Randomized trial of a nurse-administered, telephone-based disease management program for 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
The health intervention examined in the study was a nurse-administered, telephone-based, disease management programme for patients suffering from heart failure (HF). The intervention consisted of regularly scheduled telephone monitoring by specially trained nurses supervised by cardiologists specialising in HF. Telephone calls were intended to promote self-management skills, appropriate diet, and adherence to guideline-based therapy prescribed by primary physicians. Patients were encouraged to contact programme nurses any time they experienced an increase in symptoms or had questions about their disease or treatment. Some patients received home visits and were provided with bathroom scales. Patients also received an educational package describing the causes of HF, the basic principles of treatment, their role in routine care and monitoring of their condition, and appropriate strategies for managing an HF exacerbation.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients, aged 21 years or over and who showed at least one sign and one symptom of an HF exacerbation. Patients were also required to have evidence of left ventricular systolic or diastolic dysfunction by echocardiogram, cardiac catheterization, or radionuclide imaging, and to be classified as New York Heart Association (NYHA) Class II, III, or IV. Patients were excluded if they had predominantly right ventricular failure from chronic lung disease or pulmonary hypertension, chronic lung disease as the primary cause of their symptoms, significant aortic stenosis (estimated aortic valve area less than 1 cm²), chronic renal failure (creatinine clearance less than 20 mL/min or on chronic dialysis), a severe comorbidity with an anticipated survival of less than 6 months, bypass surgery during the hospital admission, heart transplant candidacy, pregnancy, cognitive or psychological impairment precluding effective telephonic monitoring, were discharged to a long-term care facility or hospice, or had no reliable home address.

Setting
The setting was primary care and the community. The economic study was carried out in the USA.

Dates to which data relate
The period during which effectiveness and resource use data were gathered was not clearly reported, but patients were enrolled in the study in 1999. The price year was not given.

Source of effectiveness data
The effectiveness evidence came from a single study.
Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
Sample selection aimed to identify eligible patients who lived within the study hospital's service area, had primary insurance coverage through Medicare, Medicaid, or Group Health Plan Advantra (a Medicare HMO) or had no insurance, and had a primary physician with whom programme personnel could communicate about their care. Patients were not contacted if they were enrolled in another treatment protocol or were unable to hear or understand English spoken over the telephone. Two strategies were used to enrol patients. Firstly, beginning 15 June 1999, Group Health Plan Advantra utilisation review personnel identified plan participants hospitalised with HF. Secondly, in October 1999, individuals with traditional Medicare or Medicaid health insurance or without health insurance were identified by daily review of the hospital admitting logs.

The initial target sample comprised 250 patients. This would have allowed the detection of a 10% difference in the primary outcome measure (readmission rate) with alpha at 0.05 and beta at 0.20. However, only 151 subjects were enrolled. Of the 647 potential candidates admitted at the authors' institution, 382 were excluded due to the strict inclusion criteria. Of the remaining admissions, 25 patients' physicians and 100 patients refused participation in the study, and 19 enrolment attempts failed. It should be noted that patients could be contacted more than once. Thus, the final study sample included 151 patients out of 647 (23.3%) potential candidates and 151 out of 276 (54.7%) individuals who met all inclusion and exclusion criteria. There were 75 patients with a mean age of 69.4 (+/- 13.9) years in the control group. 53% of the control group were female. The intervention group consisted of 76 patients with a mean age of 70.5 (+/- 12.7) years, of whom 59% were female.

Study design
This was a randomised, prospective, single-centre, controlled trial, which was carried out at the Barnes-Jewish Hospital in St Louis, Missouri, USA. Block randomisation was employed: a randomly permuted block design was used with 1:1 randomisation of patients within randomly selected blocks of 2, 4, or 6 patients. The ordering of subjects within each block was randomly assigned. The length of follow-up was one year, but outcomes were also assessed after 6 months. Patients were enrolled during their index hospitalisation or as soon as possible after discharge. Baseline interviews were conducted during the index hospitalisation or after discharge. Twenty-one patients did not complete questionnaires at 6 months (12 died, 6 refused, and 3 had other reasons) and 29 did not complete 12-month interviews (24 died, 5 refused). Clinicians involved in the management of intervention patients were not involved in assessing outcomes and data collectors and interviewers were blinded to treatment allocation.

Analysis of effectiveness
The analysis was based on intention-to-treat (ITT). The primary outcome measure was time to hospital encounter (defined as hospital readmission or emergency department visit) for any cause. Secondary outcome measures were mortality, number of hospitalisations (all-cause readmissions and HF-specific readmissions), quality of life, functional status, and satisfaction with care. Quality of life and functional status were assessed using the SF-12 Health Survey and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Changes in the NYHA class and depression (assessed using the Beck Depression Inventory) were also estimated. Study groups were well matched at baseline with respect to most demographic and clinical characteristics. However, significantly more patients in the intervention group were on target or high doses of an angiotensin-converting enzyme (ACE) inhibitor. A multivariate statistical analysis was carried out to take into account the potential impact of some confounding factors, such as comorbid disease, disease severity, and baseline ACE inhibitor doses.

Effectiveness results
At six months, the intervention group had significantly longer time to encounter (p=0.002), number of all-cause readmissions (p=0.0008), HF-specific readmissions (p=0.037), and percentage of any readmission or death (p=0.0009).
At one year, intervention patients had a longer time to encounter (hazard ratio (HR) = 0.67; 95% confidence interval (CI): 0.47 - 0.96; p=0.029) and fewer hospital readmissions (HR = 0.67; 95% CI: 0.46 - 0.99; p=0.045). These results were corroborated in the multivariate analysis. There was no statistically significant difference between the two groups in terms of mortality or other clinical outcomes at 6 or 12 months, with the exception of the physical scale for the SF-12 that showed statistically better results for the intervention group at 6 months (but not at 1-year follow-up).

Clinical conclusions
The effectiveness analysis showed that the disease management programme led to a longer time to readmission for patients with HF in comparison with usual care. The advantages of the intervention over usual care were higher at 6 months than at 1-year follow-up.

Measure of benefits used in the economic analysis
Health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
The authors did not report the perspective adopted in the study and only hospital costs were included in the analysis. Thus, the perspective of the hospital appears to have been used. A breakdown of cost items was not provided. Unit costs were not presented separately from the quantities of resources used. The estimation of resource use was based on data derived from the same sample of patients as that included in the effectiveness analysis and covered the whole one-year time horizon. Costs of inpatient care were derived from the cost accounting system at the authors’ institution. Discounting was not relevant as costs were incurred over a period of one year. The price year was not reported.

Statistical analysis of costs
Costs were presented as mean and median values. Statistical tests were carried out to test the statistical significance of cost differences. A within-group comparison was also performed to compare the first and second six months of the intervention.

Indirect Costs
Indirect costs were not included in the economic study.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported above.

Cost results
The economic analysis showed that intervention patients had significantly fewer hospital admissions and total hospital days, and statistically lower hospital costs during the first 6 months of the intervention, (p=0.012).

However, at one year, no statistically significant difference was observed in any economic outcome. Specifically, mean hospital costs per patient after 1 year were $23,276 (median: $8,143; 75th percentile: $25,498) in the control group and
$17,410 (median: $8032; 75th percentile: $27,698) in the intervention group, (p=0.49).

The within-group comparison showed that median costs decreased substantially in the second 6 months of the study for the control group, while median costs in the intervention group remained similar.

Synthesis of costs and benefits
A synthesis of costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors’ conclusions
The authors concluded that the disease management programme for patients with HF significantly delayed subsequent hospital encounters but had a negligible effect on functional status and quality of life. The intervention was cost-neutral at one year.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was appropriate as the authors stated that it represented the standard pattern of care. Furthermore, it was adequately described. You should decide whether it is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The method of randomisation was extensively described and should have reduced the impact of selection bias. Likewise, details of the sample selection process were provided. The authors noted that enrolment was slower than expected, and the final study sample was therefore smaller than planned. This affected the power of the overall analysis, which might explain the lack of statistically significant differences in most clinical outcomes. The strengths of the analysis were the blinded design, the fact that it was based on intention to treat, and the baseline comparability of the study groups. Statistical analyses were carried out to adjust clinical estimates by some baseline factors, which could have explained some of the effects observed at the end of follow-up. The issue of the representativeness of the study sample was addressed and the authors noted that patients enrolled in the trial represented a small fraction of all the patients potentially eligible for the intervention. The refusal rate was quite high, which may mean that the study sample was not representative of the patient population. Moreover, the evidence came from a single institution, which might not reflect treatment patterns in other centres.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. See the commentary above under ‘Validity of estimate of measure of effectiveness’.

Validity of estimate of costs
The perspective adopted in the analysis was not stated although it appears to have been that of the hospital providing the disease management programme. The items included in the cost analysis were not reported, thus it was unclear which resources were considered and it may therefore not be possible to replicate the analysis in other settings. The source of data appears to have been consistent with a hospital perspective. Some statistical analyses of costs were performed but cost estimates were specific to the study setting, thus the effect of altering costs was not investigated. Unit costs were not reported and the price year was not given, which limits the possibility of conducting reflation exercises in other time periods. The authors noted that the analysis of costs was incomplete as the number and cost of physician visits were not considered.

Other issues
The authors noted that their findings support those reported in previous analyses, which had shown that disease management interventions can significantly reduce hospitalisation rates but have a less clear impact on mortality and
quality of life. The issue of the generalisability of the study results to other settings was addressed and the authors stated that the use of strict eligibility criteria led to enrolment limitations, which might have reduced the external validity of the analysis. A further limitation highlighted by the authors was the fact that data on hospital encounters may have been incomplete. However, the authors reviewed the hospital database to identify and confirm all relevant admissions. The study referred to a selected population of patients with HF and this was reflected in the authors' conclusions.

Implications of the study
The study results suggest that a nurse-administered, telephone-based, disease management programme for HF patients might delay hospital readmission. A trend towards moderate improvement in quality of life was observed. The authors noted that future studies should identify which programme component had the greatest effect on clinical outcomes. Additional research should also examine the applicability of the disease management programme to a wider population of HF patients.

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Other publications of related interest


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