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Prolonged impact of home versus clinic-based management of chronic heart failure: Extended follow-up of a pragmatic, multicentre randomized trial cohort

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ABSTRACT

Objectives: We compared the longer-term impact of the two most commonly applied forms of post-discharge management designed to minimize recurrent hospitalization and prolong survival in typically older patients with chronic heart failure (CHF).
Methods: We followed a multi-center randomized controlled trial cohort of Australian patients hospitalized with CHF and initially allocated to home-based or specialized CHF clinic-based intervention for 1368 ± 216 days. Blinded endpoints included event-free survival from all-cause emergency hospitalization or death, all-cause mortality and rate of all-cause hospitalization and stay.
Results: 280 patients (73% male, aged 71 ± 14 years and 73% left ventricular systolic dysfunction) were initially randomized to home-based (n = 143) or clinic-based (n = 137) intervention. During extended follow-up (complete for 274 patients), 1139 all-cause hospitalizations (7477 days of hospital stay) and 121 (43.2%) deaths occurred. There was no difference in the primary endpoint; 20 (14.0%) home-based versus 13 (7.4%) clinic-based patients remained event-free (adjusted HR 0.89, 95% CI 0.70 to 1.15; p = 0.378). Significantly fewer home-based (51/143, 35.7%) than clinic-based intervention (71/137, 51.8%) patients died (adjusted HR 0.62, 95% CI 0.42 to 0.90: p = 0.012). Home-based versus clinic-based intervention patients accumulated 592 and 547 all-cause hospitalizations (p = 0.087) associated with 3067 (median 4.0, IQR 2.0 to 6.8) versus 4410 (6.0, IQR 3.0 to 12.0) days of hospital stay (p < 0.01 for rate and duration of hospital stay).
Conclusions: Relative to clinic-based intervention, home-based intervention was not associated with prolonged event-free survival. Home-based intervention was, however, associated with significantly fewer all-cause deaths and significantly fewer days of hospital stay in the longer-term.
Trial registration: Australian New Zealand Clinical Trials Registry number 12607000069459 (http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=81803)

1. Introduction

Since the mid-to-late 1990s [1–4] chronic heart failure management programs [CHF-MPs] have revolutionized the post-discharge management of the syndrome. Most CHF-MPs are nurse-led but multidisciplinary in application. Randomized trials comparing

Abbreviations: CHF-MPs, chronic heart failure management programs; LVSD, left ventricular systolic dysfunction; LVEF, left ventricular ejection fraction.

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these to usual care typically included older individuals with complex co-morbidity, a relatively equal gender-balance and those with preserved systolic function in whom evidence-based treatments are scarce [5]. A meta-analysis of published trials confirmed significant reductions in all-cause readmissions and prolonged survival relative to usual care [6]. Multidisciplinary CHF-MPs now form part of gold-standard care of the syndrome [7,8]. Translation into clinical practice, however, has not been easy. Contemporary debate has focused on essential components of care and mechanisms of benefit [9] including the role of home visits as part of a transitional care approach to post-discharge management [10]. Building on compelling data that a face-to-face approach to CHF management is superior to that delivered remotely [11], there are potential advantages in applying home visits to provide a more comprehensive profile of the individual, identifying physical and socio-cultural factors that influence health outcomes and developing a more personal therapeutic relationship [12]. A home-based, nurse-led program of care was the basis for the first randomized trial of any form of CHF-MP to report prolonged all-cause survival and reduced readmissions relative to usual care [3]. In the Which Intervention Is most cost-effective and Consumer friendly in reducing heart failure Hospital stay (WHICH?) Trial we prospectively tested whether a home-based intervention was superior to the same principles of CHF management but applied via a specialist outpatient clinic intervention [13]. This head-to-head, multicentre randomized study showed that there was no difference in the primary composite endpoint of event-free survival from an all-cause, unplanned hospitalization or death during initial 12–18 month follow-up. However, home-based intervention was associated with significantly reduced all-cause hospital stay and health care costs accompanied by a non-significant trend toward prolonged survival [14].

2 . Study hypothesis

Based on our initial findings and previous studies of the prolonged benefits of a home-based approach [15,16], we hypothesized that during extended follow-up (minimum 3 years) we would observe the following: 1) no difference between the two groups with respect to event-free survival from all-cause death or recurrent unplanned hospitalization (our initial primary endpoint); 2) a significant difference in all-cause mortality in favor of home-based intervention (tested in the null form) and; 3) given potentially competing trends in survival and recurrent hospitalization, no group differences in the number of recurrent hospitalization and associated length of stay.

3 . Methods

The study design and primary end-point analyses at 12–18 month follow-up of the WHICH? Trial have been previously reported [13,14]. This was a multi-center randomized controlled trial, undertaken in 3 Australian tertiary hospitals, with blinded endpoint acquisition and adjudication that adhered to guidelines for pragmatic studies [17]. Conforming to the principles outlined in the Declaration of Helsinki, approval for the original and extended follow-up components of the study was provided by relevant ethics committees for each site.

3.1 . Study cohort

Of 688 eligible hospitalized patients with CHF, 280 patients admitted to participating centers were randomized according to the following eligibility criteria: i) aged ≥ 18 years, ii) discharged to home with a cardiologist-confirmed diagnosis of CHF, iii) persistent mild to severe symptoms (NYHA II–IV) and iv) a history of≥1 admission for acute heart failure in the past 12 months (including the index admission).

3.2 . Group allocation

Prior to hospital discharge, a blinded, computer-based protocol was used to randomly allocate 143 and 137 patients, respectively into the home-based or clinic-based intervention groups. Block randomization for each site was applied with stratification for the presence or absence of left ventricular systolic dysfunction (LVSD — defined as a left ventricular ejection fraction [LVEF] of≤45%).

3.3 . Follow-up

Recruitment for this study commenced in June 2008 and was initially completed in March 2010. All study endpoint data were collected from the date of discharge from the index hospitalization to the initial census date of March 31st 2011. A total of 181/211 (86%) surviving patients underwent a standardized home or clinic-based (according to group assignment) study visit at 12–18 months. An extended census date for outcome data on March 31st 2013 was then applied (three participants in each group were lost during extended follow-up and data were censored at last known contact date). The same methods were used to compile data on: i) mortality (all-cause), ii) all-cause, unplanned hospitalization (characterized by admission via the hospital's emergency department and requiring acute treatment) and related hospital stay, iii) all forms of hospitalization and related hospital stay and iv) those hospitalizations where CHF or any other form of cardiovascular disease was the primary discharge diagnosis.

3.4 . Study endpoints

The same major endpoints (with blinded adjudication) as initially reported [12] were examined on a longer-term basis. The composite primary end-point was event-free survival to a first recorded, unplanned hospitalization or death (both all-cause). The component endpoints of all-cause mortality and unplanned hospitalization in addition to the hospital parameters outlined above were examined both in absolute terms and with adjustment for survival status.

3.5 . Post-discharge management

The Australian health care system provides universal health care for the population including public hospital inpatient, outpatient and emergency care with minimal costs to patients (capped for those with chronic disease) for pharmacotherapy and community care. The same gold-standard components of multidisciplinary CHF management [7,8] were applied across the three sites and irrespective of group allocation over an initial period of 12 months. Both arms of the study were essentially nurse-led (two teams at each site) with tertiary qualified nurses with post-graduate qualifications in cardiac care and experience in CHF management. As outlined in Appendix I, the key point of differentiation was the mode of delivery. The clinic-based intervention group received ongoing management via a specialist, multi-disciplinary clinic and no home visits were applied. Alternatively, the home intervention group was predominantly managed via an out-reach program of home visits by a specialist CHF nurse with close liaison with the patient's family physician and referral to other health care services as required. This approach did not preclude home-based intervention patients attending a cardiology outpatient clinic.