Phase 2 randomised controlled trial of future care planning in patients with advanced heart disease

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Introduction/Aims & Methods

- Patients with advanced heart disease typically have a poor prognosis. They rarely receive coordinated holistic assessment and future care planning and tend to have limited access to palliative care services.
- The FLAME trial explored the use of a future care planning intervention with patients and families following a recent unscheduled hospital admission with acute coronary syndrome (ACS) or heart failure (HF). Similar methodologies have been used to develop complex palliative care interventions for other non-cancer illnesses1-6.
- We explored whether such a complex intervention is acceptable to patients, their carers and health professionals, and if it is a practical, deliverable and feasible extension to discharge planning from hospital.
- Patients with an estimated 12 month mortality risk of 20% or greater were randomised to either early (on discharge) or delayed (after 12 weeks) intervention.
- The intervention combined 3 elements: a ‘Thinking Ahead’ booklet, a holistic needs assessment meeting with a cardiologist and cardiologist specialist nurse aimed at developing a shared future care plan, and follow-up by a specialist nurse to support care in the community.
- Primary outcome was quality of life of patients and carers, assessed using validated questionnaires.

Screened Population

We screened 408 patients admitted to hospital with ACS or HF. From this group, we recruited 50 patients with an estimated mortality risk of 20% or greater within the next 12 months, using the GRACE or EFFECT scores.

The 359 patients who were screened but not subsequently enrolled into the trial, were kept in a registry. The reasons for exclusion are detailed below:

<table>
<thead>
<tr>
<th>Screened</th>
<th>408</th>
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<tbody>
<tr>
<td>Eligible</td>
<td>310</td>
</tr>
<tr>
<td>Ineligible</td>
<td>245</td>
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<tr>
<td>Excluded</td>
<td>100</td>
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<tr>
<td>Enrolled</td>
<td>50</td>
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Recruitment and Eligibility

50 patients were enrolled into the study following an unscheduled admission with acute coronary syndrome or heart failure:
- Heart Failure: 34/50 (68%)
- Coronary Heart Disease: 11/50 (22%)
- Valvular Heart Disease: 5/50 (10%)
- 30 were male and 20 female; their average age was 81.

These were older people, often with multimorbidity. A Canadian Frailty Score was recorded for screened patients. Most enrolled patients were mildly or moderately frail compared with those in the registry who were less disabled. Many excluded patients who were too frail to participate.

Conclusion

This pilot, randomised trial demonstrated that an early identification and future care planning intervention for people with advanced heart disease was safe and acceptable. The trial design and outcome measures were feasible and deliverable. A larger clinical trial can now be planned.

Acknowledgements & References


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