Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial

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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 3-month programme of comprehensive transitional care (discharge planning and home follow-up) was examined in elders hospitalised for heart failure. Advanced practice nurses (APNs), who received a training programme guided by a multidisciplinary team of heart failure experts, delivered the programme. The intervention was based on national heart failure guidelines. The protocol comprised:

- an initial APN visit within 24 hours of index hospital admission,
- daily APN visits during the index hospitalisation,
- eight APN home visits,
- weekly visits during the first month,
- bimonthly visits during the second and third months,
- additional APN visits according to the patients’ needs, and
- APN telephone availability 7 days per week.

Type of intervention
Other: Supportive care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 65 years and older who were admitted to hospital with a diagnosis of heart failure (diagnosis-related group 127). The patients were required to speak English, be alert and oriented, be reachable by telephone after discharge, and to reside within a 60-mile-radius service area of the admitting hospital. Patients with end-stage renal disease were excluded.

Setting
The setting was secondary care and the home. The economic study was carried out in Philadelphia (PA), USA.

Dates to which data relate
The effectiveness and resource use data were gathered from February 1997 to January 2001. The price year was not reported.
Source of effectiveness data
The effectiveness evidence was derived 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 study.

Study sample
Power calculations were conducted using the results of another study. These calculations suggested that 102 patients per group were required to detect a control-to-intervention group hazard ratio in the main outcome measure of 1.61 with 80% power. Of the 641 potentially eligible patients, 239 (37.3%) were enrolled. The main reason for non-enrolment was residence located outside the defined service area, patients discharged before consent could be obtained, and patient or family member refusal (mainly because of an established relationship with a home health agency). The authors stated that the participants and non-participants were comparable in terms of their age, race and gender. There were 118 patients in the intervention group and 121 in the control group. The mean age was 76.4 (+/- 6.9) years in the intervention group and 75.6 (+/- 6.5) years in the control group. Men made up 40% (intervention group) and 44% (control group) of the two groups.

Study design
This was a prospective, randomised clinical trial that was carried out in six academic and community hospitals in Philadelphia. Randomisation was performed using a computer-generated, institution-specific block 1:1 algorithm. Research assistants were blinded to the aims of the study and groups. The length of follow-up was 52 weeks. The outcomes were assessed at 2, 6, 12, 26 and 52 weeks after index hospitalisation. Forty-nine patients (20.5%) were lost to follow-up. Patients alive and not hospitalised (190; 79.5%) were censored at study completion. Death was considered a censored event in the secondary analysis.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measure was the time to first re-hospitalisation or death. The secondary health outcomes were:

- the time to first re-hospitalisation alone;
- cumulative days of re-hospitalisation;
- mean readmission length of stay;
- persistence of the intervention effect;
- quality of life, assessed using the Minnesota Living with Heart Failure Questionnaire (a scale with 21 items and a total score ranging from 0 to 105);
- functional status, assessed using the Enforced Social Dependency Scale; and
- patient satisfaction, measured using an investigator-developed instrument at 2 and 6 weeks post-index hospitalisation.

Most of the data were extracted from patients' records requested from physicians, hospitals and home care agencies. The impact of potential confounding factors was considered in a regression analysis. Intervention and covariate effect sizes were expressed using incidence density ratios (IDRs) with 95% confidence intervals (CIs). Group-specific Kaplan-Meier survival curves were constructed. Statistical tests were conducted to account for missing values when estimating quality-of-life and functional status. The two groups were comparable at baseline in terms of sociodemographics, health status, insurance typology, use of health care resources, and co-morbidities. However, there were significantly more patients with hypertension in the control group (59%) than in the intervention group (46%), (p=0.046). The authors also stated that there were no statistically significant differences between those patients lost to follow-up and those who
remained in the study.

**Effectiveness results**
The patients were actually followed for 281 days in the control group and 279 days in the intervention group, (p=0.871).

By 52 weeks, there were 13 deaths in the control group and 11 deaths in the intervention group, (p=0.830).

The rate of re-hospitalisation or deaths at 52 weeks was 61.2% (control) and 47.5% (intervention), respectively, (p=0.01).

The distribution of times to first readmission or death was shifted toward longer time intervals in the intervention group than in the control group, (p=0.026).

The proportions of patients remaining alive and with no hospital readmission were:

- in the intervention group, 0.869 (+/- 0.033) at 30 days, 0.750 (+/- 0.043) at 60 days, 0.071 (+/- 0.045) at 90 days, 0.600 (+/- 0.047) at 180 days and 0.445 (+/- 0.050) at 365 days; and
- in the control group, 0.737 (+/- 0.041) at 30 days, 0.621 (+/- 0.047) at 60 days, 0.558 (+/- 0.047) at 90 days, 0.444 (+/- 0.047) at 180 days and 0.321 (+/- 0.047) at 365 days.

These differences were statistically significant at any time point.

Similarly, the estimated median event-free survival of patients was 131 days in the intervention group and 241 days in the control groups.

There were no statistically significant group differences by time interactions.

- The crude IDR was 1.48 (95% CI: 1.05 - 2.09; p=0.027).
- The multivariate model-adjusted IDR was 1.65 (95% CI: 1.13 - 2.40; p=0.001).

There was a non significant trend towards fewer patients re-hospitalised in the intervention group.

- The total number of re-hospitalisations was 104 in the intervention group and 162 in the control group, (p<0.047).
- The number of re-hospitalisation per patient per year was 1.18 in the intervention group and 1.79 in the control group, (p<0.001).

The total hospital days were 588 in the intervention group versus 970 in the control group.

The mean hospital days per patient and per re-hospitalised patient were not statistically significant.

The intervention effect declined slightly as the time post-intervention increased. Differences between the groups were greatest during the first 3 months.

- At 12 weeks, the overall quality of life score was better in the intervention group (3.2 +/- 1.5) than in the control group (2.7 +/- 1.5), (p<0.05).

Significantly better results in the intervention group were observed for the physical dimension of quality of life at 2 and 12 weeks.

- Satisfaction with care was significantly higher in the intervention group at both 2 weeks (83 +/- 10.3 versus 74.6 +/- 10.4; p<0.001) and 6 weeks (83.1 +/- 9.6 versus 77.8 +/- 11.2; p<0.001).

No statistically significant differences were observed in terms of functional status scores at any time point.
Clinical conclusions
The effectiveness study showed that the transitional care intervention was effective in reducing the total number of hospitalisations and in increasing the length of time between hospital discharge and readmission or death. Some short-term improvements in quality of life were also observed.

Measure of benefits used in the economic analysis
The 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
Discounting was not relevant since the costs were incurred during less than 2 years. The unit costs and the quantities of resources used were not reported separately. The health services included in the economic evaluation were hospitalisations, visits to the physician's office and emergency room, and home visits by nurse, APN, physical therapists, social workers and home health aides. The cost/resource boundary of the study was not reported explicitly, but it appears to have been that of the third-party payer. The costs were estimated from hospital bills, which were requested from physicians, hospitals and home care agencies. Resource use was estimated from actual individualised data and was examined over four periods (0 to 12 months, 0 to 3 months, 3 to 6 months, and 6 to 12 months). The costs were standardised by follow-up days to adjust for unequal observation periods. Missing data were assigned using a published method. The price year was not reported.

Statistical analysis of costs
The Wilcoxon rank sum test was used to test the statistical significance of differences in the estimated costs. Confidence intervals (95% CI) were obtained from a bootstrapped empirical sampling distribution of 1,000 iterations.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs were $1,163,810 in the control group and $725,903 in the intervention group, (p=0.404).

The costs per patient were $9,618 in the control group and $6,152 in the intervention group, (p=0.404).

The costs per patient adjusted for unequal follow-up were $12,481 in the control group and $7,636 in the intervention group, (p=0.002).

The estimated mean cost-savings were $4,845 per patient (non-parametric bootstrapped 95% CI: 8,975.84 - 1,301.02; p=0.002).
The higher costs of the programme under study were offset by reduced re-hospitalisations due to heart failure and co-morbidities.

**Synthesis of costs and benefits**
The costs and benefits were not combined because a cost-consequences analysis was carried out.

**Authors' conclusions**
The transitional care intervention delivered by advanced practice nurses (APNs) reduced the number of readmissions, increased the time between discharge and readmission or death, and led to cost-savings for the reimbursement authority.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The new programme was compared with the standard care usually provided to discharged patients suffering from heart failure. Both alternative care systems were described in detail. You should decide whether they represent valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a multicentre randomised trial, which was appropriate for the study question. The internal validity of the study was enhanced by power calculations, the baseline comparability of the study groups, and a description of the method used to select the sample. Further, randomisation was masked as the research assistants were blinded to the study's aims and interventions. However, it was unclear whether the study sample was representative of the study population because of the small number of potentially eligible patients who agreed to participate. Moreover, there was a substantial loss to follow-up. The authors noted that patients who were not enrolled and those who were lost to follow-up were comparable with those who remained in the trial. Several statistical tests were undertaken to deal with missing values. The approach used for censoring data was also reported.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The perspective of the study was implicitly reported as reimbursement rates were used to estimate the true costs of the services. A breakdown of the cost items was not reported and the costs were grouped into gross categories. The price year was not given, which would make reflation exercises in other settings difficult. The costs were treated stochastically and the type of tests carried out was reported. Estimates were also standardised so that they would be comparable between the groups. However, the cost estimates were specific to the study setting and sensitivity analyses were not performed.

**Other issues**
The authors stated that their results confirmed the findings of other studies. The issue of the generalisability of the study results to other settings was not addressed and the external validity of the analysis was low. Sensitivity analyses were not performed. The authors noted the unique characteristics of the APN interventions delivered in the study. The study referred to patients with heart failure and this was reflected in the conclusions of the analysis.

**Implications of the study**
The study results highlighted the benefits associated with a multidisciplinary intervention directed by expert nurses, which aimed to promote collaboration between discharging hospitals and home care in patients with heart failure. The authors suggested that future studies should investigate the cost-effectiveness of an extended transitional APN
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**Source of funding**
Funded by the National Institute for Nursing Research, National Institutes of Health, grant number 1RO1-NR04315.

**Bibliographic details**

**PubMedID**
15086645

**DOI**
10.1111/j.1532-5415.2004.52202.x

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
African Americans; Aftercare; Aged; Aged, 80 and over; Comorbidity; Confidence Intervals; Continuity of Patient Care; Costs and Cost Analysis; European Continental Ancestry Group; Female; Follow-Up Studies; Heart Failure /economics /mortality /nursing /therapy; Home Care Services; Hospitalization; Humans; Male; Patient Readmission; Patient Satisfaction; Quality of Life; Regression Analysis; Socioeconomic Factors; Time Factors; Treatment Outcome

**AccessionNumber**
22004000592

**Date bibliographic record published**
30/09/2004

**Date abstract record published**
30/09/2004