Lessons learned from a multidisciplinary heart failure clinic for older women: a randomised controlled trial

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Abstract

Background: many heart failure disease management programs are primarily conducted in the male population. An approach incorporating disciplines such as physiotherapy, occupational therapy, social work, dietary and pharmacy in a standardized clinical pathway merits further investigation in older women with HF.

Methods: in this randomized controlled trial, female patients in the intervention group received the multidisciplinary clinical pathway consisting of a series of 12 visits over a 6-week period in an outpatient clinic.

Results: ninety-one community dwelling female patients aged 63 to 89 were randomized. Comparison of change between the two groups from baseline in the Minnesota Living with Heart Failure Questionnaire score did not show a difference (P<0.470). There was also no difference between the two groups in functional outcome as measured by change from baseline by the Physical Self-Maintenance Scale (P<0.321). The treatment group had significantly more hospitalizations, and cardiologist visits during the study period (P < 0.0001).

Conclusion: It is feasible to conduct a randomized study in a frail community-based older female population and to test a complex multidisciplinary pathway. Future studies should provide insight into the optimal intensity and duration of heart failure management programs with optimal targeting.

Keywords: multidisciplinary, chronic heart failure, older women, frailty, elderly

Introduction

In the past few decades, chronic heart failure (CHF), principally a cardio-geriatric syndrome, has become a major illness for older adults [1, 2]. More than 400,000 Canadian are affected by heart failure, and over 50,000 new cases are diagnosed each year [3].

Women constitute a larger proportion of older individuals; however, women have been historically under-represented in cardiovascular research [4]. Women have a unique risk-factor profile and difference in clinical manifestations of heart failure symptoms in comparison to men [5, 6]. For example, a gender difference in LV remodelling is responsible for the preponderance of LV diastolic over systolic dysfunction in older women. Both hypertension and diabetes are stronger risk factors for CHF for women, whereas prior myocardial infarction is a more important risk factor for men [7]. In addition, women present with a wider range of symptoms, are more likely to delay seeking medical care, and are less likely to be investigated and treated with evidence-based medications and therapies in comparison to men [8, 9].

Two recent meta-analyses have demonstrated that multidisciplinary heart failure disease management programs, primarily in a male population, resulted in reduction of hospitalisation and unplanned admission rates in addition to improved knowledge of the patient about CHF [10, 11]. However, gender-specific data on functional capacity and quality of life remain inconclusive. A recent survey
demonstrated variability in the approach to outpatient management of CHF employed among members of the Canadian CHF Clinics Network [12]. An enhanced approach routinely incorporating disciplines such as physiotherapy, occupational therapy, social work, dietary and pharmacy in a standardised clinical pathway merits further investigation, particularly in older women with heart failure.

Hypothesis

We hypothesised that a structured multidisciplinary clinical pathway, a blueprint of the patient care processes, can result in better outcomes in older women with CHF (e.g. quality of life, and functional capacity) in comparison to the less structured usual care approach that is offered.

The primary outcome measure for the study was the Minnesota Living with Heart Failure Questionnaire (MLHQF) [13]. The secondary outcome measures included the MOS 36-Item Short-Form Health Survey (SF-36) [14], the Folstein Mini-Mental State Examination (MMSE) [15], the 15-item Geriatric Depression Scale (GDS) [16], the Physical Self-maintenance Scale (PSMS) [17], and survival and health service utilisation over 6 months.

Methods

The study design was a randomised controlled trial (RCT). Patients referred from the Ottawa Hospital and the community were diagnosed with CHF based on clinical presentation, abnormal chest x-ray and confirmation of the diagnosis by the treating physician. Patients were screened by the clinic coordinator to ensure that they met the eligibility criteria. The inclusion criteria included English or French speaking patients with CHF who resided in the Ottawa–Carleton region, and were deemed medically stable and capable of engaging in the exercise program. The exclusion criteria included those with significant cognitive impairment (MMSE score <20), NYHA class IV, or at a palliative stage of care. The clinic coordinator provided information about the study and obtained written informed consent. Family caregivers were identified by the consenting participants. This study received approval from the Research Ethics Board of The Ottawa Hospital.

Following recruitment, patients were randomly assigned (via computer-generated randomisation) to either usual care (control group), or the clinical pathway program (treatment group). Once randomised, the intervention arm individuals met with the interdisciplinary team. The treatment group received optimal medical care as the control group plus the clinical interdisciplinary intervention pathway. The intervention consisted of a series of 12 visits over a period of 6 weeks to optimise medical care, and to engage in an exercise program with strong educational, counselling and dietary management, involving physician, nursing, dietary, physiotherapy, pharmacy, occupational therapy and social work input (please see Appendix 1 ‘The Intervention Clinical Pathway planned visits with designated disciplines’ available on the journal website http://www.ageing.oxfordjournals.org/). To optimise the impact of the pathway, we incorporated the ‘Partners in Care’ for CHF recommendations as a teaching tool [18]. The multidisciplinary interventions were partly chosen based on this teaching tool as well as on consensus from the experts in their respective allied health fields. A prior national survey of the CHF clinics in Canada failed to demonstrate a consistent approach to clinic care, therefore, we arbitrarily chose a 6 week intervention of bi-weekly visits [12].

Data was collected, by an assessor, blinded from both treatment and control groups at four points in time: in a pre-visit telephone call (T0), at the first visit (T1), after 6 weeks duration of a treatment cycle (T2), and after 6 months follow-up (T3). Only the clinic coordinator was aware of the patients’ randomisation status. Data-entry personnel were also blinded to group assignment.

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Statistical analysis

Initially, the planned sample size was 100 participants in each group. This would have provided 90% power to detect a 5.45-point improvement in the SF-36 PCS (Physical Component Summary) with \( P < 0.05 \) and anticipating a 25% dropout rate. Unfortunately, due to poor recruitment and limited resources it was not possible to recruit 200 participants. The default sample size was 48 participants in each group, which provided adequate power (0.80) to detect a 24.42-point difference in the MLHQF score giving an effect size of 0.58. This reduced sample size remains comparable to previously published CHF studies [10]. The MLHQF asks each person to indicate, using a 6-point (0–5) Likert scale, how much each of the 21 facets prevented them from living as they desired (total 105 points). A clinically meaningful change is felt to be approximately five points or greater [19].

Analysis of continuous variables (SF-36, MLHQF, MMSE, GDS, and PSMS) was performed by calculating the change in these scores between the initial assessment and after 6–8 weeks (i.e. the length of a cycle for the treatment group). The two groups were compared using the Student’s \( t \)-test (two-tailed) with respect to changes in these continuous measures. The McNemar’s test was used for the discordant pairs in comparing medications before and after trial between two groups. Results were analysed via an intent-to-treat approach (i.e. employing last observation carried forward for dropouts) as well as an analysis of those who completed the test (i.e. excluding drop outs).

Results

Ninety-one patients were enrolled in this study. The group characteristics are shown in Table 1. Randomisation
appears to have been partially successful in balancing the characteristics of the two groups. The groups were similar with respect to baseline age, NYHA class, MMSE, GDS, MLHFQ and PSMS. Presence of co-morbidities such as strokes, depression, hypertension, DM, past MI, angina, atrial fibrillation, coronary artery bypass graft, current smoker, and chronic obstructive airway disease were similar between two groups.

There was no difference in MMSE or GDS scores between the two groups by the end of the 6-week cycle. Comparison of change from baseline MLHFQ score, including physical and emotional components, did not show a difference ($P<0.470$). There was also no difference between the two groups in functional outcome as measured by change from baseline PSMS score ($P<0.321$).

Based on the report from patients and their caregivers, the 6 months' patients' outcomes post-intervention follow-up is presented in Table 2. While not statistically significant, the treatment group had a tendency to more ER visits (for all reasons and for CHF) and hospitalisations, and more Family MD visits. These visits were mainly due to other medical problems rather than CHF symptoms. These included visits to the Family MD for non-cardiac pain, flu, fatigue, sciatica, pneumonia, epistaxis and deep vein thrombosis. There was a significant difference between the two groups in the number of cardiologist visits during the study period ($P<0.0001$). The treatment group had 38 visits and control group had 17 visits.

In the general measures of quality of life, a positive pre-post-difference in SF-36 indicates deterioration, while a negative pre-post-difference indicates improvement. An independent group's $t$-test on the pre-post-differences (change scores) was statistically non-significant, but there was a trend demonstrating that the treatment group deteriorated more than the control group.

Please see the Table Appendix 2 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/. This table presents the cardiac medications before and after the treatment cycle between the two groups. Drug therapy with other cardiac medications was similar between the two groups. While not achieving statistical significance, there were two deaths in the control group and none in the treatment group. No significant changes in results were uncovered when dropouts (seven in control group) were excluded.

### Discussion

There are a variety of CHF management strategies in the literature to improve health outcomes, mainly in men, and many with positive results [10, 20–23].

Negative trials are as important as positive trials in sorting out the factors that determine intervention effectiveness. What differentiates interventions that improve outcomes from those that do not? Wagner argues that the most logical explanations fall into three categories: target population, quality of usual care and program design [24]. We will expand upon Wagner's classification scheme while maintaining the emphasis on problems particular to the treatment of CHF, as per Figure 1.

In a true negative trial, the treatment or management approach is less effective. In false negative results, several key questions such as target population (i.e. which patients derive the greatest benefit) can be discussed. For example, Riegel and colleagues reported that their generally ineffective CHF disease management intervention was most effective among...

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### Table 1. Baseline patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Treatment group</th>
<th>Control group</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>45</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td><strong>Mean age</strong></td>
<td>74.20 (range 63–88)</td>
<td>75.79 (range 63–89)</td>
<td>0.304</td>
</tr>
<tr>
<td><strong>Baseline MMSE</strong></td>
<td>28.18 (range 21–30)</td>
<td>28.47 (range 20–30)</td>
<td>0.527</td>
</tr>
<tr>
<td><strong>Baseline GDS</strong></td>
<td>3.64 (range 0–13)</td>
<td>3.40 (range 0–10)</td>
<td>0.673</td>
</tr>
<tr>
<td><strong>Baseline MLHFQ</strong></td>
<td>28.66 (range 0–69)</td>
<td>23.99 (range 3–51)</td>
<td>0.158</td>
</tr>
<tr>
<td><strong>Baseline PSMS scale</strong></td>
<td>6.91 (range 6–10)</td>
<td>7.02 (range 6–13)</td>
<td>0.720</td>
</tr>
<tr>
<td><strong>Number of patients seen by a cardiologist prior to study</strong></td>
<td>35</td>
<td>35</td>
<td>0.3664</td>
</tr>
<tr>
<td><strong>NYHA I</strong></td>
<td>11</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td><strong>NYHA II</strong></td>
<td>19</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td><strong>NYHA III</strong></td>
<td>14</td>
<td>11</td>
<td>0.736</td>
</tr>
<tr>
<td><strong>NYHA IV</strong></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>NYHA class missing</strong></td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2. Patient outcomes—6 months' post-intervention

<table>
<thead>
<tr>
<th></th>
<th>Treatment group</th>
<th>Control group</th>
<th>Difference between groups</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality</strong></td>
<td>0</td>
<td>2</td>
<td></td>
<td>0.218</td>
</tr>
<tr>
<td><strong>Mean # ER visits</strong></td>
<td>0.64</td>
<td>0.24</td>
<td>0.4</td>
<td>0.108</td>
</tr>
<tr>
<td><strong>Mean # hospitalisations</strong></td>
<td>0.36</td>
<td>0.05</td>
<td>0.31</td>
<td>0.081</td>
</tr>
<tr>
<td><strong>Mean # hospitalisations for CHF symptoms</strong></td>
<td>0.48</td>
<td>0.08</td>
<td>−0.051</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Mean # MD visits</strong></td>
<td>4.77</td>
<td>3.35</td>
<td>1.42</td>
<td>0.018</td>
</tr>
<tr>
<td><strong>Mean # MD visits for CHF symptoms</strong></td>
<td>0.27</td>
<td>0.41</td>
<td>−0.14</td>
<td>0.608</td>
</tr>
<tr>
<td><strong>Mean # cardiologist visits</strong></td>
<td>1.05</td>
<td>0.57</td>
<td>0.478</td>
<td>0.057</td>
</tr>
<tr>
<td><strong>Visit cardiologist during study</strong></td>
<td>38</td>
<td>17</td>
<td>$&lt;0.0001$</td>
<td></td>
</tr>
<tr>
<td><strong>Lost to follow-up</strong></td>
<td>0</td>
<td>7</td>
<td></td>
<td></td>
</tr>
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</table>
Interpretations of Negative Trials in CHF

- True Negative
- False Negative
  - Suboptimal Target Population
    - Time since hospitalization
    - CHF class
    - Age/gender
  - High Quality of Usual Care in Control Group
    - A ceiling effect
    - Hawthorne effect
  - Suboptimal Program Design
    - Inadequate intensity and duration
  - Poor Study Design
    - Inadequate sample size
    - Variability in attendance
    - Poor randomization
    - Team instability

Figure 1. Interpretations of negative trials in CHF.

patients in NYHA class II [25]. In our study, only about 40% of patients were in class II. In a negative trial by Laramee and colleagues, disease management improved only one subgroup, i.e. patients cared for by local cardiologists who had established relationships with the nurse care manager [26].

Perhaps, acuity of the case (time since last hospitalisation) was an important feature for recruitment. In our study we had a mix of recently discharged patients and those from the community. The quality of standard of care in the community in which research is conducted is very important in the outcome of the study [27]. The high quality of care in the control group in our community may have left little opportunity for improvement.

In the interpretation of negative outcomes, researchers have wondered about the Hawthorne effect in the control group negating the potential positive effects of disease management services in the intervention group. Just being notified that a patient was in a CHF trial possibly could have motivated the family physicians and cardiologists in our study to enhance their usual CHF management or increase use of multidisciplinary team members effectively reproducing elements of the intervention. Other factors to consider include: quality of our program design such as, inadequate intensity or duration of the intervention, inadequate sample size and the high level of variance in attendance in the treatment group (i.e. not everybody had 12 sessions). There were three patients who had missed more than three visits, and as well partially completed three or more visits.

We experienced challenges in recruiting the population of older women with CHF who often are frail and lack resources, such as transportation, to commit themselves to a program such as this. A multi-centre recruitment trial may be needed to achieve the desired sample size. The other issue was stability and duration of multidisciplinary team membership. It is possible that new members (employing new models of care) require more time to learn and to work together in order to mature as a team and to optimise the benefits of the multidisciplinary team approach. In our study, this problem was magnified by difficulties in retaining part-time clinical multidisciplinary staff as they were often attracted to more lucrative permanent or full time positions elsewhere.

The baseline quality-of-life domains in our patients, at least for the Minnesota Scale, indicates rather mild heart failure which may be rather difficult to improve with any program. The important observation was that, over 6 months, patients in the treatment group were more likely to seek medical help, and in particular, more likely to be hospitalised for heart failure. It may be they receive more medical attention and appropriate therapy and investigation. Indeed, this is the hypothesis for why more intense health surveillance reduces mortality in trials of heart failure as shown in a recent meta-analyses that heart failure programmes may have a larger impact on mortality rather than on hospitalisation [28]. An intervention that increases the rate of hospitalisation but reduces mortality should be seen as a valuable and effective intervention.

**Conclusion**

Our study demonstrates that it is feasible to conduct a randomised study in a frail community-based older female population, and to test a complex multidisciplinary pathway. As it is highlighted by Rich, ongoing and future studies should provide further insight into several key questions, including the optimal intensity and duration of heart failure management programs, and which patients derive the greatest benefit (i.e. targeting) [29]. Are such interventions cost-effective during long-term follow-up, and how best can the results of clinical trials be translated into routine gender-based patient care? In addition, adherence to heart failure medication and self-efficacy needs to be measured. Such research should strive to avoid the causes of false negative studies listed in Figure 1 with particular emphasis on larger sample sizes as well as better targeting practices.
N. Azad et al.

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Key points

- Older women constitute a larger proportion of older individuals with HF, but they have been under-represented in cardiovascular research.
- Women present with a wider range of HF symptoms, are more likely to delay seeking medical care, and are less likely to be investigated and treated with evidence-based medications and therapies in comparison to men.
- Multidisciplinary HF management programs, primarily tested in male populations, resulted in the reduction of hospitalisation and unplanned admission rates, in addition to improved knowledge of the patient about HF.
- In the interpretation of negative multidisciplinary intervention trials in HF, false negative results may be as a result of sub-optimal target population recruitment, high quality of usual care offered in control group, sub-optimal intervention program or poor study design.
- Our study demonstrates that it is feasible to conduct a randomised study in a frail community-based women population of older HF patients, and to test a complex multidisciplinary management pathway.

Conflicts of interest declaration

The authors declare that there are no conflicts of interest.

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Supplementary data

Supplementary data for this article are available online at http://ageing.oxfordjournals.org.

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Multidisc CHF clinic for older women: RCT