

Education and Telephone Monitoring by Nurses of Patients with Heart Failure: Randomized Clinical Trial

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Abstract

Background: Nursing approaches to manage patients with heart failure (HF) showed benefits in reducing the morbidity and mortality. However, combining intra-hospital education with telephone contact after hospital discharge has been little explored.

Objective: To compare two nursing intervention groups among patients hospitalized due to decompensated HF: the intervention group (IG) received educational nursing intervention during hospitalization followed by telephone monitoring after discharge and the control group (CG) received in-hospital intervention only. Outcomes were levels of HF and self-care knowledge, the frequency of visits to the emergency room, rehospitalizations and deaths in a three-month period.

Methods: Randomized clinical trial. We studied adult HF patients with left ventricle ejection fraction (LVEF) \leq 45% who could be contacted by telephone after discharge. HF awareness was evaluated through a standardized questionnaire that also included questions regarding self-care knowledge, which was answered during the hospitalization period and three months later. For patients in the IG group contacts were made using phone calls and final interviews were conducted in both groups at end of the study.

Results: Forty-eight patients were assigned to the IG and 63 to the CG. Mean age $(63 \pm 13 \text{ years})$ and L (around 29%) were similar in the two groups. Scores for HF and self-care knowledge were similar at baseline. Three months later, both groups showed significantly improved HF awareness and self-care knowledge scores (P<0.001). Other outcomes were similar.

Conclusion: An in-hospital educational nursing intervention benefitted all HF patients in understanding their disease, regardless of telephone contact after discharge. (Arq Bras Cardiol 2011;96(3):233-239)

Keywords: Heart failure; education, nursing; health personnel; clinical trial; telephone/utilization.

Introduction

Although there has been much progress in the treatment of heart failure (HF), it remains a main cause of hospitalizations in several countries and is associated with high morbidity and mortality, high medical care costs, and in particular, an impaired quality of life^{1,2}. The various new approaches to HF care that have been investigated in clinical trials have increased the complexity of the treatment³. Recent meta-analyses have shown that, in addition to optimal pharmacological treatment, the care of HF patients by a multidisciplinary team reduces mortality and rehospitalization rates and improves the quality of life of patients⁴⁻⁶.

Different educational strategies and intensive follow-up care of HF patients provided by nurses have been employed. Randomized studies of nursing interventions that include home visits and systematic telephone contact have shown that these

interventions were effective in preventing rehospitalizations and in reducing costs related to the HF treatment⁷⁻¹⁰.

A North-American study of an intervention that incorporated telephone contact and home visits by an HF-specialized nurse after hospital discharge found that the intervention effectively reduced morbidity and mortality rates⁸. Another study conducted in Latin America by GESICA Investigators⁹, of a telephone intervention performed by trained nurses showed similar results.

However, the evidence for the potential synergistic effect of combining different strategies has not been explored. In particular, combining an intra-hospital educational program followed by telephone contact by nurses after hospital discharge is virtually non-existent. In fact, most of the data related to nurse-provided educational strategies in HF have been derived from studies conducted at outpatient settings^{9,10}.

Thus, we conducted a randomized clinical trial comparing an educational nursing intervention during the hospitalization period followed by telephone contact after hospital discharge to the educational intervention without the telephone monitoring. The outcomes assessed were the level of HF awareness and self-care knowledge, as well as the effect of these strategies on the frequency of visits

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to the emergency room, rehospitalizations and deaths in a three-month period.

Methods

Study population

Patients consecutively admitted with HF from January 2005 to July 2008 were selected at a tertiary university hospital in Porto Alegre, Brazil. A diagnosis of HF was made by the attending team using the Boston diagnosis criteria. The inclusion criteria were patients ≥ 18 years old with HF regardless of the etiology and left ventricle ejection fraction \leq 45%. Only patients who had a telephone number available for after-discharge contact were included. We excluded HF patients who had had an acute myocardial infarction three months prior to hospitalization, those who had undergone myocardial revascularization surgery in the previous month, those with HF secondary to sepsis and patients with cognitive neurological sequelae. The study protocol was approved by the institution's research ethics committee. All individuals signed the Free and Informed Consent prior to enrollment.

Study protocol

One of the authors of this study located potential participants in the study through an active daily search in the hospital wards. Patients considered eligible were included in the study and received the educational nursing intervention during their hospitalization. Patients received at least three, but no more than five visits. The frequency of visits was determined based on the content of the information conveyed and the time needed for the patient to assimilate the advice received. This was done until the patients were discharged from the hospital. At the first visit, the HF and Self-Care Information Questionnaire were administered, followed by an educational session providing comprehensive information on HF, pharmacological treatment and mainly non-pharmacological care. At the end of the first visit, the patients received the HF Patient Manual, which was developed by the institution's HF Group. This visit lasted 45 to 60 minutes on average. A chart was attached to each bed for self-monitoring of weight during the hospitalization period and for use after discharge from hospital. Patients were encouraged to fill out the chart on a daily basis. From the second to the fifth visit, the HF Manual was read aloud with the patients by one of the authors, reinforcing the instructions and questions related to the treatment and self-care were answered. Also, the weight entered in the chart was reviewed with the patient, and the patient was prepared for discharge. Such visits lasted 30 to 40 minutes on average. During all visits, caregivers (relatives, friends) of the patients were invited to listen to the instructions. After discharge from the hospital, patients were randomized to receive systematic telephone contacts for a three-month investigational period (intervention group - IG) or to receive the usual care that consisted of the follow-up of the patient at the return appointment at the outpatient clinic (control group - CG) without any telephone contact.

Intervention group - patients in the IG received telephone calls from the study nurse during a three-month period. One telephone contact per week was performed in the first month, followed by one every 15 days in the second month and one every 15 days in the third month, totaling eight calls per patient. Telephone calls started seven days after the discharge from the hospital, aiming at clarifying and reinforcing instructions received during hospitalization and monitoring signs and symptoms of decompensation and investigating possible visits to the emergency care unit and rehospitalizations. The telephone call was standardized and followed the study protocol. The nurse did not interfere with or change the patients' pharmacological treatment, but recommended seeing the doctor or going to the emergency care unit when there were signs of HF decompensation.

Control group - patients in the CG received the usual care after discharge that consisted of the patient being followed at the return appointment to the outpatient clinic without any phone calls within the three-month period. Similarly to the IG, the patients were asked to come to the hospital at the end of the three-month period to complete the same questionnaires that they responded to at the baseline assessment.

Instruments

HF and self-care information questionnaire

This questionnaire was based on instruments found in the literature and validated by our group and also based on recommendations for instructing and assessing patients, provided by the Council on Cardiovascular Nursing Department of the American Heart Association. These instruments resulted in scores (range 0-10 points) for the two outcomes, which were compared between the two groups¹¹⁻¹⁴.

Studied outcomes

The scores for the levels of HF awareness and knowledge of self-care were considered as primary outcomes. The frequency of visits to the emergency care unit, rehospitalizations and deaths at the end of the three-month period were considered as the secondary outcomes.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation, quartiles and interquartile intervals. Categorical variables are expressed in frequencies and percentages. For quantitative variables, the Student's t-test and Mann-Whitney U were used to analyze differences between groups. For categorical variables, the comparison between groups was performed using the Pearson's chi-square test. The Relative Risk and the Confidence Interval (95%CI) were also calculated. An analysis of variance (ANOVA) was performed for repeated measurements to compare the change in HF awareness score between the groups. The comparison of the Kaplan-Meier curves depicting the time to the first event was performed using the Log-rank test. A bivariate P-value < 0.05 was considered statistically significant for all analyses. All data were analyzed with the Statistical Package for the Social Sciences 15.0.

Results

Studied population

Between January 2006 and July 2008, 334 potentially eligible patients were admitted with decompensated HF. Among them, 214 were excluded because of the presence of at least one exclusion criterion. Initially, 120 patients were randomized for the study, with 57 in the IG (with telephone contact) and 63 in the CG (no telephone contact). After randomization, 9 patients were excluded from the IG for the reasons shown in Figure 1. In total, 48 patients received the intervention. During the study period, there were 6 deaths in the IG and 13 deaths in the CG. At the end of the study, 87 patients completed the study protocol, of which 40 were from the IG and 47 from the CG.

Characteristics of the population

The study included 48 patients with decompensated HF in the IG and 63 patients in the CG. The left ventricle ejection fraction was similar in both groups, as well as the distribution of HF etiologies. Other clinical characteristics of the patients are presented in Table 1.

Primary outcomes

Level of HF awareness and self-care knowledge

At the end of the study, improvement was observed in the level of HF awareness and self-care knowledge from baseline (Figure 2). Based on the 111 included patients, the mean score (points) in the baseline period was 4.6 \pm 1.9 for the IG and 4.5 \pm 1.9 for the CG. Three months later, both groups had significantly improved from baseline regarding the HF awareness score (P <

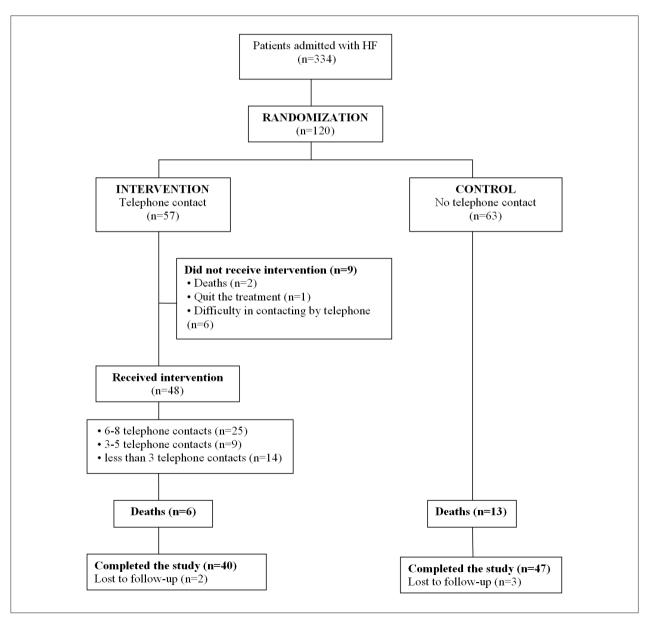


Figure 1 - Study diagram representation.

Table 1 - Characteristics of the population

Characteristics	All (n=111)	Intervention group (n=48)	Control group (n=63)	Р
Age (years)	63 ± 13	62 ± 12	63 ± 13	0.91 *
Sex (male)	64 (68)	32 (67)	32 (51)	0.14 §
Caucasian	90 (81)	38 (79)	52 (82)	0.84 §
School education (years)	4 (1-8)	4.5 (0.25-7)	4.0 (1-8)	0.87 [‡]
Body mass index (kg/m²)	26 ± 5	26 ± 5	27 ± 6	0.28 *
Occupation (retired)	75 (68)	29 (60)	46 (73)	0.23 §
Left ventricle ejection fraction (%)	29 ± 8	29 ± 8	29 ± 9	0.76 *
Specific activities scale				0.53 §
Specific activities scale II	3 (3)	1 (2)	2 (3)	
Specific activities scale III	65 (58)	31 (65)	34 (54)	
Specific activities scale IV	43 (39)	16 (33)	27 (43)	
Etiology				0.22 §
Ischemic	35 (31)	13 (27)	22 (35)	
Hypertensive	33 (30)	12 (25)	21 (33)	
Other	43 (39)	23 (48)	20 (32)	
Systolic arterial pressure (mmHg)	124 ± 23	121 ± 24	126 ± 22	0.26 *
Diastolic arterial pressure (mmHg)	78 ±17	76 ± 16	79 ± 18	0.38 *

Values expressed as mean ± standard deviation, n (%) or mean (percentile 25; percentile 75). Student's t-test, *Mann-Whitney U test, *Pearson's chi-square test.

0.001). There were no statistically significant differences between the two groups (6.1 \pm 2.1 *versus* 5.8 \pm 1.9, P=0.41).

Secondary outcomes

Visits to the emergency room, re-hospitalizations and deaths

Although not statistically significant, there was a difference in the occurrence of clinical events (visits to the emergency room, rehospitalizations and deaths) between the two groups, as shown in Table 2. The IG had 34% less visits to the emergency care unit than the CG. Similarly, we observed that patients from the IG were 39% less likely to die. All these data were collected from electronic medical records, and where information was not available, patients were directly contacted.

Concerning rehospitalization or death within the three-month period, the IG had a non-significant 10% less frequent rate of rehospitalization or death due to all causes (combined outcomes) when compared to the CG (P=0.74). Similarly, the IG had a 4%

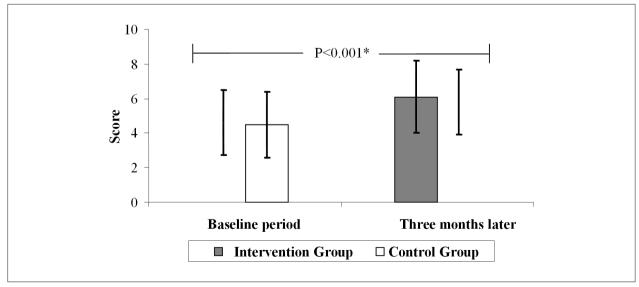


Figure 2 - HF and self-care scores. *P-value of the comparison of the baseline period scores versus the scores obtained three months later.

Table 2 - Clinical events including rehospitalization or death in the three-month period (combined outcomes)

Clinical events	Intervention group (n=48)	Control group (n=63)	RR (CI 95%)	P §
Clinical events				
Visits to the emergency room	4 (8)	8 (13)	0.66 (0.21 to 2.05)	0.67
Re-hospitalizations	20 (42)	23 (37)	1.14 (0.72 to 1.82)	0.72
Deaths	6 (13)	13 (21)	0.61 (0.25 to 1.48)	0.38
Rehospitalization or death				
Rehospitalization or death due to all causes	22 (46)	32 (51)	0.90 (0.61 to 1.34)	0.74
Rehospitalization or death caused by HF	11 (23)	14 (22)	1.03 (0.52 to 2.07)	0.99
Rehospitalization or death caused by HF or other cardiovascular diseases	16 (33)	22 (35)	0.96 (0.57 to 1.61)	0.99

Values expressed as n (%). § Pearson's chi-square test. RR - relative risk; CI - confidence interval.

reduction in rehospitalization or death caused by HF or other cardiovascular diseases (P = 0.99) (combined outcomes).

The time to the occurrence of the first event (visit to the emergency room, rehospitalization or death) was 21 (9.5 - 55) days for all patients. For patients in the IG, it took longer for the occurrence of the first event, when compared to the patients in the CG (26 (10.75 - 43.75) versus 19 (6.25 - 60.50) days, respectively), although this difference was not statistically significant (P = 0.56) (Figure 3). The probability of a clinical event occurring within 90 days after discharge was around 50% for both groups.

Discussion

The results of this study showed that there was no significant difference in the level of HF awareness and self-care knowledge

between patients in the IG who received an educational nursing intervention during the hospitalization period followed by telephone contact after the hospital discharge and control patients who only received the in-hospital intervention without the telephone monitoring post-discharge. In addition, there were no significant differences in the frequency of visits to the emergency room, rehospitalization and death in the three-month period between the groups.

Our study showed that both groups improved from baseline in their level of HF awareness and self-care knowledge after the three-month period of the study regardless of telephone contacts after discharge. Overall, our data suggested that the period of hospitalization may be the best time to begin a health education program and this has also been suggested by previous studies of patients with HF¹⁵. In this context, the nurse

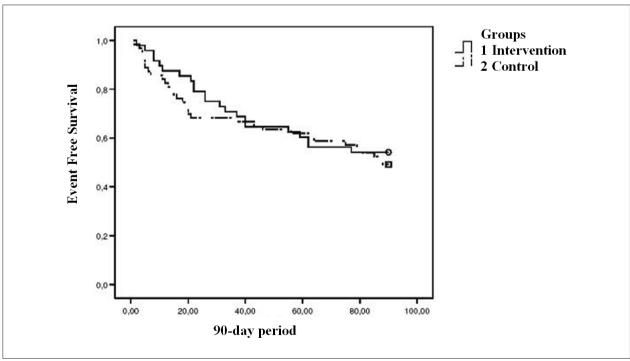


Figure 3 - Kaplan-Meier curve: time to the occurrence of the first event.

plays an essential role in educating patients about important aspects of their self-care such as medications and in taking the time to provide explanations and answer common questions of patients and caregivers¹⁶.

A North-American study, which was published in 2002 and conducted by Artinian et al¹², evaluated similar variables and it also found that overall, the HF patients had limited HF knowledge. In this sample, those who had previously received instructions on HF had higher scores on HF knowledge, but they made up only 12% of the patients¹². Another European study, which was published in 2005 and conducted by Lainscak et al14, also evaluated patients' HF knowledge through a guestionnaire and found that the patients who received the usual treatment without any follow-up at the HF clinic had reduced mean knowledge scores¹⁴. In our study, after the three-month period, both groups of patients improved their knowledge score. Although previous studies have used different evaluation instruments, they suggest a similar message: HF education and self-care instructions seem to be important allies in patients' treatments.

Telephone monitoring is one of the strategies employed to promote the continuity of the treatment provided during the hospitalization period¹⁷. However, in the present study, the combination of post-discharge telephone monitoring and the intra-hospital education failed to be more effective than the intra-hospital education alone, which was different from other positive results published in the literature^{7-9,17}. Our study was different in that our patients had more severe disease (mean ejection fraction of $29 \pm 8\%$) and a shorter period of followup, which might have limited the ability to assess changes in the subjects' understanding of disease-related aspects and their lifestyle.

Finally, the frequencies of visits to the emergency room, re-hospitalizations and death in the three-month period were similar in both groups. The results from this randomized clinical trial are comparable to those recently published by our group in a cohort study¹⁸. In order to describe the non-pharmacological treatment of HF patients hospitalized in our institution, 283 hospitalizations of 239 patients were evaluated. In this study, we showed that although education improved patients' knowledge of HF and self-care, these changes were not sufficient to reduce rehospitalizations and probably did not lead to greater treatment adherence¹⁸. Similar results were also reported in a recent North-American study¹⁹. However, the three-month period of the study may have been relatively short for patients to make the necessary changes in their lifestyle to help stabilize their clinical conditions. New habits are difficult to incorporate into the daily routine, which also may have contributed to these results. Recent data from a study conducted in Brazil of outpatients submitted to a systematic/repeated program and monitoring by telephone showed a 54% improvement in compliance with the program and overall reductions in death or unplanned hospitalizations.

Study limitations

Some study limitations should be addressed. First, some patients could not be located at the beginning of the intervention and after the three-month period due to wrong telephone numbers, changed numbers or blocked telephone calls. The second limitation is related to our patients' specific social and economic statuses and cultural norms. Unlike some other international studies, our population may not have been prepared for this type of telephone contact monitoring approach. Finally, the three-month period of the study is perhaps too short for the patients to change their health habits and behaviors to the extent that could reduce the frequency of visits to the emergency care unit, rehospitalizations and deaths.

Conclusions

Our results show that the educational nursing intervention performed during the hospitalization period brought about improved knowledge of HF and self-care in all patients, regardless of any telephone contact after their discharge from the hospital. There was no difference in the frequency of visits to the emergency room, rehospitalizations and deaths in the three-month period between the intervention and control groups.

Our data indicate that it is useful to implement education strategies and early hospital discharge planning during the hospitalization period. Given that the combination of these educational strategies were tested for the first time in this study, we suggest that further studies should be conducted in order to evaluate and test different methods of monitoring and following patients with HF after discharge from hospital.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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