Cost/utility ratio in chronic heart failure: comparison between heart failure management program delivered by day-hospital and usual care


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 heart failure (HF) outpatient management programme, delivered by day-hospital (DH) for chronic heart failure (CHF) patients, was examined. The programme consisted of a team comprising a cardiologist, four trained nurses and two physiotherapists, with part-time participation of a dietician, a psychologist and a social assistant. The objective of the programme was to define a tailored plan for patient care to prevent repeated readmissions for CHF.

Type of intervention
Other: management programme.

Economic study type
Cost-utility analysis.

Study population
The study population consisted of all patients with CHF referred to the Heart Failure Unit of Montescano Medical Centre and the Heart Transplantation Program of the Cardiac Surgery Division of Policlinico, S. Matteo, Pavia.

Setting
The setting was the community. The economic study was carried out at the Department of Cardiology, at the Scientific Institute of Montescano, Pavia, Italy.

Dates to which data relate
The effectiveness and resource use data were gathered between July 1999 and December 2000. No price year was 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 patient sample as that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. All patients admitted to the study hospital between July 1999 and December 2000 were enrolled in the study. Overall, a sample of 234 patients was identified. There were 122 patients in the usual care group and 112 patients in the DH group. In the usual care group, the mean age was 56 (+/- 9) years and there were 102 men. In the DH group, the mean age was 56 (+/- 8) years and there were 94
Study design
This was a randomised controlled trial that was carried out in a single centre, the Scientific Institute of Montescano in Italy. The method of randomisation was not reported. After hospital discharge, the patients were followed for one year. No loss to follow-up was reported.

Analysis of effectiveness
The basis of the analysis of the clinical study was intention to treat. Three types of primary health outcomes were assessed in the analysis:

management outcomes, such as the type of therapy, number of patients rehospitalised, number of rehospitalisations, and individual access;

functional outcomes, such as systolic pressure, peak oxygen uptake (VO2), left ventricular end-diastolic diameter (LVEED), left ventricular end-systolic diameter (LVESD), left ventricular ejection fraction (LVEF), deceleration time E, mitral regurgitation, and ratio of patients in New York Heart Association (NYHA) functional classes (I-II/III-IV); and

hard outcomes such as cardiac death and urgent transplantation.

In addition, the actuarial survival at one year (Kaplan-Meier approach) and mean utility values (time-trade-off method) were estimated. The study groups were shown to be similar in terms of their demographics and clinical conditions.

Effectiveness results
In terms of the management outcomes at one year, 37 patients (35%) were hospitalised in the usual care group versus 9 (8%) in the DH group;

there were 78 (86%) hospitalisations in the usual care group (86%) and 13 (14%) in the DH group, (p<0.05);

cases of individual access occurred only in the DH group and were 5.5 (+/- 3.8);

the regimen of almost all therapies increased sensibly in the DH group compared with the usual care group.

In terms of the functional outcomes, the systolic pressure changed from 120 (+/- 18) to 113 (+/- 18) mmHg in the usual care group, and from 114 (+/- 16) to 117 (+/- 20) mmHg in the DH group;

the peak VO2 changed from 17 (+/- 4) to 14.4 (+/- 4) mL/minute per kg in the usual care group, and from 17 (+/- 4) to 17.8 (+/- 5) mL/minute per kg in the DH group;

the LVEED changed from 70 (+/- 9) to 71 (+/- 10) mm in the usual care group, and from 68 (+/- 10) to 68 (+/- 10) mm in the DH group;

the LVESD changed from 59 (+/- 11) to 59 (+/- 10) mm in the usual care group, and from 61 (+/- 10) to 54 (+/- 12) mm in the DH group, (p<0.05);

the LVEF changed from 31% (+/- 7) to 30% (+/- 9) in the usual care group, and from 29% (+/- 10) to 34% (+/- 7) in the DH group, (p<0.05);

the deceleration time E changed from 163 (+/- 50) to 163 (+/- 52) ms in the usual care group, and from 155 (+/- 55) to 172 (+/- 49) ms in the DH group;

the mitral regurgitation (>= 2+) changed from 2.4 (+/- 0.4) to 2.5 (+/- 0.9) in the usual care group, and from 2.7 (+/-...
0.5) to 2.1 (+/- 0.9) in the DH group, (p<0.05);

the ratio of patients in NYHA functional classes (I-II/III-IV) changed from 80/42 patients to 73/49 patients in the usual care group, and from 73/39 patients to 91/22 patients in the DH group, (p<0.05).

In terms of the hard outcomes, 21 cardiac deaths (17.2%) occurred in the usual care group while only 3 (2.7%) occurred in the DH group, (p<0.0007); and

only one case of urgent transplantation was observed in the DH group.

A Cox regression analysis showed that DH significantly protected against the appearance of hard events (relative risk 0.17, 95% confidence interval: 0.06 - 0.66).

Actuarial survival at one year was 78% in the usual care group and 96% in the DH group, (p<0.0002).

The incremental life expectancy was 0.083 years per patient, and the cumulative incremental life expectancy in the DH group was 9.8 years.

In terms of utility values, the weighted mean utility was 0.63 (+/- 0.22) in the usual care group and 0.72 (+/- 0.17) in the DH group, (p<0.008).

Clinical conclusions
The effectiveness analysis showed that the DH intervention was more effective than usual care in terms of many health outcomes. In particular, more favourable changes in NYHA functional class and fewer cardiac deaths were observed in the DH group in comparison with usual care patients.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was the quality-adjusted life-years (QALYs). The data on survival and quality of life, as obtained from the effectiveness analysis, were used to derive the QALYs. The time-trade-off method was used to assess quality weights. No discount rate was applied to the benefits.

Direct costs
No discount rate was used as the costs were estimated over one year. The unit costs and the quantities of resources were not reported separately. A detailed breakdown of the costs was not given. The costs were categorised according to annual pharmacology costs, health management costs, re-hospitalisation costs and strategy costs. The cost/resource boundary adopted was that of the third-party payer, as only the reimbursed costs were included in the analysis. The resource use data were obtained from the clinical trial, while the unit costs were derived from actual DRG reimbursement rates in Italy. The drug costs were estimated using the national annual formulary. The costs were actualised using a 5% annual increase rate, but no price year was explicitly reported.

Statistical analysis of costs
Standard statistical analyses were performed to test the statistical significance of the total costs.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).
Sensitivity analysis
Sensitivity analyses were conducted to assess the impact of changing both survival and overall costs on the estimated cost per QALY. The ranges used in the analyses were taken from the 95% confidence intervals. The type of analysis was not reported.

Estimated benefits used in the economic analysis
The QALYs gained were 70.5 in the usual care group and 79.4 in the DH group, (p<0.01).

Cost results
The annual pharmacology costs were $490 (+/- 164) in the usual care group and $741 (+/- 206) in the DH group, (p<0.000001);
the health management costs were assessed only in the DH group and were $1,243 (+/- 868);
the re-hospitalisation costs were $1,332 (+/- 1,992) in the usual care group and $268 (+/- 801) in the DH group, (p<0.000001); and
the strategy costs were $178,559 in the usual care group and $167,785 in the DH group.

The authors stated that a cost comparison of the two strategies led to the conclusion that the DH intervention was cost-saving, costing $10,768 less than usual care.

Synthesis of costs and benefits
An incremental cost-utility analysis was conducted to combine the costs and benefits of the interventions. The DH intervention dominated usual care since it was both more effective and less costly. Nevertheless, the authors computed the cost-utility ratio: "considering an increase of 0.080 QALY per patient, an annual cost of $1,483 per patient and a 5% annual increase of costs ($1,557), the cost/utility ratio for the integration of DH management of CHF was $19,462". The 95% confidence interval, as derived from the sensitivity analysis, ranged from $13,904 to $34,048.

Authors’ conclusions
The heart failure (HF) outpatient management programme delivered by day-hospital (DH) for chronic heart failure (CHF) patients increased one-year survival and was cost-effective when compared with the standard care provided to such patients. The authors highlighted the reduction of hospital re-admissions as a positive result of the DH programme.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Usual care was selected as it represented the standard management intervention for patients with CHF. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised controlled trial, which was appropriate for the study question. The study sample appears to have been representative of the study population, although the authors stated that elderly patients were poorly represented in their sample. The study groups were shown to be similar at baseline. Regression analyses were conducted to assess the impact of several factors on the main outcome measures. All of the patients included in the study were accounted for in the clinical analysis. Details on the two interventions compared in the analysis were reported clearly. However, the method of randomisation was not reported and power calculations were not performed.
Validity of estimate of measure of benefit
QALYs were used as the benefit measure in the economic analysis. The methods used to elicit patient utility values were reported. The use of QALYs enhances the comparison of the benefit of the study intervention with the benefits of other interventions funded in the health care system. The authors stated that the use of a time horizon longer than one year could result in further gains in QALYs.

Validity of estimate of costs
The cost analysis was conducted from the perspective of the third-party payer, although the authors stated that a societal perspective was adopted. It would appear that all the relevant categories of costs were included in the economic evaluation. However, a detailed breakdown of the costs was not provided. Standard statistical analyses were conducted on the costs. Although the costs were actualised, no price year was given, thus limiting the reproducibility of the study in other settings. In addition, neither the unit costs nor quantities of resources were reported in the analysis. The authors commented that the inclusion of the indirect costs should not affect the study results, as these costs could be equally distributed between the study groups. Overall, only limited details of the economic analysis were reported.

Other issues
The authors made some comparisons of their findings with those from other studies, especially on the effectiveness side of the analysis. The issue of the generalisability of the study results to other settings was not addressed, and sensitivity analyses were conducted on aggregated cost data. The overall external validity of the analysis appears to have been fairly low, as the unit costs were not reported and the price year was not given. The study enrolled a sample of patients with CHF and this was reflected in the conclusions of the analysis. The authors reported some limitations of their analysis.

Implications of the study
The DH management of patients with CHF proved to be a cost-effective intervention, compared with the usual care provided to such patients after hospital discharge.

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