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THE EFFECT OF EDUCATION AND FOLLOW UP AFTER DISCHARGE (FAD) ON REDUCING READMISSION RATE OF CHF PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Patients with heart failure (HF) more often visit emergency rooms, are admitted to hospital repeatedly, and have longer lengths of hospitalization. Moreover, inadequate and ineffective follow-up after discharge has increased the risk of unplanned readmissions, which have been a financial burden for healthcare systems.

Objectives: The aim of this study was to determine the effects of patient education and post-discharge follow-up on outpatient visits to physician, adherence to medications and hospital readmission rate among HF patients.

Methods: This randomized controlled trial was conducted on patients aged 20 and older with diagnosis of heart failure admitted to Taleghani hospital, Tehran, Iran**.** The patients in intervention group were educated based on recent guidelines and were followed up for 3 months by 9 telephone interviews (every week for the first month after discharge, then every two weeks for the next two months), but the control group received usual care. Every two weeks after discharge, data about main outcome measures were collected by telephone interviews, including frequency of outpatient visits to physician, frequency of readmissions and adherence to medications.

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Results: Overall, 190 patients were screened and 120 patients were allocated equally with block randomization method. Readmission rate was 19.3% in intervention and 38.2% in control group (P-value = 0.05, odds ratio = 2.21). Outpatient visits was not significantly different between both groups (17.5% in intervention vs 28.3% in control group). In intervention group, 94.7% of patients and in control group, 84.9% of patients took medications completely as prescribed, which was not statistically significant.

Conclusion: In the present study, post-discharge intervention was effective on reduction of readmission rate among HF patients.

INTRODUCTION

Background: Prevention and treatment of heart failure (HF) is considered a major public health concern, which is associated with a significant prevalence (over 23 million) and growing incidence worldwide (1, 2). In Iran, the incidence rate of HF was estimated 1027 cases per 100000 persons and readmission rate within 3-6 months after discharge was up to 61% with mortality rate of 21% (3). Cardiovascular diseases have been the leading cause of death worldwide and in Iran they have accounted for 26% of all deaths (4, 5). Patients with heart failure more often visit emergency rooms and are admitted to hospital repeatedly, and have longer lengths of hospitalization which represents a substantial financial burden for healthcare systems (6).

Patient discharge is the process of care transition from health care providers in hospital to patients and their caregivers and physicians (7). Use of discharge surveys has decreased medication errors in patients' discharge orders (8), furthermore, early post-discharge follow-up has resulted in a reduced risk of 30 day rehospitalization (9). Patients with poverty and lack of social support have been more probable to be readmitted due to inability to gain post-discharge care, which increases the costs (10, 11). For example, it was estimated that the cost of unplanned readmissions for Medicare in 2004 was $17.4 billion (12), thus, in 2012, center for Medicare and Medicaid services of the United States has reduced payments to hospitals with extra readmissions (13).

Objectives: On this regard, in the present study, we aimed to evaluate the effects of patient education and post-discharge follow-up on outpatient visits to physician, adherence to medications and hospital readmission rate among heart failure patients.

METHODS

Trial Design and Participants

This randomized controlled trial was conducted on patients with diagnosis of heart failure admitted to Taleghani hospital, Tehran, Iran. Participants were enrolled in the study from August 2014 to December 2014, and were randomly allocated to intervention and control groups and were followed for 3 months after discharge. The study was registered at clinical trials registry with code IRCT2014051717727N1, and was approved by the Medical Ethics Committee of Shahid Beheshti University. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

We recruited literate patients (with ability of reading and writing) aged 20 and older that had confirmed heart failure disease and signed the written informed consent for participating in the study. Exclusion criteria consisted of known psychiatric illness, any lethal disease like cancer, severe hearing impairment and inability to participate in a telephone conversation.

Sample size was calculated according to a similar article that reported readmission rate before intervention as 51% and after intervention as 11% with standard deviation of 61%. Based on Altman's nomogram with 80% power and α (statistical significance) of 0.05, the sample size was determined as 100 patients but with assumption of attrition, we added the patients up to 120 (14).

Randomization and Intervention

Participants were enrolled in the study in a 1:1 ratio to control and intervention by block randomization method. For this purpose, randomization was done by an independent member who was not involved in any other parts of the study, and the research team were blinded to participant allocation. The randomization sequence was in permuted blocks of 4 patients including 1) AABB, 2) ABAB, 3) ABBA, 4) BABA, 5) BAAB, 6) BBAA. Each block was selected based on a list of random numbers so that a sequence was replaced instead of numbers 1 to 6 and numbers 0, 7, 8 and 9 were ignored. Then, the sequence was placed in a sealed envelope. Every morning, the medical records of patients discharged from CCU, Post CCU and Cardiac ward, were reviewed and eligible patients were selected, an envelope was received and allocation of treatment for the four consecutive patients was determined.

After obtaining informed consent, sociodemographic information and baseline characteristics of patients with heart failure including age, gender, occupation, education, marital status, duration of disease and

smoking were collected. Co-existing diseases that could impact the results including hypertension, diabetes, renal failure and hyperlipidemia were recorded. The stage of disease was determined using New York Heart Association (NYHA) classification. Then, a landline or mobile number was obtained and the questions to be interviewed on telephone calls were explained.

After we reviewed the literature, the most common readmission factors in heart failure patients were determined, including stressful events, non-adherence to medications, diet and exercise, insufficient follow-up care and inadequate social support (15-18). We explored guidelines of different countries such as United States, England, Australia, Sweden and Scotland and according to educational needs of patients and their frequently asked questions gathered by oral interviews with fifteen heart failure patients admitted to the hospital, we provided an educational pamphlet for patients. Moreover, drug interactions and adverse effects of commonly used medications in these patients were gathered as a reference for physicians.

Intervention consisted of two parts; first, educating the patients and their guardians immediately after discharge according to the educational content verified by experts, and then the educational pamphlets were presented. Second, telephone follow-up was done every week for one month and then every two weeks for two months. Telephone calls were made on the due date and if unsuccessful, it was repeated for three times. On each telephone call that lasted an average of 20 minutes, questions about medication and diet were answered and necessary guidance was given upon request. In addition, information about re-hospitalization, outpatient visits to physician and compliance with prescribed medications were recorded every two weeks according to a check list.

Control group received usual care and every two weeks a telephone call was made to record the information about re-hospitalization, outpatient visits to physician, cardiac symptoms and compliance with prescribed medications.

Statistical Analysis

All analyses were performed using IBM SPSS (version 20.0. Armonk, NY, United States) and STATA (version 11. College Station, TX, United States). Data analysis used chi square test, Fisher and t-test, and evaluation of intervention effect was done using generalized estimating equations (GEE) model.

RESULTS

A total of 190 patients were screened and 120 patients were recruited and randomized to 60 in intervention and 60 in control group, from August 2014 to December 2014. Baseline characteristics and sociodemographic information were recorded. During 3-months follow-up, two male patients died in control group due to cardiac disease. Three patients in intervention and five patients in control group were removed from the study because three patients were unresponsive to telephone calls, two patients travelled abroad, one was unwilling to continue participation in the study, one wrong number and one lived in a nursing home (Figure 1).

Baseline characteristics and sociodemographic variables were not significantly different between both groups (Table 1).

In intervention group, 4.8% of females were readmitted, whereas, the proportion of males was 27.8% (P-value = 0.03). The readmission rate of hypertensive patients in intervention group was 27%, whereas, in normotensive patients was 5% (P-value = 0.04). In intervention group, 66.7% of patients with renal failure were readmitted, while 13.7% of patients with normal renal function were rehospitalized (P-value = 0.01). In control group there was no correlation between readmission rate with gender, hypertension or renal failure. The readmission rate of patients with NYHA class I was 12%, class II was 15%, class III was 43.3% and class IV was 58.8%, which there was a significant association between stage of disease and readmission (P-value < 0.001). Of all patients, 8% of class I, 10% of class II, 27.6% of class III and 68.8% of class IV needed urgent visit to a physician. As for outpatient visits to physician, there was a significant association with stage of disease (P-value = 0.001), but not other factors in both groups.

In intervention group, 94.7% of patients and in control group, 84.9% of patients took medications completely as prescribed, which was not statistically significant.

Overall, 11 patients (19.3%) in intervention group and 21 patients (38.2%) in control group were rehospitalized (P-value = 0.05). The patients that needed critical care did not differ significantly between both groups (17.5% in intervention vs 28.3% in control group).

Since the data of this study were longitudinal and were measured seven times in 3 months, GEE model was used for data analysis, thus, the results demonstrated that the readmission rate was significantly different between both groups. The variable of time was not

significant, but at fourth telephone call, it was close to significance and had a high odd ratio compared to other calls. In other words, at fourth telephone call that was two months after discharge, there was the highest rate of readmission, approximately 5 times more (Table 2, Figure 2).

There was no significant difference of outpatient visits to physician between both groups. The variable of time was significant at fourth, fifth and seventh telephone calls and the odds ratio of fourth call was higher than the others (Table 3, Figure 3).

Table 1. Comparison of baseline characteristics and sociodemographic variables between intervention and control group.

	Intervention	Control	P-value
N	60	60	
Age, mean ± SD, years	64.6±7.9	66.1±9	0.34
Education, mean ± SD, years	7.8±4.6	7.1±4.3	0.42
Length of disease, mean ± SD, years	3.7±3.2	3.7±3	0.95
Gender female, N (%)	21 (35)	16 (26.7)	0.32
Marital status, N (%)	13 (21.7)	15 (25)	0.66
Single/ Divorced/ Widowed	47 (78.3)	45 (75)	
Married			
Smoking pack-year, mean ± SD, years	23.1±27	23.5±26.4	0.96
NYHA class, N (%)	12 (20)	15 (25)	0.78
I	21 (35)	20 (33.3)	
II	19 (31.7)	15 (25)	
III	8 (13.3)	10 (16.7)	
IV			
Hypertension, N (%)	40 (66.7)	40 (66.7)	1
Diabetes, N (%)	22 (36.7)	21 (35)	0.84
Hyperlipidemia, N (%)	40 (66.7)	34 (56.7)	0.26
Renal failure, N (%)	6 (10)	6 (10)	1

Note: NYHA = New York Heart Association

Table 2. Analysis of readmission rate according to generalized estimating equations (GEE) model.

Variable		Odds Ratio	P-value	Confidence Interval	
				Lower limit	Upper limit
Groups	**Control**	2.21	0.05	0.98	5.01
	Intervention	1			
Time	**2**	0.55	0.55	0.07	3.87
	3	2.32	0.33	0.41	13.2
	4	4.95	0.07	0.87	28.15
	5	2.59	0.30	0.42	15.96
	6	3.23	0.20	0.52	19.94
	7	1.25	0.82	0.17	8.94

Table 3. Analysis of outpatient visits to physicians according to GEE model.

Variable		Odds Ratio	P-value	Confidence Interval	
				Lower limit	Upper limit
Groups	**Control**	0.82	0.31	0.57	1.19
	Intervention	1			
Time	**2**	1.34	0.49	0.57	3.11
	3	2.02	0.08	0.90	4.54
	4	6.41	0.001	3.02	13.6
	5	2.77	0.01	1.26	6.12
	6	1.63	0.25	0.70	3.78
	7	3.10	0.005	1.41	6.78

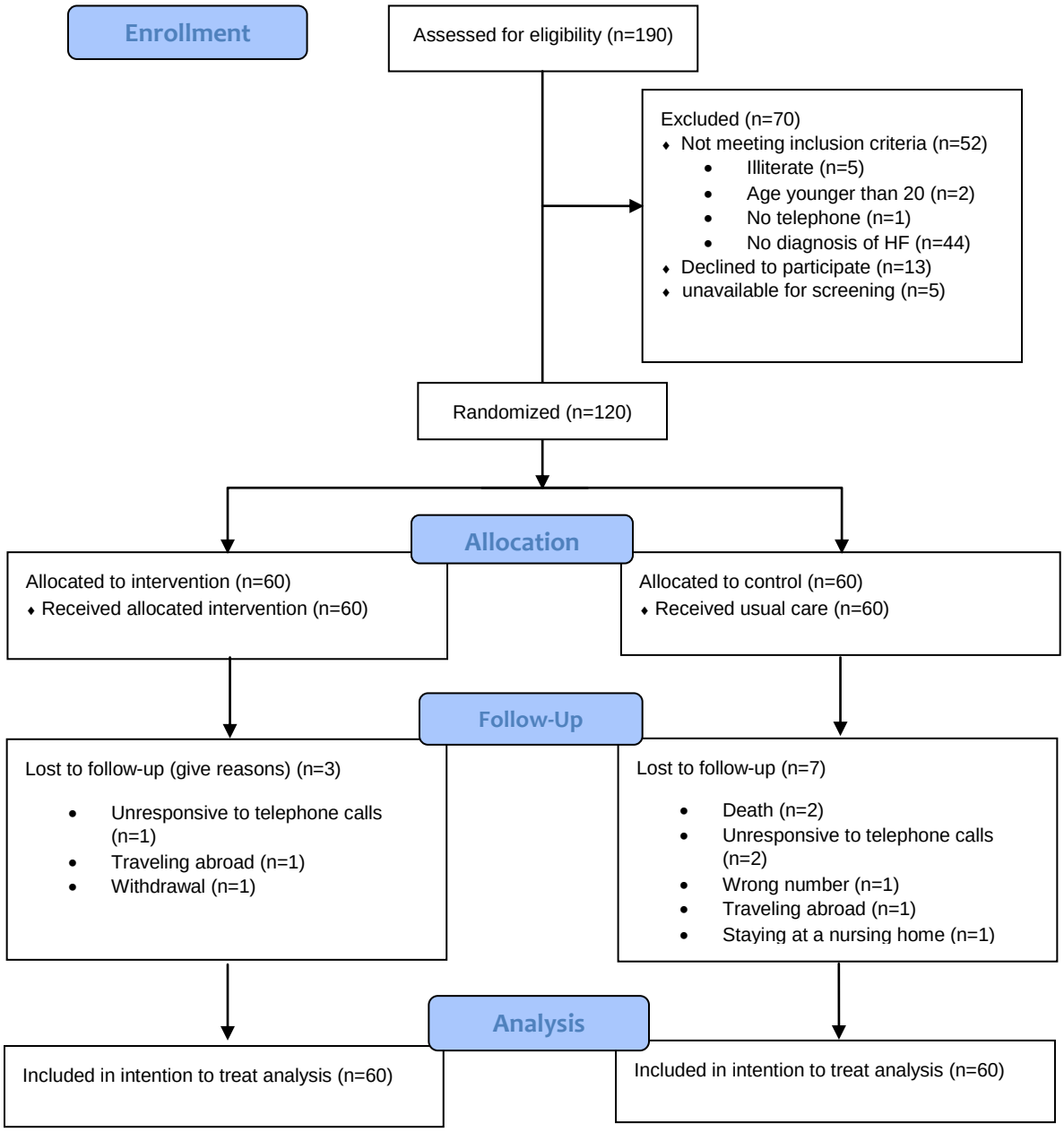

Figure 1. Study Flow Diagram

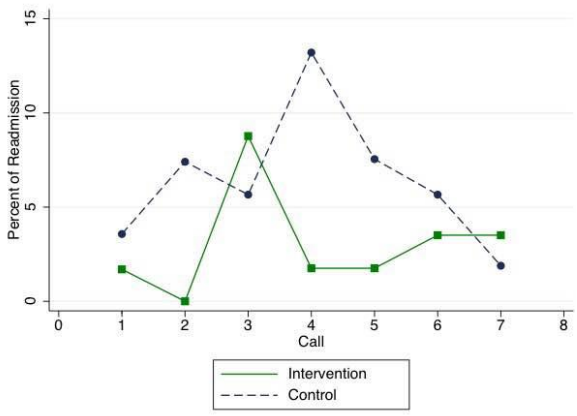

Figure 2. Comparison of readmission between intervention and control group during seven telephone calls.

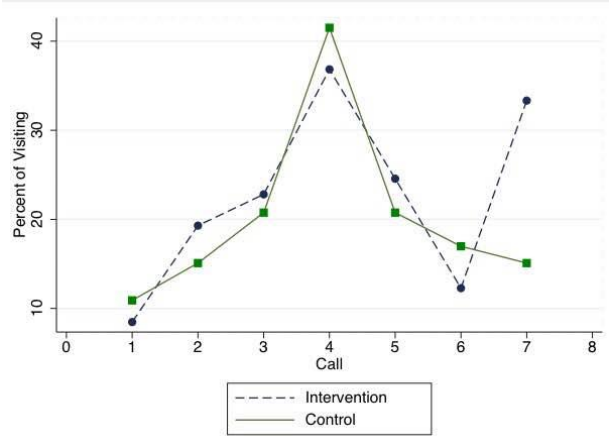

Figure 3. Comparison of outpatient visits to physicians between intervention and control group during seven telephone calls.

DISCUSSION

Since patients encounter numerous problems after discharge (7, 18), this study was conducted to evaluate effects of patient education and 3-months telephone follow-up on readmission rate and outpatient visits to physician. The results demonstrated that the admission rate in intervention group was significantly lower than control group (19.3% vs 38.2%, respectively), and the odds ratio of readmission in control group was 2.21 times more than intervention group. These results were consistent with the study by Hekmatpou et al., the difference was that they had home visits too, but we only performed telephone follow-up (14). The results were also integrated with the research by Shojaee et al., that suggested lower readmission rate with patient education and telephone follow-up (19) . In an article by Ducharme et al., the impact of care at an outpatient clinic compared with standard care among congestive heart failure patients was evaluated and the results showed that 39% of patients in intervention group and 57% of control group required readmission (20).

One possible cause of lower readmission rate in our study was that we recruited NYHA class I-IV heart failure patients in order to evaluate outpatient visits, whereas, class III and IV patients are mostly readmitted (20). A study by Meisinger et al., reported no significant effect of one-year home visits and telephone follow-up on readmission rate, which was not consistent with our results (21). Braun et al., found no significant decrease of readmission after 3-months telephone follow-up, although, the improvement of symptoms in intervention group was significantly more than control group (22).

The results of this study also presented that outpatient visits to physician in intervention group were more than control group, but the difference was not statistically significant. The variable of time was significant at fourth, fifth and seventh telephone calls and the odds ratio of fourth call was higher than the others, which suggests that the patients required a visit to physician were 6.5 times more than whom didn't require a visit, two months after discharge. The most common cause of visits was for treatment follow-up. These results were not compatible with the study by Shojaee et al., that demonstrated fewer visits after telephone follow-up (19).

The association of gender and hospital readmission was significant, so that male patients were more likely to be hospitalized, which was consistent with the study by Harrison et al. (23). There was no correlation between gender and outpatient visits to physician.

The readmission rate of patients with stage I of disease was 12%, stage II was 15%, stage III was 43.3% and stage IV was 58.8%, thus, there was a significant association between stage of disease and hospital readmission. Dahl et al. also reported that the most readmission rate was for patients with stage III and IV of cardiac disease (24). In addition, a correlation between stage of disease and urgent need for visit to a physician was observed, accordingly, stage IV patients required the most visits (68.8%) and stage I patients needed less visits (8%). There was no record of similar results in other studies.

We found no significant difference of adherence to medications between both groups, and there was no article to evaluate such correlation. Although, Heydari et al. reported that non-adherence to medications accounted for 11% of factors contributing to readmission (16).

The other outcomes that we evaluated were the association of diabetes, hypertension, hyperlipidemia and renal failure with readmission rate and outpatient visits to physician between both groups. The results represented that heart failure patients with hypertension and renal failure were more likely to be readmitted in intervention group. In other studies, similar correlation was not described.

Limitations

This study had some limitations. Since we evaluated adherence to medication by oral interviews with the patients, thus, it may have led to a bias in comparing both groups. Moreover, the participants in the study were patients of five different cardiologists and had some slightly different treatment strategies that might have caused an underestimate of intervention benefit. Additionally, two patients in control group visited another hospital and participated in some educational programs that could also lead to another bias. We recommend that the future studies should have larger sample size and longer follow-up time, since it is expected that educational intervention affects more over time. Furthermore, future research should focus on intervention effect on cardiovascular disease progression to higher stages.

Conflicts of Interest

Authors declare no conflicts of interest related to the material in the manuscript.

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