Complexity of program and clinical outcomes of heart failure disease management incorporating specialist nurse-led heart failure clinics: a meta-regression analysis  
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CRD summary
A meta-analysis to determine the benefits of specialist nurse-led heart failure (HF) interventions in comparison with usual care found that hospital usage and HF readmissions were lower in patients offered interventions that included discharge planning, but there was no effect on all-cause mortality and quality of life. The authors' conclusions appear optimistic given the evidence presented. There were several limitations in the review methodology which render the results potentially unreliable.

Authors' objectives
To determine the relationship between the complexity of heart failure (HF) management protocols involving specialist nurse-led HF clinics and the effectiveness of these interventions.

Searching
Electronic searches of MEDLINE (1966 to November 2004), EMBASE (1980 to November 2004) and the Cochrane Library (Controlled Trials Register, Database of Systematic Reviews and the EPOC Register; all years) were conducted. In addition, the bibliographies of retrieved articles were searched manually and experts were contacted. The search was limited to papers published in English. The MeSH and text terms used were listed in the review.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) that involved at least 100 patients were eligible for inclusion.

Specific interventions included in the review
Studies that assessed protocols for HF management that used specialist nurse-led HF clinics were eligible for inclusion. The included studies assessed a variety of protocols, details of which were in the review; all involved post-discharge HF education, medication counselling and review, and telephone follow-up. The included studies compared the assessed protocols with usual care, which was not always defined. The duration of treatment ranged from 3 to 12 months.

Participants included in the review
No inclusion criteria for the participants were stated. In the included studies, the mean age was 73 years (range: 62 to 79) and mean left ventricular ejection fraction (LVEF) was 34% (range: 27 to 41). The mean proportion of male patients was 58% (range: 52 to 66). Co-morbidities and medication use were reported as mean percentages of patients with ranges.

Outcomes assessed in the review
Studies in which hospital readmission was reported as a primary outcome were eligible for inclusion. The outcomes reported in the review were hospital readmission (all and HF readmission), the number of hospital days used, all-cause mortality, quality of life (QOL) and medical costs. QOL was measured in the individual studies using one of the following three instruments: Nottingham Health Profile, the Minnesota Living with Heart Failure Questionnaire and the Heart Failure Self Care Behaviour Scale.

How were decisions on the relevance of primary studies made?
Two authors assessed the relevance of studies without the use of masking. The authors did not describe how disagreements were resolved.
Assessment of study quality
Studies were assessed using the Jadad score, based on the following criteria: randomisation, randomisation generation, allocation concealment, double blinding, and loss to follow-up. Two authors assessed the validity of the studies without the use of masking. The authors did not describe how disagreements were resolved.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

The complexity of the intervention was assessed for each study using qualitative methods, but no further details of these methods were given. Relative risks (RRs) and 95% confidence interval (CIs) were calculated on an intention-to-treat basis. The mean number of hospital days used was also extracted, along with the standard deviation. Missing variance was imputed based on the mean number of hospital days per patient within strata defined by intervention complexity.

Methods of synthesis
How were the studies combined?
Summary RRs were computed using both fixed-effect (Mantel-Haenszel) and random-effects (DerSimonian and Laird) models, weighting by inverse variance. Publication bias was assessed using Begg's test. Descriptive statistics were used to summarise data for QOL and medical costs. Differences between the intervention and control groups in mean QOL and medical costs were assessed using t-tests; both weighted (by sample size) and unweighted analyses were performed. QOL was standardised to the percentage improvement or decline in comparison with the baseline QOL. The costs were reported in US$, adjusted for inflation using the 2004 Consumer Price Index.

How were differences between studies investigated?
Statistical heterogeneity was investigated using a chi-squared test. Subgroup analyses were conducted based on predefined groups: age; LVEF less than 35% versus at least 35%; and angiotensin-converting enzyme (ACE) inhibitor use of more than 75% versus less than or equal to 75% use at baseline. Analyses were also stratified to include interventions with and without discharge planning. A meta-regression was used to assess the effect of the complexity of the intervention on the outcomes.

Results of the review
Six RCTs involving 949 patients were included. The secondary outcomes were based on fewer than 6 studies. Two studies (288 participants) used more complex interventions, while 4 studies (661 participants) used less complex interventions.

The studies had a median Jadad score of 4 out of 5 (range: 3 to 4) for study quality.

There was no evidence of publication bias for the outcomes of hospital readmission or number of hospital days used. No results of the test for publication bias were reported for other outcomes.

Overall, the interventions did not affect hospital readmission rates in comparison with usual care. No effect on readmission rate was observed for any level of protocol complexity. Interventions that included discharge planning reduced HF readmissions (compared with usual care) to a greater extent than those that did not: RR 0.09 (95% CI: 0.10, 0.65) versus RR 0.65 (95% CI: 0.43, 1.00).

Interventions that incorporated discharge planning slightly reduced the number of hospital days used during follow-up (0.26 fewer days, 95% CI: 0.02, 0.49), whereas those that did not had no effect.

Overall, the interventions did not affect all-cause mortality in comparison with usual care. No effect on all-cause mortality was observed for any level of protocol complexity. There was also no effect of the interventions on the combined outcome of mortality and hospitalisation.

QOL improved for patients offered the intervention and usual care, but there was no difference in QOL between the
two groups. The QOL data used in the review were incomplete.

Subgroup analyses.

There were no differences in the results for hospital readmission rates or number of hospital days used according to the patient’s age or percentage LVEF. All-cause mortality was reduced by the intervention (compared with usual care) in studies with ACE inhibitor use of more than 75% (RR 0.59, 95% CI: 0.40, 0.86), but there was no effect of the intervention on all-cause mortality in those studies with suboptimal ACE inhibitor use.

Cost information

Cost data were only available for the 2 studies that used protocols incorporating discharge planning. In these studies, the potential saving associated with using the HF management intervention was US$277.88 per patient per month, but this was not statistically significantly different from the provision of usual care.

Authors’ conclusions

Specialist nurse-led HF clinics are a promising strategy for patients with HF. The benefit of these programmes may be optimised by a homogeneous structure and consistency in delivery of the components of the programmes.

CRD commentary

The research question of this review seemed vague. Although the authors set out to investigate the effect of the complexity of interventions on the outcomes, the definition of 'complexity' was not stated a priori. The review largely addressed whether or not nurse-led HF clinics are effective relative to usual care. The impact of complexity was only minimally addressed using subgroup analyses of protocols that included discharge planning versus those that did not (i.e. only one component of complexity was considered. The authors mentioned the use of meta-regression analyses to investigate the impact of complexity, but no such analyses were reported.

Inclusion and exclusion criteria for study design were clear. The authors searched a range of relevant sources, however, it is possible that some relevant trials were omitted since their search strategy was limited to English language papers and they made no specific attempts to locate unpublished studies. The methods used to select studies, assess the studies for validity, and extract the data were not described in sufficient detail. Some efforts to reduce errors and bias in the review process (duplicate data extraction) appear to have been made. Although study quality was assessed, the findings were not considered in the context of study quality.

Relevant details of the participants in the individual studies were provided. The appropriateness of pooling is unclear: data both with and without statistically significant heterogeneity were pooled, heterogeneity statistics were not reported for all pooled groups, and the application of fixed-effect or random-effects models was unclear. Relevant subgroup analyses were conducted. There are several concerns regarding the statistical methodology of this review. Although the authors stated that they used meta-regression, no results from this type of analyses were given in the paper. In addition, no statistical tests comparing outcomes for studies with more complex versus less complex interventions were described. Since the included studies had differing lengths of follow-up, it seems inappropriate to compare numbers of days of hospital stay during follow-up across different studies.

The authors’ conclusions appear optimistic since only protocols incorporating discharge planning showed any indication of a statistically significant benefit; this was for only two outcome measures (HF readmissions and hospital days used) and was based upon data from only 2 studies. Since only protocols that included discharge planning appeared to produce significant effects, it might be argued that the review in fact measures the effect of discharge planning rather than the effect of post-discharge, nurse-led clinics.

Implications of the review for practice and research

Practice: The authors stated that specialist nurse-led HF clinics may benefit carefully selected patients.

Research: The authors stated that further research is needed to identify which patient subgroups would benefit most...
from complex specialist nurse-led HF clinics; to determine which intervention components are most effective; and to determine the minimal intensity of these HF clinics that would be most cost-effective.

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