (17)	−6.5 (16.3)	0.308
Nurse (20)	−0.7 (17.7)	
Vitality		
Computer (20)	0.3 (13.1)	0.736
Nurse (21)	−1.4 (18.0)	
Social Functioning		
Computer (20)	−8.1 (20.4)	0.107
Nurse (20)	5.0 (29.1)	
Role—Emotional		
Computer (20)	−20.0 (36.5)	0.443
Nurse (20)	−10.0 (44.7)	
Mental Health		
Computer (20)	−1.0 (9.4)	0.521
Nurse (20)	2.2 (19.9)	

The values reported are the difference in transformed scores. Positive values reflect an improvement in the scale over time; negative values reflect a worsening. Forty-five subjects returned forms at year 1, but 2 were outside the acceptable time window, and 2 did not submit baseline forms and were excluded from the analysis.

SD, standard deviation.

Our data provide insights into the potential for developing computer-assisted systems for managing patient populations. We observed comparable results between nurse and computerized systems for detecting early changes in pulmonary status in lung recipients. Our Bayesian system evolved over time through an iterative process improving its accuracy. The demonstrated safety and feasibility of computer monitoring coupled with the lack of evidence for differences in clinical and QOL estimates between computer and nurse triage suggest the potential for such an approach. Although broader-scale implementation of such systems requires confirmatory data to assure the safety and equivalence of computer-based systems, the results of the current study are promising.

The implications of monitoring critical patient data with computer-based systems are significant. In addition to the increased speed and capacity that can be designed into these systems, they can offload part of the surveillance process that is tedious and time consuming for health professionals. In addition, computer-based monitoring has less likelihood of making human errors (e.g., due to inattentiveness or fatigue). The fact that computer systems are operational and effective 24/7 suggests the possibility of more timely detection of problems that in turn allows for more immediate clinical intervention.

The potential cost implications for the healthcare system are also noteworthy. Although this study did not examine cost data, the creation of safe and accurate computer-based surveillance systems means that the clinical workforce necessary to monitor patients does not need to grow at a rate corresponding to the increasing rates of transplants. If transplant centers develop uniform processes for monitoring and managing patients, it becomes possible for HM data systems to be shared across centers, resulting in additional potential savings as a whole because each center would not need to build and maintain its own system. Such applications will incur programming and technical staff costs to develop, implement, and maintain/support the systems. As such, cost-effectiveness comparisons in this area are probably a logical next step to examine if the overall (and disease-specific) medical care costs differ between patients who receive these two forms of HM.

Despite the potential clinical and cost benefits suggested by this study, there are limitations to the study that may impact its generalizability. The study is limited by its sample size, which may introduce potential bias, as well as adherence issues that impact data collection. Validation of these results with larger numbers of subjects and multisite collaboration would provide further evidence of the feasibility and clinical appropriateness of instituting such programs more broadly.

Finally, this study has implications for the management of other pulmonary patient groups for whom HM may be a means of maximizing health management and health outcomes (e.g., transplant waiting lists, asthma, cystic fibrosis, chronic obstructive pulmonary disease). The monitoring of common symptoms or subgroups suggests it may be possible to implement similar systems across diverse pulmonary populations, as well as to establish standard procedures for clinical care in centers of excellence for lung health.

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Disclosure Statement

No competing financial interests exist.

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