A prospective feasibility study to compare patient reported outcomes, health service utilisation and place of care/death between patients with advanced heart failure attending a palliative cardiology clinic and a control group of those receiving usual care.

THE SYMPTOMS, QUALITY OF LIFE AND PLACE OF CARE STUDY

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Report prepared by

Miriam J Johnson

MD, FRCP, MBChB(hons). Wolfson Palliative Care Research Centre, Hull York Medical School, University of Hull, Hull, UK

Paula McSkimming

BSc (Hons) Statistics, Robertson Centre for Biostatistics, Institute of Health and Wellbeing, University of Glasgow, UK

Alex McConnachie

PhD, Robertson Centre for Biostatistics, Institute of Health and Wellbeing, University of Glasgow, UK

Claudia Geue

PhD, Lecturer, Health Economics & Health Technology Assessment, Institute of Health & Wellbeing, University of Glasgow, UK

Zahidul Quayyum

BSS (Hons), MA, MSc, PhD. Health Economics & Health Technology Assessment, Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

Yvonne Millerick

MSc, BSc, PgCert, RGN, Heart Failure Palliative Care Nurse Consultant, Glasgow Caledonian University Glasgow, British Heart Foundation , NHS, Greater Glasgow & Clyde.

Karen Hogg

MD FRCP. Consultant Cardiologist and honorary clinical lecturer, Glasgow University, Glasgow, UK

SUMMARY REPORT

Background

People with advanced heart failure (HF) have palliative care needs which are similar in nature and quantity to people with cancer, experienced often over a longer period of time and with poorer access to supportive and palliative care services. Despite policy changes, access to palliative care remains inadequate. Although trials demonstrate benefit for patients allocated to specialist palliative care in addition to usual HF care, it is not known whether cardiology-led, palliative care integrated, models of care are effective in terms of patient-report symptoms, health-related quality of life (HRQoL) or health service use and costs.

Methods

A prospective feasibility exploratory cohort study with measures at baseline, 2 and 4 months using two groups: one study (patients attending a comprehensive cardiac and generalist palliative assessment and management service – Caring Together Group [CTG]) and one unmatched convenience comparator from the local heart failure liaison service (Usual Care Group [UCG]. Participants could opt to provide 2 monthly follow up measures until the last recruit had completed 4 months. All participants in the CTG had been seen at least once in the CT clinic at the time of enrolment.
Eligible participants were consenting patients with HF (LVSD or non-LVSD) and persistent limiting symptoms, and their carers. Study outcomes included: symptoms, HRQoL, performance status, understanding of disease, evidence of anticipatory care planning (ACP), health service utilisation and survival. Feasibility study outcomes included; recruitment, retention, data quality, variability of measures and sample size estimation.

Results

77 participants (53% men; mean age 77, range 33 to 100) were recruited between 8th April and 18th December 2015; 43 to CTG and 34 to UCG. The average duration of attendance at the CT clinic prior to enrolment was 8 months.

At baseline, fewer CTG participants had HF with reduced ejection fraction compared with the UCG (50% *vs* 97%). CTG patients had worse NYHA class, were more symptomatic and had worse quality of life but had fewer hospital admissions in the preceding 6 months (47.1% UCG *vs* 32.6% CTG). The overwhelming majority had documented evidence of ACP compared with few in the UCG ($p<0.001$) and had a better understanding of their condition (Likert scale; $p =0.04$). Both groups were on optimal cardiac treatment. Participants with follow up data were older, less symptomatic, had better quality of life and health status.

During follow up, symptoms and quality of life improved in both groups and by 4 months, the change from baseline was greater in the UCG even when adjusted for baseline differences although, in the repeated measures model, there were no statistically significant between group differences. Caregiver burden improved in both groups, to a greater extent in the UCG,

but this was not statistically significant and numbers were small. Documentation of ACP and understanding of the condition remained better in the CTG. Unprompted free comments were made to the research nurse from both groups. CTG participants commented favourably on the continuity of care and planning between hospital and community. Conversely those from the UCG commented on the fragmentation of care and dissatisfaction of "seeing a different doctor at clinic every time".

There was no statistically significant difference in survival between the two groups.

Overall, the average costs to the NHS were lower for the patients in the CTG (£785 cost saving per patient; £645 if adjusted for baseline cost differences). CTG participants had fewer nights in hospital, fewer nurse contacts and lower drug costs, but more GP and out-patient contacts than those in the UCG. Cost savings are likely to be an underestimate given the length of time CTG patients had been attending clinic at baseline, reflected in the smaller proportion of CTG patients with preceding admissions at baseline. Due to the small sample size the uncertainty around the findings is too great to draw definitive conclusions and must be seen as exploratory.

The screen/consent ratio was higher in the UCG than the CTG (1: 2.8 *vs* 1:1.7) and the attrition greater at 4 months (29% *vs* 25%). Attrition was mainly due to death or deterioration. Data quality was good, although from 6 months.

Estimated sample sizes for a subsequent phase III trial are given including, i) 176 (252 allowing for 30% attrition) total participants to detect a change in 10.5 points in the KCCQ-12 and ii) 141 (202 with 30% attrition) to detect a 1 point clinically important change in ESAS shortness of breath (80% power, 0.05 alpha).

Conclusions

This exploratory study shows that a trial in people with advanced HF, to investigate the cost-effectiveness of a cardiology-driven palliative care service using patient-report data as a primary outcome is feasible in terms of recruitment and data quality. These exploratory data provide preliminary evidence that the CT intervention is cost-effective and that CT participants spent fewer nights in hospital. Symptoms and HRQoL improved in both groups. Despite optimally tolerated cardiac treatment, patients in both groups had moderately severe levels of tiredness and shortness of breath, which were strongly related to HRQoL. A future trial should recruit from usual community care, and any intervention should include the CT components of care. In particular, the intervention should be able to help the cardiology team identify and manage basic palliative care needs, and identify those who need referral to specialist palliative care.

Summary findings

- At baseline, compared with the UCG, CTG participants had: worse symptom burden, poorer HRQoL, worse NYHA class, much higher proportion of those with HFpEF, better understanding of disease, evidence of anticipatory care planning in nearly all and fewer hospital admissions.
- Despite being on optimally tolerated cardiac treatment, all participants had significant symptoms, especially that of tiredness and shortness of breath which were on average moderately severe. These symptoms were most closely related to HRQoL.
- All participants had improved symptoms and HRQoL at 4 months, but improvement appeared to be greatest in the UCG. This was statistically significant in the 4 month change from baseline comparison, but in the repeated measures model, adjusting for baseline demographics and individual symptoms, there was no statistically significant difference in HRQoL or health status over time between the two groups at each time point.
- CTG participants had fewer nights in hospital both at baseline and during follow up
- There was an average cost saving of £785 per patient in the CTG (£645 if adjusted for baseline differences in costs) despite the CT model deliberating aiming to increase use of the multi-disciplinary team.

These data provide evidence to support a hypothesis that the CT clinic, despite a population of people with advanced, symptomatic HF, and an emphasis on MDT working, improves symptoms, HRQoL, allows individual patient planning and reduces hospital admissions and health care costs.

Further study is needed