Randomized trial of an education and support intervention to prevent readmission of patients with heart failure


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A targeted education and support intervention to prevent readmission was examined in patients with heart failure (HF). The intervention comprised five sequential care domains for chronic illness. These included patient knowledge of the illness, the relationship between medication and illness, the relationship between health behaviours and illness, knowledge of early signs and symptoms of decompensation, and where and when to obtain assistance. An initial face-to-face interview was followed by a telemonitoring phase to assess the patients' understanding of the domains. Also, to reinforce the educational foundation by empowering patients and offering strategies to improve their compliance.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients aged 50 years or over who met the clinical criteria for presence of HF. These included a diagnosis of HF on admission or radiological signs of HF on the admission chest X-ray, and additional symptom and sign criteria. The additional were based on a modification of the National Health and Nutrition Examination Survey I study and the criteria of Schocken et al. and Harlan et al. The study excluded patients transferred from other hospitals or admitted from nursing homes, patients with HF secondary to high-output states or noncardiac diseases, and patients with terminal illnesses in addition to HF.

Setting
The setting was a hospital. The economic study was conducted in the Yale-New Haven hospital (YNHH), Connecticut, USA.

Dates to which data relate
The effectiveness and resource use data were gathered from October 1997 to September 1998. The price year was not stated.

Source of effectiveness data
The effectiveness data were gathered from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same group of patients as that used in the effectiveness study.
Study sample
Power calculations were reported. The study was powered to detect a 40% relative reduction in the total rate of readmission or death in the intervention group. This assumed a 75% rate of death or readmission for the control group. A total of 390 patients were screened from October 1997 to September 1998. Among them, 248 (63.6%) were not eligible due to at least one exclusion criterion. An additional 54 patients (13.6%) were eligible but, for a variety of reasons, were not enrolled. The final 88 patients included in the study were randomly allocated to either the intervention group (n=44) or the control group (n=44). The median age of the patients was 74 years, 57% were men and 74% were Caucasian. The two groups were well balanced with respect to most characteristics, although the intervention group was slightly older, had a lower rate of prior coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty and acute myocardial infarction, and used less calcium-channel blockers and beta-blockers.

Study design
The study was a prospective, randomised trial that was conducted in a single centre. The method of randomisation was not reported and it was unclear whether blinding took place. The duration of follow-up was one year. No loss to follow-up was reported.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes were readmission, with cause classified by a clinician blinded to the treatment allocation, or death. The secondary end points included the number of all-cause, HF and HF-related readmissions, or other cardiovascular disease (CVD)-related readmissions. The two groups were compared using Mantel-Haenszel chi-squared, relative risks (RR) and log-rank tests. Sub-group analyses, stratified by cause of readmission, and analyses of outcomes adjusted for early mortality were conducted. A Cox proportional-hazards model was used to assess readmission-free survival. Adjustments for clinical and demographic characteristics were made.

Effectiveness results
For the primary outcome of readmission or death, 25 patients (56.8%) in the intervention group and 36 patients (81.8%) in the control group had at least one readmission or died during the follow-up (RR 0.69; 95% confidence interval, CI: 0.52 - 0.92, p=0.01).

There was a 39% reduction in all-cause readmissions in the intervention group compared with the control group. There were 49 in the intervention group versus 80 in the control group, (p=0.06).

Twenty-two patients (50.0%) in the intervention group and 35 patients (79.6%) in the control group experienced HF or other CVD readmission or death (RR 0.63, 95% CI: 0.46 - 0.86, p=0.004).

After adjusting for clinical and demographic characteristics, the intervention group had a significantly lower risk of all-cause readmission or death (hazard ratio, HR, 0.56, 95% CI: 0.32 - 0.96, p=0.03) in comparison with the control group. The intervention group also had a lower risk of HF or other CVD readmission or death (HR 0.51, 95% CI: 0.29 - 0.90, p=0.02), and a lower risk of HF readmission or death (HR 0.52, 95% CI: 0.28 - 0.98, p=0.04).

Clinical conclusions
A formal education and support intervention substantially reduced adverse clinical outcomes.

Measure of benefits used in the economic analysis
The authors did not develop a summary benefit measure. A cost-consequences analysis was therefore conducted.

Direct costs
The direct costs were for readmission and the intervention, including nursing and social work time. Outpatient costs
were not included, nor were the costs associated with start-up, research and monitoring. Discounting was not relevant since the costs were incurred in less than one year. The unit costs and the quantities were not reported, except for the intervention (an hourly rate of $50). Only the mean costs were reported. The Transition Accounting System was used to calculate the YNHH readmission costs. For rehospitalisation outside of the YNHH, the costs were calculated using an equation derived from a prospective cohort of patients with HF at the YNHH, the lengths of stay and cost-to-charge ratios from billing information.

Statistical analysis of costs
A statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The hospital readmission costs were lower in the intervention group by an average of $7,515 per patient, (p=0.02). The costs were $21,935 in the control group and $14,420 in the intervention group.

During the one-year follow-up, the overall cost of care was $6,958 less in the intervention group when taking into consideration the average cost of the study intervention.

Synthesis of costs and benefits
The authors did not produce a summary measure that combined the costs and effectiveness. The intervention was presented as the dominant strategy in terms of lower adverse clinical outcomes and lower costs.

Authors' conclusions
A formal education and support intervention substantially reduced adverse clinical outcomes and costs for patients with heart failure (HF).

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator (no intervention) was clear. The patients assigned to the control group received usual care, as ordered by their physician. You should decide if this represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The estimate of effectiveness is likely to be internally valid, given that a randomised controlled trial was used. However, no details on the method of randomisation were reported. In addition, it was unclear whether the design incorporated
blinding or concealment of treatment allocation. Without these details it is very difficult to judge the internal validity, as many sources of bias may have been introduced. The authors acknowledged that the optimal length of education and support through telemonitoring, and the minimum time period necessary for patients to manifest the benefits of this intervention, are both unknown. This raises doubt over the one-year time horizon of the study. Power calculations were conducted, but these assumed a 75% death or readmission rate for the control group. The basis of this assumption was unclear. The study sample appears to have been quite small, despite the use of power calculations.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The use of a measure of benefit such as life-years saved or quality-adjusted life-years would have enabled the findings to be compared with other cost-effectiveness studies.

**Validity of estimate of costs**
The perspective adopted for the economic analysis was not clearly stated, but it is likely to have been that of the hospital. Although the outpatient costs were not included, the authors stated that these were unlikely to have affected their conclusions (Rich et al., see Other Publications of Related Interest). The costs and the quantities were reported separately, which will enhance the external validity of the results. However, no price year was reported, thus hindering any reflation exercises. A statistical analysis of the quantities was performed. Discounting was unnecessary, as all the costs were incurred in 24 months, and was not conducted.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. They did not, however, address the issue of the generalisability of the results to other settings or countries. The authors did not appear to have presented their results selectively. The study enrolled patients with HF and this was reflected in the authors’ conclusions.

**Implications of the study**
The authors recommend that all patients with HF should be offered an education and support programme that extends beyond hospitalisation. Future studies may explore potential mechanisms for maximal benefits of education and support.

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None stated.

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**Other publications of related interest**


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