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Randomized Trial of a Discharge Planning and Telehealth Intervention for Patients Aged 65 and older after Coronary Artery Bypass Surgery

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Abstract

Background: It is well established that older patients are at increased risk for developing complications after cardiac surgery due to advanced disease, impaired cardiac status, and comorbidities.

Objective: This study reports on the results of a telehealth and telephone Discharge Intervention for Cardiac Elderly (DICE) for patients ≥ age 65.

Materials and methods: A 3 group randomized study design was used with randomization to home telemonitoring of twice daily vital signs and reinforcement of the discharge plan with advanced practice nurse telephone follow up on the day of discharge, day 3 after discharge and weekly for 4 weeks to assess post discharge status in the areas of activity level, assistance needed, reinforce the discharge home plan, and assess for complications ; Modified DICE, which consisted of telephone follow up only at the same intervals post discharge; and Control, with routine postoperative follow up with no telephone or telehealth intervention.

Results: Two-hundred-six subjects aged 65 to 92 (mean age 73), from 4 hospitals were enrolled in the study. There were no differences between the study groups with respect to age (p = .115), sex (Pearson Chi-Square .434, p = .80), or race (Pearson Chi Square = 9.93, p = .128). There were also no differences in demographics, length of stay or hospital related characteristics among the groups. A total of 31 of 204 patients (15.2%) were rehospitalized within 3 months after discharge. There were no differences in rehospitalization rates among the 3 groups (Pearson Chi-Square 2.35, p = .309). However, differences were found among the 3 groups with respect to rehospitalizations when age was taken into consideration. Elderly female patients (aged 75 and older) who received the telehealth intervention had fewer hospital readmissions and ER visits compared to telephone and control groups (Pearson Chi-Square 8.914, p = 0.12). Patients aged ≥ 75 who received the DICE telehealth intervention had fewer ER visits compared to Modified DICE and control groups (Likelihood Ratio = 7.377, p = .026). Telephone interviews at one month after discharge revealed that patients in the DICE telehealth group reported a higher degree of post discharge knowledge of medications compared to Modified DICE and control (p < .05).

Discussion and conclusion: The results of the study demonstrated a positive impact of a post-discharge telehealth and telephone intervention led by advanced practice nurses for elderly cardiac surgery patients at high risk for readmission.

Keywords

Telehealth, Cardiac surgery patients, Readmission intervention, Telephone nursing intervention, Advanced practice nurse

Introduction

Despite diagnostic and treatment advances, coronary heart disease (CHD) remains the leading cause of death in Americans over the age of 65 [1]. Coronary artery bypass surgery (CABG) is the most frequently performed major surgery for CHD in the United States (U.S.) [2]. While the rates of CABG surgeries have declined in recent years due to the increased use of percutaneous coronary procedures, current treatment guidelines from the American Heart Association and the American College of Cardiology identify that CABG is recommended over angioplasty for patients with severe coronary artery disease [2]. More than a million coronary revascularizations are performed in the U.S. each year, with majority (54%), being performed in patients ≥ age 65 [3,4]. These patients are at increased risk for developing postoperative complications due to advanced disease, impaired cardiac status, and comorbidities. Therefore this study focused on cardiac surgery patients aged 65 and older to assess the impact of a telehealth intervention.

Telehealth, or the use of electronic information technologies to support long-distance clinical health care, has the potential to optimize outcomes for cardiac patients after hospital discharge. However, the use of telehealth for cardiac patients has predominantly focused on managing patients with heart failure. A number of studies have found that home-based telephone and telehealth programs reduce readmission rates for patients with heart failure. A recent Cochrane Collaboration review on the use of structured telephone and telemonitoring, or the use of information technology

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to monitor patients at a distance, for patients with chronic heart failure concluded that both interventions are effective in reducing the risk of all-cause mortality and congestive heart failure related hospitalizations [5]. Several investigators have used post-discharge telephone calls to cardiac surgery patients to monitor recovery and reinforce medication, diet, and activity instructions [6-10], however, limited studies have been performed on the use of telehealth for postoperative cardiac surgery management. The few studies that have integrated telehealth have focused on the use of health information and tailored messages provided via a WebTV device with modem internet access to facilitate CABG recovery [11], and providing a symptom management intervention using an interactive telehealth device [12,13].

The objective of this study was to test the effects of a telehealth and telephone Discharge Intervention for Cardiac Elderly (DICE) for patients age ≥ 65 status post cardiac surgery on hospital readmission and emergency room (ER) visits within 30 days after discharge. The study hypotheses were 1) DICE patients will report better functional and health status compared with Modified DICE or Control patients; 2) Patients receiving DICE will have less health care utilization (primary care physician and clinic visits, acute care visits, emergency room visits, rehospitalization) compared with Modified DICE or Control patients; and 3) The DICE intervention will be more costly than either Modified DICE or Control group.

Materials and Methods

A 3 group randomized study design was used and subjects from four Midwestern hospital settings were randomized using a computer-generated sequence of random numbers to either the DICE intervention with telehealth and structured telephone follow up with focused reinforcement of the discharge plan by an advanced practice nurse (APN) on the day of discharge, day 3 after discharge, and weekly for 4 weeks; Modified DICE, with structured telephone follow up only at the same postoperative time intervals, or Control, which consisted of routine patient and family education and discharge planning with regular postoperative follow-up as per normal with the treating physician. Table 1 outlines the components of the study intervention components. The outcomes of interest included post discharge health and functional status, satisfaction with care and health care utilization as measured by rehospitalizations, emergency room visits, and primary care physician and clinic visits post discharge.

The AvidCare telehealth monitoring system (Avidcare Company) was used for home telehealth monitoring and was installed in the patients' home on the day of, or day after discharge. The system consisted of a stand up scale, a blood pressure cuff and pulse oximetry connected to a portable module which recorded and transmitted the readings via the patients telephone server to a secure password protected website located at the university. Patients were instructed on use of the telehealth machine by the study advanced practice nurse (APN), a master's prepared nurse with advanced education and training and clinical expertise. Patients were given a home instruction manual, and return demonstrated the use of the machine prior to using the machine independently. Alarms were generated for vital sign or weight parameter changes and received by the APN via a digital pager with alarm response actions based on a standardized protocol. A copy of the patient's discharge plan and medication reconciliation form was provided to the APN on the day of patient discharge. The plan of care and prescribed medications were reviewed during the telephone follow up calls on day one and three after discharge and at the weekly phone follow up calls to reinforce patient knowledge of the discharge plan and home medications. The post discharge telephone follow up calls were conducted by an APN to assess for post discharge concerns, physical symptoms, knowledge of discharge medications and verification of a scheduled physician follow up visit. A structured procedure manual was used by the intervention APNs and a dedicated APN were used for each of the intervention groups. Fidelity of the APN intervention was tested during a structured training session and through random auditing of adherence to the study procedures.

The study sample was drawn from CABG and valve surgery patients aged ≥ 65 who were approached for study participation during their hospital stay on day 2 or 3 post surgery. Inclusion criteria for the study included subjects aged ≥ 65 at high risk for postoperative complications [documented history of congestive heart failure; New York Heart Association functional classification III or IV, ejection fraction of ≤ 40%, or history of atrial fibrillation or for post-discharge complications of myocardial infarction, arrhythmias requiring treatment, reoperation, cardiac arrest, wound dehiscence, positive wound culture, ICU stay >2 days, mechanical ventilation >2 days, or failure to meet clinical pathway discharge goals by post operative day five. Institutional board review approval was received and all study personnel completed training on protection of human subjects regulations.

The SF-36, Version 2, was used to assess health and functional status at 1 month after hospital discharge. The SF-36 consists of 36 items in 8 subscales which measure 3 major concepts of health status: overall evaluation of health (general health), functional status (physical functioning, social functioning, role limitations attributed to emotional problems, and bodily pain) and well-being (mental health and energy or fatigue). SF-36 items and scales are scored so that a higher score indicates a better health state [14]. Subscale scores were transformed to have a consistent range from 0 to 100, with 0 = worst possible health and 100 = best possible health, to enable comparisons with national norms. Reliability and validity have been demonstrated [14].

The Acute Physiology Age and Chronic Health Evaluation III (APACHE III) was used to assess illness acuity at 24 hours of ICU admission. APACHE III calculates a score based upon the values of 16 routine physiological measurements, age, and comorbidities [15,16]. The score (range 0 to 299) provides a general measure of illness acuity. A five-point increase in score is associated with a statistically significant increase in the relative risk of hospital death. Reliability and validity have been established (APACHE Medical Systems) [17].

Satisfaction with care was measured by the Transition and Continuity items of the Picker-Commonwealth Patient Interview Questionnaire [18]. The tool consists of 8 items that assess the adequacy of discharge planning given to the patient prior to hospital discharge. Response choices range from "very" to "not at all". Two open-ended questions assess suggestions for enhanced discharge planning. Instrument development of the interview tool via a national survey of 6,455 adult patients regarding aspects of hospital care established face and content validity. The instrument has been used in several studies including a large-scale research study of 4,600 adult medical-surgical patients and components form the basis for the Consumer Assessment of Health Plans survey [19].

Heath care utilization was measured by one month rehospitalizations, emergency room visits, and primary care physician and clinic visits post discharge. Telephone follow up at one month post discharge was conducted using the Beth Israel Quality Assurance

Table 1: Components of the Discharge Intervention for Cardiac Elderly (DICE) study intervention

DICE: Telehealth & Telephone follow up	Modified DICE: Telephone follow up only	Control
Telehealth: Home telemonitoring of twice daily vital signs including heart rate, blood pressure and pulse oximetry and daily weight	No telehealth monitoring	No telehealth monitoring
Telephone: Focused reinforcement of the discharge plan with advanced practice nurse (APN) telephone follow up on the day of discharge, day 3 after discharge and weekly for 4 weeks to assess post discharge status in the areas of activity level, assistance needed, reinforce the discharge home plan, and assess for complications.	Telephone: Focused reinforcement of the discharge plan with advanced practice nurse (APN) telephone follow up on the day of discharge, day 3 after discharge and weekly for 4 weeks to assess post discharge status in the areas of activity level, assistance needed, reinforce the discharge home plan, and assess for complications.	No telephone follow up

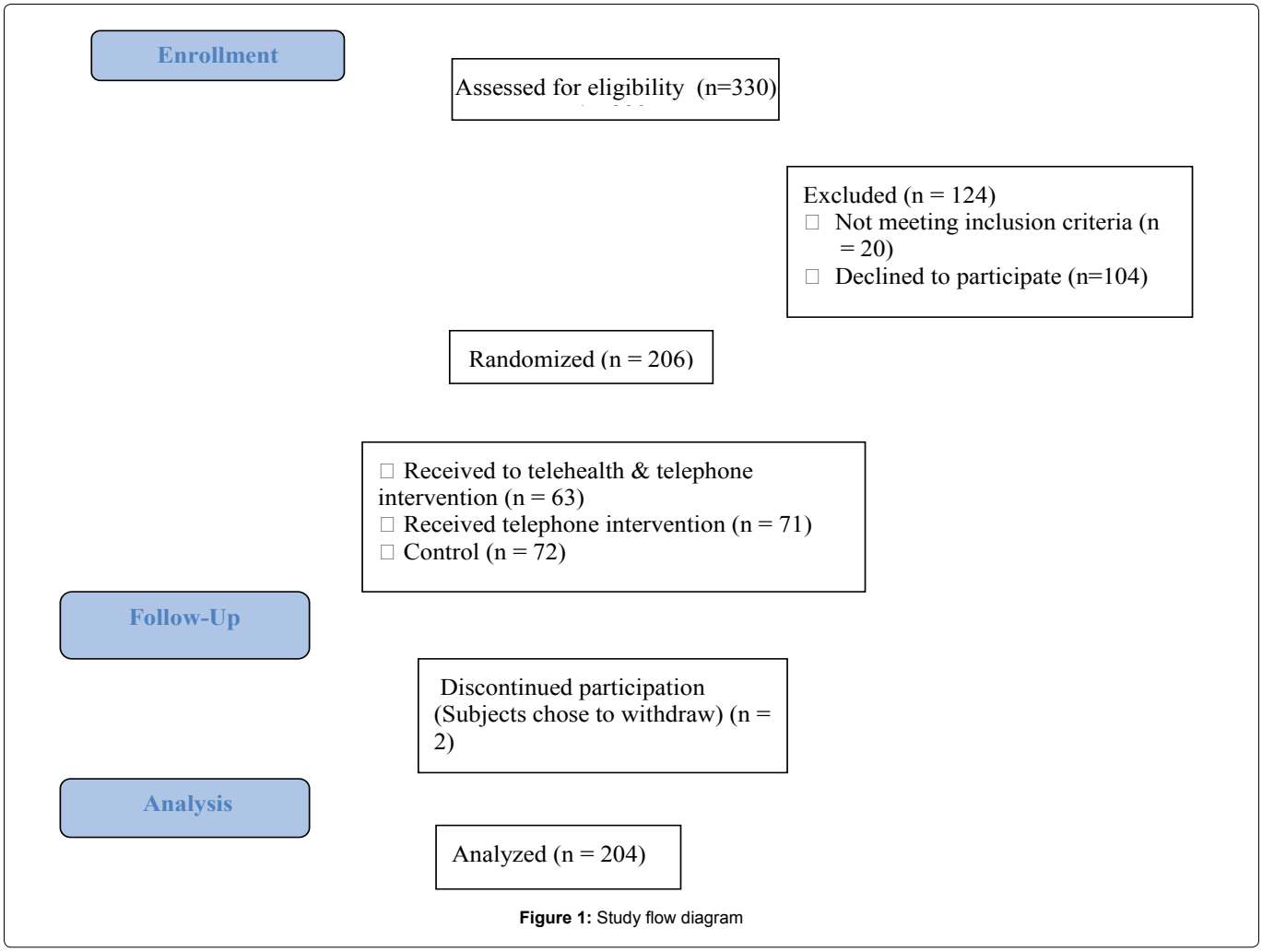

Figure 1: Study flow diagram

Table 2: Demographics of study participants

Age	N	Minimum	Maximum	Mean	Std Deviation
	204	65	90	72.70	6.076
Sex	**N**	**Present**			
Female	81	39.7			
Male	123	60.3			
Race	**N**	**Present**			
African American	42	20.6			
Asian	3	1.5			
Caucasian	156	76.5			
Hispanic	3	1.5			

Post discharge Patient Questionnaire, which consists of 18 questions that assess the patient's post discharge status in the areas of activity level, assistance needed, and complications [20].

Telephone interviews, lasting an average of ten minutes, were conducted by a trained nursing research assistant, blinded to group assignment, to assess health and physical functioning (SF-36), health care utilization, and satisfaction with hospital discharge process. Inter-rater reliability of telephone interviews was verified by one of the co-investigators at random periods throughout the study.

SPSS (v. 11), and S+ (v. 6.2) was used for data analysis. Frequencies, percentages, medians, and range were used to describe the type and amount of post hospitalization health care utilization. Kruskal-Wallis and Mann-Whitney tests were used for group comparisons .Means and standard deviations were used to describe the distributions of the composite scores and subscales of the SF36 and perceptions of health ratings at each time point. Two-factor repeated measures analysis of variance (RMANOVA) was used to compare the behavior of the SF36 composite scores over time.

Results

Of the 330 subjects approached for the study, 206 subjects met criteria for participation and 63 were randomized to the DICE intervention with telehealth monitoring and telephone follow up, 71 to the Modified DICE intervention with telephone follow up only and 72 to the control group. Power analyses were performed in PASS 2000, based on two-sided tests at a conservative significance level of 0.01 so that adjusted and repeated measures analyses would have the nominal 0.05 level of significance. A sample size of 300 (100 per group) was estimated to insure 80% power to detect differences in the study aims.

Figure 1 outlines the flow of study patients. There were no differences between the study groups with respect to age (p = .115), sex (Pearson Chi-Square .434, p = .80), or race (Pearson Chi Square = 9.93, p = .128). One hundred twenty three subjects were male and 81 were female. The age range was 65-90 (mean = 73). Twenty-one percent of the subjects were African American, 77% were Caucasian, 1.5% were Asian and 1.5% were Hispanic. Hospital length of stay ranged from 4 to 33 days (mean = 9.61, standard deviation 4.48) and ICU length of stay ranged from 1 to 16 days (mean = 4.68, standard deviation 2.51). There were no differences in demographics, length of stay or hospital related characteristics among the groups (Table 2). All patients randomized to the respective groups received the treatment that they were assigned.

A total of 31 of 204 patients (15.2%) were rehospitalized within 3 months after discharge. There were no differences in rehospitalization rates among the 3 groups (Pearson Chi-Square 2.35, p = .309) (Table 3). However, a priori subgroup analysis was conducted and differences were found among the 3 groups with respect to rehospitalizations when age was taken into consideration. Elderly female patients (aged 75 and older) who received the DICE telehealth intervention had fewer hospital readmissions compared to Modified DICE (telephone only) and control groups (Pearson Chi-Square 8.914, p = 0.12). A total of 36 patients (17% of the sample) reported an ER visit within

Table 3: Rehospitalization Rates and Emergency Room (ER) Visit Rates Post Discharge

Rehospitalizations	Number	Percent
DICE	6	9.5%
Modified DICE	12	16.9%
Control	13	18.6%

p = .309

Reasons for Rehospitalizations: Arrhythmia, syncope, palpitations, EKG changes, chest pain, pleural effusion, cellulitis, pneumonia, hypertension, anemia, sterna infection

ER visits	Number	Percent
DICE	8	12.6%
Modified DICE	11	15.4%
Control	17	24.2%

p = .544

Reasons for ER Visits: Chest pain, lightheadedness, shortness of breath, cough with fever, nosebleed, syncope, hypoglycemia

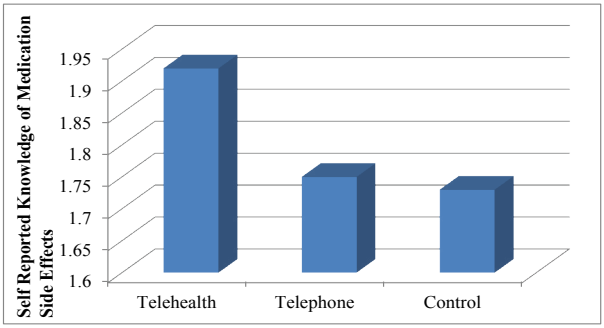

Figure 2: Post Discharge telephone follow up: Reports of knowledge of medication side effects

3 months after discharge. There were no differences in ER visits among the 3 groups (Pearson Chi-Square 1.28, p = .544) (Table 3). However, differences were found among the 3 groups with respect to ER visits when age was taken into consideration. Patients aged ≥75 who received the DICE telehealth intervention had fewer ER visits compared to Modified DICE and control groups (Likelihood Ratio = 7.377, p = .026).

There were no differences in severity of illness, as measured by the Apache III during the first 24 hours of ICU admission between the three groups (p = .328), with scores ranging from 23 to 104 (Mean 58.35, standard deviation 12.01). However, patients with higher severity of illness, as measured by APACHE III scores of >65, had fewer hospital readmissions in the DICE telehealth group compared to Modified DICE and control groups (Kendall's tau-b = -.225 p = .056).

SF-36 scores did not differ between the groups and overall the total scores ranged from 46.05 (SD = 6.10) for DICE subjects, 47.05 (SD 6.45) for Modified DICE, and 47.39 (SD = 6.41) for Control patients (p = .328).

Telephone interviews at one month after discharge revealed that patients in the DICE telehealth group reported a higher degree of post discharge knowledge of medications compared to Modified DICE and control (p < .05) (Figure 2). In evaluating the impact of the DICE and Modified DICE interventions, patients reported that the telephone and telehealth interventions were very useful in clarifying information and in monitoring their postoperative recovery. Patients also reported a number of concerns related to the discharge planning process, regardless of group assignment. Inadequate preparation for discharge, uncertainty about discharge medications and side effects, problems with obtaining home equipment and scheduling of home health nursing visits were among the most frequently reported problems.

Table 4: Cost of intervention components, in US dollars

	DICE	Modified DICE	Control
	N = 63	N = 71	N = 72
Equipment and set-up	$275	$0	$0
Telephone	$66	$66	$0
Physician visits	$165	$0	$0
Follow-up telephone calls	$165	$165	$0
Cost per participant	**$671**	**$231**	**$0**

Notes: The cost of telephone follow-up calls based on the cost of an advanced nurse practitioner conducting the calls on day of discharge, day 3 after discharge, and weekly for 4 weeks.

Table 5: Participants Reporting Improvement in Health Status, SF-36 and Perception of Health

	DICE	Modified DICE	Control	
	n (%)	n (%)	n (%)	p value
SF-36				
Physical health	45 (72.6)	54 (76.1)	54 (77.1)	0.820
Mental health	35 (56.5)	46 (64.8)	43 (61.4)	0.615
Perception of Health	35 (55.7)	39 (54.9)	34 (48.9)	0.663

Telehealth monitoring

A total of 4709 alarms were generated for the patients receiving telehealth monitoring. Majority (3809) were for blood pressure, followed by heart rate alarms (603) and oxygen saturation alarms (297). Majority (>80%) of the alarms were deemed "clinically nonsignificant" based on telephone follow up by the telehealth nurse. Most often the vital sign parameter was within normal limits after a repeat reading was taken. Six patients required an intervention based on the telehealth alarms including an 80 year old female who required readjustment of antihypertensive medication on day 7 post discharge for elevated blood pressures (range 158/65 to 178/78 mm Hg); a 69 year old male who required the addition of a second antihypertensive medication on day 13 post discharge for elevated blood pressures (range 149/74 to 175/76 mmHg); a 73 year old female who required an increase in beta blocker medication on day 5 post discharge for an elevated heart rate (range 110 to 125); a 70 year old male who required adjustment of dosing of an antiarrhythmic agent on day 15 post discharge for bradycardia (range 44 to 48); a 67 year old female who required adjustment of insulin dosing day 1 post discharge for elevated blood sugars; and a 74 year old male who required an increase in antihypertensive medication dosing on day 45 post discharge for elevated blood pressures (range 165/84 to 186/90 mmHg).

Cost analysis

A cost-effectiveness analysis of the DICE and modified DICE interventions was conducted using the incremental costs relative to the control group. Costs were estimated for the intervention components, including telehealth equipment and set-up costs, telephone costs, physician visit costs, and APN costs for telephone follow-up calls. APN telephone follow up time ranged from 10 minutes to 40 minutes per call. Majority of patients had between 1 and 3 follow up physician office visits the first month post discharge, depending on whether they were followed by a cardiologist and a primary care physician in addition to the cardiac surgeon. Costs associated with the telehealth equipment and telephone costs depended on the patient's geographic location from the study coordinating site (local versus long distance call, and number of miles to travel for telehealth set up by a telehealth technician). The costs of these components were summed to calculate the total cost per participant (Table 4). The estimated intervention ("program") costs were $671 per participant for DICE, $231 per participant for modified DICE compared to control.

The total cost per participant experiencing a positive health outcome was calculated by dividing the number of participants experiencing an increase in total SF-36 score by the total cost of the intervention (i.e., cost per participant x number of participants in each group). Table 5 reports the number of participants experiencing a positive health outcome. Table 6 reports the total cost per participant experiencing a positive health outcome. Because the

Table 6: Cost per Participant with Improvement in Health Status, SF-36 and Perception of Health

	DICE	Modified DICE	Control
	N = 63	N = 71	N = 72
SF-36			
Physical health	$939	$304	$0
Mental health	$1,208	$357	$0
Perception of Health	$1,208	$421	$0

cost per participant was substantially higher for DICE compared to modified DICE and the proportion of participants experiencing a positive health outcome was not higher for DICE, the cost per participant experiencing a positive health outcome was substantially higher for DICE.

Discussion

The results of this study demonstrated that post discharge telehealth monitoring for elderly cardiac surgery patients resulted in fewer rehospitalizations and ER visits compared to telephone follow up for older female patients who received the DICE intervention. In addition, patients with a higher severity of illness, as measured by the APACHE III who were in the DICE group had less hospital readmissions and ER visits compared to modified DICE and control groups.

Studies on the use of telemedicine interventions for cardiac surgery patients have demonstrated beneficial results including an increase in activity levels with the use of home based exercise with telemedicine [21], decreased rehospitalizations and fewer ER visits for heart failure patients [22], and improved health perception and satisfaction rates for recently discharged older patients [23]. The results of the current study demonstrate a benefit of a telehealth and telephone intervention in decreasing rehospitalizations and ED visits for patients aged 75 and older. This information is especially useful as recent data indicates that patients aged ≥ 75 years constitute 20% or more of patients undergoing coronary revascularization in the U.S. [4,24].

In the current study, patients in the DICE group reported a higher degree of post discharge knowledge of medications compared to telephone and control ($p<.05$). The most common intervention for DICE patients was focused on medication adjustment as a result of blood pressure or heart rate alarms. Similarly, a study of 148 patients comparing the impact of telephone and videophone follow up for patients with heart failure found that patients randomized to a home telehealth intervention were more likely to have medications adjusted during the 90 day intervention period. In addition, these patients had higher knowledge scores related to home medications [25]. Telehealth and telephone interventions can help to reinforce the discharge plan with review of medications. As medication management is often needed in the post hospital care phase, programs targeting hospital to home transition with a focus on promoting patient self-management of discharge medications remain a priority area of focus [26].

The results of the study demonstrated a positive impact of a post discharge telehealth and telephone intervention led by APNs for elderly cardiac surgery patients at high risk for readmission. Other studies utilizing APN led telehealth interventions have demonstrated conflicting results ranging from no impact on hospital readmissions, ER visits, or costs of care [27] to beneficial results including decreased hospital readmissions and improved quality of life [28]. Other studies of APN led interventions have demonstrated efficacy for elderly patients with heart failure in preventing readmissions and improving self care [29-33]. Additional research on APN led interventions is needed to identify the impact of care by this growing number of healthcare providers who can help to augment care for older patients. In addition, cost effectiveness of care provided by APNs needs to be further explored. Ongoing research exploring the impact of telemonitoring in cardiac patients, including the Better Effectiveness After Transition – Heart Failure (BEAT-HF), the largest randomized clinical trial to date of telemonitoring in patients with heart failure, will provide further information on how care transitions can best be combined with telemonitoring [34].

In the current study, the cost analysis did not demonstrate that the use of telehealth was cost effective in promoting a positive health outcome. The use of telemonitoring has been found to increase the costs of care and other studies have found that while telemonitoring resulted in positive outcomes such as decreased rehospitalizations or improved satisfaction or quality of life, an increase in costs resulted due to the cost of the telemonitoring system [35]. Other studies however have demonstrated reductions in inpatient costs with the use of telehealth interventions attributed to decreased rehospitalization that have offset intervention costs [36,37]. Yet a recent randomized study of the use of telemonitoring of 1653 patients with heart failure failed to demonstrate an improvement in outcomes including hospitalizations for heart failure, number of days in the hospital, and number of hospitalizations [38]. While the use of telehealth has been demonstrated to improve clinical outcomes at lower cost for home healthcare and promote continuity of care [39,40], additional research related to cost effectiveness is needed. Telehealth interventions have been identified as an emerging strategy to prevent readmissions, particularly in elderly patients at high risk for readmission [41-42]. Additional research is needed which further explores the impact of telehealth interventions on costs of care, especially with the increased emphasis on decreasing length of hospital stays while simultaneously targeting decreased readmissions.

Despite the use of a randomized control design and the use of four data collection sites, several study limitations may have impacted the results including a sample size drawn from one geographical region; the inclusion criteria requirement to have a land line phone to enable telehealth data transmission, preventing enrollment of subjects with only cell phones and limiting generalizability of the study results; and changes that may have occurred in the discharge planning process over the duration of the four year study that were unknown to the study staff but which might have impacted the discharge preparation of subjects.

The number of cardiac surgery procedures at all four sites decreased during the study timeline and paralleled national trends in decreasing surgical rates with increasing use of minimally invasive procedures and reperfusion techniques. This may have resulted in a study sample that was less heterogenous, additionally limiting the generalizability of the study results.

Conclusions

The results of this randomized clinical trial demonstrated a positive impact of a post discharge telehealth and telephone intervention led by APNs for elderly cardiac surgery patients at high risk for readmission. There were no differences in rehospitalization rates among the 3 groups. However, patients aged ≥ 75 who received the post discharge telehealth and telephone intervention had fewer ER visits compared to the telephone and control groups. Patients receiving the telehealth and telephone intervention reported a higher degree of post discharge knowledge of medications compared to telephone and control. A cost analysis demonstrated that the cost per participant was higher for the telehealth monitored subjects compared to telephone follow up alone, and the cost per participant experiencing a positive health outcome was higher for the telehealth group. Further studies which address the use of telemonitoring of patients to promote transition from hospital to home are needed in order to further explore benefits including cost effectiveness, to ensure optimal recovery and minimize post discharge complications for elderly patients undergoing cardiac surgery. As the Affordable Care Act recognizes the value of coordinated care in promoting cost effective, high quality health-care in the United States [43], opportunities for APN-led initiatives using telehealth is one solution to meet the healthcare needs of a growing number of patients with complex healthcare needs, including elderly cardiac surgery patients at risk for readmission [44].

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