A single educational intervention on Heart failure self-care: extended follow up from a multisite randomised controlled trial

Abstract

Background: Heart failure outcomes remain poor and little is known about the causes and predictors of these outcomes in Lebanon.

Aim: To report the causes and predictors of the six and 12-month readmission and mortality of patients previously recruited to the FAMILY study.

Methods: A multi-site block randomised controlled trial in three tertiary medical centres in Beirut. Initially, participants were randomised to either the control or the intervention group. The latter group, with their family caregivers, received heart failure self-care resources and an educational intervention on self-care and symptom management during their index admission. Participants from the FAMILY study were followed up with through phone calls for readmission and mortality at 6 and 12 months following their hospital discharge.

Results: A total of 218 (85%) patients were followed up with for this evaluation. There was a significant difference between the intervention group and the control group in terms of mortality at 6 months (n= 18 (16%) vs. n=36 (33%); $p<0.05$) and 12 months (n=29 (26%) vs. n=45 (42%); $p<0.05$) post the index discharge. Mortality at 6 and 12 months was associated with aging, lower BMI scores and readmission at 30 days post the index admission. Results of a logistic regression for mortality at 6 months showed hypertensive etiology of heart failure to be the only significant predictor.

Conclusion: A single session intervention showed significant improvement even after an extended period of time. Multi-session trials and longer periods of follow up are suggested for future studies to improve patient outcomes.

Key words: Heart failure; Nursing, Intervention; Follow up; Education; Family

Introduction

The complexity of heart failure, its treatment and complications have been previously documented (1). The treatment has evolved over the past many years to include non-medical management and complex interventions such as telemonitoring and remote home support (2-4). However, even the simplest interventions involving education and follow up are lacking in some regions of the world (5). We previously reported the findings of the first randomised controlled trial on heart failure management in Lebanon (6). That study involved a simple educational intervention that included the patient and his/her family about the self-care of these patients using a culturally appropriate approach. The findings were rewarding in terms of readmission and mortality rates and in self-care scores after 30 days of follow up. The short follow up period, however, was a limitation to the study and raised concerns about the validity of the findings, which led us to continue a 6 and a 12 month follow up for readmission and mortality rates on these same patients.

Heart failure is a complex clinical condition that progresses rapidly and causes debilitation to the persons affected (7). It impacts the lives of the patients and their families, in addition to the healthcare system (8, 9). High rates of readmission and mortality have been associated with this condition worldwide, where more than 50% of those hospitalised are either readmitted or pass away within the first year (10). While more than half of the readmissions can be prevented, this can only be achieved with proper discharge planning and follow up (11). Discharge planning includes education on self-care, which comprises a group of practices the patient undertakes to maintain his/her wellbeing and manage his/her symptoms (12). The implementation of educational interventions in heart failure disease management programs has shown its positive impact on patients' clinical outcomes in many countries of the world (13). However, and despite the established need, these programs remain limited in the Arab countries, and Lebanon is no exception.

Heart failure management programs have addressed the self-care needs of patients but generally did not address cultural considerations (14). For instance in collectivist societies, as in the Arab World, cultural considerations include involving the family members in the care of patients (15). As this involvement occurs naturally, structuring the care with proper education was hypothesised to improve outcomes (16). In fact, the psychosocial factor was presented as vital in improving the self-care of patients with heart failure (17). The FAMILY study included the patient and the family caregiver identified by the patient, in an educational intervention on self-care and symptoms management. The theory-inspired FAMILY intervention Heart Failure Model was put together using mixed methods of theoretical model critique, review of evidence, expert consultations, and socio-cultural evaluation and consideration (18). The concepts derived included partnership, behaviour change, support and empowerment.

The current study aimed to explore the readmission and mortality rates after a single educational intervention on self-care that involved the family in patients with heart failure and report the difference between the intervention and the control groups after 6 and 12 months of their hospital discharge.

Methods

Study design

The investigation conforms with the principles outlined in the Declaration of Helsinki. The protocol of this study was presented elsewhere (Blinded author). In brief, the study was a multi-site randomised controlled trial with blocks of four, conducted in three tertiary medical centres in Beirut and Mount Lebanon. The trial was registered at the Iranian Registry of Clinical Trials with the number: IRCT2014101919593N1. The structure of the methodology conformed to the CONSORT Guidelines (19). Following the initial phase of the study, ethical approval was secured from all sites for two additional phone calls at 6 and 12 months

following the initial discharge. The calls were to collect data on readmission and mortality from the participants who were willing to answer our calls since they accepted the previous call at 30 days post their index discharge. There were no formal ethical scrutinies required according to the local Lebanese regulations.

Participants

Patients with heart failure were recruited to this study if they met the following eligibility criteria; adults with confirmed diagnosis of heart failure validated against the Framingham criteria (20), and willingness of the patients and their primary family caregivers to participate. Patients aged less than 18, or those with limited life expectancy of less than 30 days as evaluated by their physician were excluded from the study.

Settings

The study settings were three tertiary medical centres that admit patients for multiple medical and surgical conditions. The three centres have experienced cardiology nurses and large cardiac care units that are equipped to care for patients presenting for exacerbation of heart failure.

Sample size calculation

Sample size was determined using the G power program (21) using the outcomes of interest; readmission. The formula included two equal groups with a pre-set p value of 0.05 and an attrition rate of 10%. The program estimated a sample size of 130 participant in each group.

Randomization

A list of random numbers was generated by the Statistical Product and Service Solutions with blocks of four. The list was kept with a researcher who was not involved in the

data collection where she was contacted for participant allocation following baseline data collection.

The intervention

The intervention model was put together using selected references from the literature on the Lebanese culture and previous studies identifying components of effective interventions, in addition to consultation with experts on collectivism in the Lebanese setting (22, 23). During the index admission, baseline data were collected and patients were randomised to a control group and an intervention group and both groups were given self-care resources. Patients in the intervention group with their identified family caregiver were educated through a single comprehensive educational session on self-care on how to manage their symptoms. They were also educated on how to use the self-care resources that included a weighing scale, a calibrated bottle for accurate fluid intake, a medication box and a diary with designated blanks for recording their daily weight and their prescribed medication. The control group was not provided with any education but was provided with the self-care resources only. This was done to assure equal treatment to both groups and rule out any effect other than the educational intervention on the outcomes of interest.

Data collection and study outcomes

The 6 and 12 months follow up data collection was done by a researcher unaware of the primary patient allocation to the intervention and control group and who was not involved neither in the baseline nor in the first round of follow up data collection. Baseline data collection was done during the index admission and included demographic characteristics, physical assessment findings such as fluid retention and vital signs, medical history, the frailty index (24), and medications that were previously prescribed. The primary study was initiated in November, 2013 where 256 patients were recruited over a 12 months period. The extended follow up was started 6 months following the study commencement and continued

till November, 2015 and the data were collected by phone call. The outcomes of interest for this extended follow up were readmission and mortality within the first 6 and 12 months following the index discharge.

Data analysis

Data were entered and analysed using version 21 of the Statistical Product and Service Solutions (SPSS). Continuous variables were reported in means and standard deviations, and nominal variables were reported in frequencies and percentages. Group differences (group allocations and 6 and 12 month outcomes) were analysed using Chi square for categorical variables with presented odds ratios and confidence intervals and independent t test for continuous variables. Logistic regression was conducted to determine the predictors for mortality at 6 months. Variables were chosen from those that were significant at the bivariate level analysis and those that were found to be significant in the literature. The p-value was set to less than 0.05.

Results

The participant flow diagram is presented elsewhere but briefed here (Blinded author). In the first round of the study, 128 participants were allocated to the intervention group and 132 to the control group. Two patients in each group passed away during the index admission, thus 126 and 130 patients completed the study. During the first phase of the trial (30 day follow up), 5% were lost to follow up. However, during this extended follow up phase, all participants were contacted for further follow up. This time we were able to follow up with 218 participants (85%) from the initial sample.

The demographic and clinical characteristics are presented in Table 1. The mean age of the sample was 67 years (SD=13), and the majority were male (59%). Almost half of the participants were cared for by their spouse (46%) and almost 40% were illiterate. When

studying their risk factors, 35% were current smokers and mostly were overweight, with a mean body mass index (BMI) of 29 Kg/m^2 (SD = 8). Almost half were diabetic (46%), 73% were hypertensive, and half of the sample had hypercholesterolemia. Heart failure was mainly caused by ischemic heart disease, accounting for 57% of cases followed by hypertension (46%) and almost 70% of the cases were chronic. Upon discharge, 33% were classified under New York Heart Association (NYHA) class III or IV with a mean ejection fraction (EF) of 36% for the whole sample and almost all patients were frail (98%). The mean length of hospital stay during the index admission was 9 (SD=7) days. Medication prescription was in line with the international guidelines, with 83% discharged on beta-blocker, almost 70% on Angiotensin converting enzyme inhibitor/Angiotensinogen receptor blocker (ACEI/ARB), and 62% on both. There were baseline differences between the two groups at baseline were significantly more in the control group had a history of atrial fibrillation compared to those in the intervention group and more in the latter group were chronic cases.

Study outcomes

When looking at the outcome profile, it was found that 51 (31%) were readmitted within the 6 months interval and 71 (44%) were readmitted within year of their discharge. There was no difference in readmission rates at 6 and 12 months between the intervention and the control group. In terms of mortality, 54 patients passed away (25%) at 6 months and this number increased to 74 deaths at 12 months (34%). When looking at these rates between the groups, it was found that there was a significant difference between the intervention group and the control group in terms of mortality at 6 months (df=1, OR=2.5, CI=1.35, 4.76; p=0.02) and 12 months (df=1, OR=2, CI= 1.11, 3.33; p=0.01) respectively, post the index discharge.

The 6-month mortality was significantly associated with older age, male gender, longer length of stay at index admission, lower body mass index (BMI), higher diastolic blood pressure, atrial fibrillation at discharge, hypertensive aetiology of heart failure and readmission within 30 days of the index admission. Additionally, mortality at 6 months was significantly less among those who were discharged on a combination of ACEI/ARB and beta-blocker. These findings are presented in Table 2. Similarly, older age, lower BMI lower systolic blood pressure and readmission within 30 days and 6 months after the index admission were significantly associated with 12-month mortality as presented in Table 3.

Logistic regression was carried out to predict mortality at six months. After a number of trials, the best fitting model included age, group allocation, self-care maintenance score at the 30-day follow-up, hypertensive aetiology of heart failure, gender and hospitalization at 30 days following the index admission. The overall model was significant (x^2=24.505, df=6, p=0.000). The model predicted 85.6% of the whole sample and had a good fit to the data with a non-significant Hosmer-Lemeshow test (x^2=6.272, df=8, p=0.617). The Nagelkerke R^2 model was moderate with a value of 0.22. The results of this analysis are presented in Table 4.

Discussion

The aim of this study was to evaluate the effect of a single educational intervention on readmission and mortality at an extended period of time. The findings revealed no significant difference between the intervention and the control groups in readmission rates but showed a significant difference in mortality at both time intervals. Although the latter findings are pleasing, they need to be interpreted with caution, as the sample size was not powered for the outcome mortality rather for readmission. The higher mortality rates in the control group compared to the intervention group might have been attributed to other causes. These include

higher rates of atrial fibrillation and diuretic use in the control group suggesting a sicker group compared to the intervention group. Moreover, the study was originally powered for readmission, which was the primary outcome of interest at 30 days. This powering yielded a need for a sample size of 260 patients considering the attrition rates. Readmission was significantly reduced in the intervention group compared to the control group for this short follow up period. Despite this powering, readmission rates were not reduced in the intervention group later and the difference became insignificant at 6 and 12 months.

Other studies measuring their outcomes at extended periods showed similar trends in outcomes (25). This was seen in a study comparing the effect of home-based vs. the conventional clinic-based chronic heart failure management on readmission and mortality. There was no significant difference in readmission between the two groups, however, significantly more patients died in the clinic-based group as compared to those in the home-based group. When looking at the whole sample, their study cohort was somewhat similar to our study cohort in terms of comorbidities, initial length of stay, prescribed medication at discharge and gender. However, their study cohort was relatively older (mean age 71 vs. 67 years) and had more smokers (69% vs. 35%) among the patients (25). The similarities in readmission trends in both studies could be attributed to the educational elements on health seeking behaviours when no control can be practiced over symptoms. The 12-month mortality rate was slightly higher than that yielded from a registry of 12,400 patients conducted in 21 countries across Europe and the Mediterranean with acute and chronic heart failure (34% vs. 30%) (26).

The association between clinical characteristics and the six and 12-month mortality has been previously addressed. Although obesity was named as one of the risk factors for developing heart failure, higher BMI was shown to be associated with lower risk of mortality on patients with an established diagnosis (27). This comes in line with the findings of the

current study where higher BMI was associated with significantly lower mortality at 6 and 12 months. Similar trends were found in the literature in lowering mortality risk for patients having higher systolic blood pressure (28), female gender (29) and discharged on optimized medication regimen (30).

The significant difference between the groups in terms of chronicity of heart failure and atrial fibrillation did not fit in any of the tried regression models. When doing a separate analysis it was found that these variables were significantly correlated and might have produced the negative impact on the model. Although most of the variables in the model were not significant, but the addition of each of these variables yielded a better fitting. The non-significant findings of the included variables could be due to the number of participants included in the final model, since any variable with missing data will be excluded. The hypertensive aetiology was significantly associated with mortality at 6 month. This finding is alarming as most of the attention is focused on the primary cause of heart failure which is coronary artery disease, in Lebanon (31) and globally (32). Additionally, this comes in controversy to the findings of another study which presented a longer survival time for heart failure patients with non-ischemic aetiology (29). These findings draw major queries and propose gaps that need to be addressed in future research.

The limitations of this study are similar to those reported at 30 days. The lack of significant difference between the groups maybe due to the offering of self-care resources to both groups, which also included a booklet with detailed instructions. The effect of the intervention might have faded off. Moreover, the booklet may have been used as a reference even after an extended period of time due to the lack of educational material routinely provided to the patients. Additionally, the study was conducted in the capital city only, which limits its generalisability to other urban as well as rural areas of the country. This calls for national studies that include patients from all regions of the country and account for the

differences in care provided. Additionally, future studies should aim to evaluate the effect of interventions on both readmission and mortality and so should have sample sizes large enough to rule out any other causes of death.

Conclusion

Mortality was significantly reduced in the intervention group when compared to the control group at the six and 12-month time intervals. Mortality was significabntly associated with age, BMI and blood pressure. Future studies should power for mortality as well as readmission for more reliable results. Multi-session, national trials with longer periods of follow ups are also suggested for improving patient outcomes.

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Table 1: Demographical presentations and baseline data of the study participants

Variables	Total (N=218, 100%)	Control group (n=107,49%)	Intervention group (n=111,51%)	P value
Socio-demographic profile				
Age [mean (SD)]	67 (13)	69 (13)	66 (13)	0.11
Male	128 (59)	65 (61)	63 (57)	0.32
Married	139 (34)	69 (64)	70 (63)	0.88
At least high school education	57 (26)	21 ((20)	36 (32)	0.21
Caregiver spouse	101 (46)	50 (47)	51 (45)	0.90
Caregiver education	192 (88)	95 (89)	97 (87)	0.83
Risk factors				
Smoker	76 (35)	38 (36)	38 (34)	0.88
BMI [mean (SD)]	29 (8)	29 (8)	29 (8)	0.79
DM	100 (46)	47 (44)	53 (48)	0.58
HTN	160 (73)	81 (76)	79 (71)	0.54
COPD	41 (19)	21 (20)	20 (18)	0.86
CRF	61 (28)	30 (28)	31 (28)	0.98
Hypercholesterolemia	108 (50)	50 (47)	58 (52)	0.41
A fib	66 (30)	40 (37)	26 (23)	0.028
CAD	145 (67)	69 (64)	76 (68)	0.53
CHF profile				
Ischemic aetiology	125 (57)	64 (60)	61 (55)	0.46
HTN aetiology	100 (46)	48 (45)	52 (47)	0.78
Chronic HF	149 (69)	66 (62)	83 (75)	0.04
NYHA class III or IV	72 (33)	37 (35)	35 (31)	0.63
EF [mean (SD)]	36 (12)	36 (12)	37 (11)	0.43
Clinical profile				
Systolic blood pressure [mean (SD)]	132 (26)	122 (20)	124 (19)	0.46
Diastolic blood pressure [mean (SD)]	75 (8)	68 (12)	71 (13)	0.18
Sodium [mean (SD)]	140 (21)	138 (4)	141 (28)	0.33
Potassium [mean (SD)] *	4 (1)	4 (1)	4 (1)	0.79
Creatinine [mean (SD)]	1 (1)	1 (1)	2 (1)	0.11
Blood urea nitrogen [mean (SD)]	35 (29)	37 (33)	33 (24)	0.25
Haemoglobin [mean (SD)]	12 (3)	12 (2)	12 (3)	0.63
Frail	75 (94)	38 (95)	37 (92)	0.77

LEGEND: BMI: body mass index; DM: diabetes mellitus; HTN: hypertension; COPD: chronic obstructive pulmonary disease; CRF: chronic renal failure; A fib: atrial fibrillation; CAD: coronary artery disease; HF: heart failure; EF: ejection fraction; NYHA: New York Heart Association class; ACEI: angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker.

*: non-parametric testing used; continuous variables presented in mean and standard variation. Categorical variables presented in frequencies and percentages

Table 2 Association between 6-month mortality and clinical demographics

Variables	Deceased at 6 months	Alive at 6 months	P value
Age*	71 (11)	66 (14)	0.019***
Male	89 (55)	38 (70)	0.042***
LOS*	12 (10)	9 (6)	0.037***
BMI*	26 (7)	30 (8)	0.014***
SBP*	128 (25)	134 (27)	0.114
DBP*	70 (16)	76 (15)	0.007***
EF*	33 (10)	38 (12)	0.013***
Potassium at discharge* **	4 (1)	4 (1)	0.062
Atrial fibrillation at discharge	25 (46)	42 (26)	0.005***
Hypertension etiology of heart failure	16 (30)	84 (51)	0.005***
Discharged on beta-blocker and ACEI/ARB	26 (48)	108 (66)	0.018***
30-day readmission	8 (30)	19 (12)	0.015***
Self-care maintenance score at 30 days	56 (18)	65 (17)	0.018***

LEGEND: *presented in means and standard deviation; **similarities in numbers due to rounding; ***significant p value; LOS: Length of hospital stay; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; EF: ejection fraction; ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin receptor blocker.

Table 3 Association between 12-month mortality and clinical demographics

Variables	Deceased at 6 months	Alive at 6 months	P value
Age*	72 (8)	67 (14)	0.014**
BMI*	25 (4)	29 (8)	0.002**
Current smoker	17 (85)	127 (65)	0.064
SBP at admission*	119 (20)	134 (26)	0.024**
DBP at admission*	71 (14)	75 (16)	0.259
30-day readmission	6 (30)	21 (13)	0.036**
6-month readmission	6 (67)	45 (30)	0.019**

LEGEND: *presented in means and standard deviation;**significant p value; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure

Table 4: Regression analysis predicting mortality at 6 months.

Variable	B	SE	Wald	P value	OR	CI for OR
Group allocation	0.463	0.490	0.892	0.345	1.588	0.608-4.147
Age	0.029	0.018	2.692	0.101	1.029	0.994-1.065
Gender	-0.712	0.488	2.134	0.144	0.491	0.189-1.276
Hypertension etiology of heart failure	1.611	0.541	8.856	0.003	5.006	1.733-14.458
Self-care maintenance score at 30 days	-0.022	0.015	2.197	0.138	0.979	0.951-1.007
30-day readmission	-0.805	0.570	1.993	0.158	0.447	0.146-1.367
Constant	-2.829	1.666	2.883	0.089	0.059	