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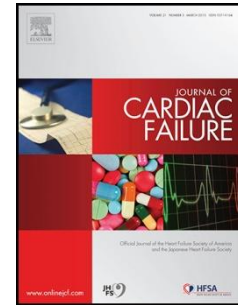
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Results of a Hospital Based Palliative- Care Intervention for Patients with an Acute Exacerbation of Chronic Heart Failure

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Abstract

Background: Palliative interventions are an important part of advanced heart failure (HF) care. However, these interventions are historically underutilized, particularly by African Americans.

Methods and Results: We performed a prospective, randomized intervention trial in patients with advanced HF who were hospitalized for acute decompensation at three urban hospitals, comparing the effect of palliative care consultation (PCC) with usual care. The primary end-point was the proportion choosing comfort oriented care (hospice and/or DNR) between three and six months post-randomization. A total of 85 patients (91.8% African American; mean age 68 years) were enrolled over a two-year period. Four of the 43 (9.3%) patients randomized to the PCC group chose comfort oriented care, versus 0 of the 42 control group members (risk difference=9.3%; 95% confidence interval = -11.8% to 30.0%).

Conclusions: In this predominantly African American cohort of hospitalized patients with advanced HF, PCC did not lead to a greater likelihood of comfort care election compared with usual care. More robust palliative interventions should be developed to meet the needs of diverse groups of patients with HF.

Key words: Palliative Care, Heart Failure, African American, Hospice

Introduction

This study investigated whether initiation of hospital-based palliative care consultation (PCC) for patients with advanced HF admitted for acute an episode of acute decompensation was associated with greater election of comfort care measures (1-3).

Methods

Research Design

This was a prospective, open-label behavioral intervention pilot trial of PCC versus usual care in patients with advanced HF who were hospitalized for an acute HF exacerbation at one of three hospitals in a predominantly African American urban community.

Study Population/Inclusion-Exclusion Criteria

Participants had an admission diagnosis of acute HF (ICD-9 Codes and sub-codes associated with: 425, 428), a one-year mortality risk of $\geq 33\%$ based on EFFECT score; (4) and/or NYHA class III or IV (5). Exclusion criteria included cognitive impairment, a life limiting non-HF illness, acute severe psychiatric illness other than major depression, symptoms too severe for study consent, anticipated cardiac transplantation, or an attending physician who rejected the need for PCC.

Enrollment and Randomization Procedure

Patients were screened using computer-generated lists of diagnoses and charts were reviewed for inclusion/exclusion criteria. After written informed consent was obtained, baseline questionnaires were completed, and randomization to either PCC or control groups was conducted.

The PCC team included a physician and advanced nurse practitioner. Other professionals (chaplains and social workers) participated as requested. Clinical interviews assessed for uncontrolled, distressing symptoms, goals of care, advance care planning, code status, and desired post-treatment residential setting. All PCC patients had at least one palliative care consult, with the opportunity for additional meetings as desired.

Study Outcomes

The primary outcome assessed between 3 and 6 months was a dichotomous (election vs. non-election) measure of comfort-oriented care, which included : (1) outpatient hospice, (2) inpatient hospice, (3) a DNR order during the index or a subsequent hospitalization, or (4) a DNR order at home or at a nursing home, as assessed via telephone interviews and medical records.

Sample Size and Analysis Plan

The study was powered to detect a moderate to large effect of at least 20% absolute group differences in palliative outcomes (24% PCC vs. 4% control) A sample size of 88 has 80% power to detecting the pre-specified 20% proportion difference with a significance, or alpha, of 0.05 ($p=0.05$).

Baseline variables were compared between groups using chi-square or Fisher's exact test for categorical data and t-tests for ordinal and interval data. Baseline data included patient demographics, health-related quality of life (McGill QOL Score) (6, 7), patient satisfaction (Rand PSQ) (8), and EFFECT mortality risk score (4). The difference in the proportion of patients meeting the primary outcome for PCC and control groups, and associated 95% confidence intervals were calculated using the exact unconditional confidence limits for the risk difference.

Results

Quantitative Data

At total of 85 patients were recruited over 22 months (September 2006-June 2008). The sample was 48.2 % female, and 91.8% African American, with a mean (SD) age of 67.5 (12.0) years. Mean (SD) LVEF was 38.8 (16.7); 81.2% were on beta blockers, and 66.3% were on either angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) at baseline. Among those with LVEF < 35% (n=32 [37.6%]), slightly more than half (56.3%) had an implantable cardioverter-defibrillator (ICD), or a cardiac resynchronization therapy defibrillator (CRT-D) device. There were no significant differences in these or other baseline variables by treatment group (Table).

Primary Outcome

Between three and six months, 4 of 43 (9.3%) patients in the PCC group had met the primary end-point compared to 0 of 42 (0.0%) controls (difference = 9.3%, 95% CI -11.8% to 30.0%; $p=0.12$). Three of the four patients PCC group had a DNR. Two elected hospice care, one of whom signed out of hospice care after just a few days.

Overall, 19 of 80 patients (23.8%) died between 3 and 6 months post randomization with no difference by group (11 PCC and 8 control; $p=0.47$). Non-significant differences were found in EFFECT scores by decedent status (decedents: mean=114.8, SD=21.1; non-decedents: mean=106.7, SD=19.0; $t=-1.6$, $p=0.12$).

Qualitative Data

Clinical records were qualitatively reviewed to determine reasons for not electing a palliative approach. Some patients explicitly expressed concerns that comfort choices might prevent receiving more aggressive disease-targeted care. Many were unwilling to

talk about advance directives. One patient asked the nurse practitioner to leave the room after she attempted to ask about advanced care choices. Another patient recounted electing DNR status during a prior hospitalization and feeling that doctors simply watched as she got more and more short of breath, instead of providing interventions. She reported revoking her DNR, choosing “to just bring it on,” meaning to engage in attempts at treating HF. Another patient revoked inpatient hospice after several days due to a perception that nurses were sometimes reluctant to provide scheduled opiates. These views are consistent with studies documenting stronger choices for aggressive end of life care rather than comfort care among African Americans (9, 10).

Discussion

This study was conducted for a cohort of predominantly African American patients with advanced HF who were admitted to two urban hospitals with acute decompensation. The primary outcome of the intervention was the election of late stage palliative options such as hospice and DNR orders. This intervention was not effective in terms of increasing these palliative related outcomes compared to controls. Reasons cited for not choosing hospice care or DNR status included concerns that such elections might preclude receiving aggressive disease-targeted care. These findings are consistent with prior work noting stronger choices for aggressive end of life care, and reluctance to elect hospice and DNR status among African Americans (9, 10). Our study findings (Table 1), indicate that only 66.3% of study participants across both study arms were on ACEI or ARB treatment, and that slightly over half(56.3%) of those with EF < 35% were on ICD or CRT-D devices. This finding suggests that not all of the patients were optimally treated, and that there is a need for greater guideline-driven treatment toward the goal of increasing comfort by improving

symptom control. Notably, some patients enrolled in the study had NYHA class III heart failure. For such patients, in the absence of other life limiting comorbidities, an early stage palliative care approach that combines a focus on symptom control and disease control would likely receive higher acceptance. Symptom alleviation and enhanced longevity through appropriate treatment is perhaps a more useful strategy for this subgroup.

This study targeted persons with a one-year mortality risk of $\geq 33\%$. In future studies, targeting persons with late stage disease ($> 50\%$ risk scores) may result in greater interest in hospice election. However, many patients with even very advanced HF have a history of multiple “successfully” treated relapses, contributing to future decisional uncertainty, and a wish not to forgo resuscitation. More qualitative research from an empathetic, patient-focused, and communication enhancing perspective is needed to help determine needs and preferences among African Americans with advanced HF (11).

This study had several limitations. First, the small sample size was only powered to find moderate to large effects rather than the small group differences actually observed in the palliative endpoint. Second, demographic and health data were not collected on those who refused consent, and such persons may differ from participants on key demographic and health factors. Third, it should be noted that our PCC team was largely Caucasian and served a primarily African American population (12). Future studies should consider ensuring a more racially/ethnically diverse composition among palliative care team members, enhancing the cultural competency of non-diverse teams, and explicitly examine the possible impact of team racial composition on palliative outcomes. Finally, the palliative care team did not have all designated team members, as recommended by The Joint Commission, in all four core palliative care disciplines. Social workers (13) and chaplains (14) play a vital role on

palliative care teams, and should be included in HF palliative care planning and treatment.

Conclusion

This study did not find a significant relationship between a PCC intervention and the election of hospice care and DNR status. Potential issues that warrant further exploration include the importance of palliative care knowledge, health care mistrust, and the role of advance care planning among historically underserved African American patients. As suggested by our qualitative data, to be most effective palliative approaches should be a incorporated into existing advanced HF disease management programs, and include a focus on addressing and relieving symptoms, assurance of aggressive symptom resolution as well as a discussion of disease modifying options (15)

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Author Disclosure Statement

The authors disclose that no competing financial interests exist.

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Table: Baseline Characteristics

Variables	Total Sample (n=85)	PCC Group (n=43)	Control Group (n=42)	<i>P</i>
Demographics				
Age	67.5 (12.0)	67.0 (11.0)	68.0 (13.0)	0.71
Gender				
Female	41 (48.2%)	17 (39.5%)	24 (57.1%)	0.10
Male	44 (51.8%)	26 (60.5%)	18 (42.9%)	
Race				
African American	78 (91.8%)	39 (90.7%)	39 (92.9%)	1.00
Other	7 (8.2%)	4 (9.3%)	3 (7.1%)	
Health Status				
EFFECT Mortality Risk Score	108.5 (19.6)	109.3(19.9)	107.7 (19.6)	0.70
Clinical Parameters ¹				
LVEF % : Mean (SD)	38.8 (16.7)	39.4 (16.7)	38.1 (16.8)	0.71
% on Beta Blockers	69 (81.2%)	38 (86.4%)	31 (75.6%)	0.20
% on ACEI or ARB	55 (66.3%)	28 (66.7%)	27 (65.9%)	0.94
% EF < 35% + on ICD or CRT-D	18 (56.3%)	11 (64.7%)	7 (46.7%)	0.30
Quality of Life (QOL)				
QOL-Physical	3.6 (2.3)	3.4 (2.4)	3.8(2.3)	0.51
QOL-Psychological	5.9 (3.3)	5.6 (3.4)	6.1 (3.3)	0.46
QOL-Support	8.1 (2.6)	8.2 (2.5)	7.9 (2.8)	0.60
Patient Satisfaction				
Satisfaction-General	3.4 (0.9)	3.4 (0.8)	3.4 (0.9)	0.85
Satisfaction-technical Quality	3.5 (0.5)	3.6 (0.6)	3.5 (0.5)	0.37
Satisfaction- interpersonal Manner	3.8 (0.6)	3.8 (0.6)	3.7 (0.6)	0.31
Satisfaction-Communication	3.5 (0.8)	3.5(0.9)	3.5 (0.7)	0.84
Satisfaction-Financial Aspects	3.5 (0.7)	3.4 (0.8)	3.6 (0.6)	0.18
Satisfaction-Time with Doctor	3.5(0.8)	3.5 (0.9)	3.4 (0.8)	0.64
Satisfaction-Access and Convenience	3.5 (0.6)	3.6 (0.6)	3.4 (0.6)	0.14

¹ Sample sizes for clinical parameters: EF (n=81); Beta Blockers (n=85); ACEI or ARB (n=83)