Safety and cost-effectiveness of early discharge after primary angioplasty in low risk patients with acute myocardial infarction


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
Primary percutaneous transluminal coronary angioplasty (PTCA) followed by accelerated care and discharge from hospital 3 days later for low risk patients with acute myocardial infarction. Accelerated care consisted of admission to a non-intensive care unit used for elective PTCA, and full dose heparin for 48 hours followed by half dose for 12 hours. Non-invasive testing was not recommended and patients would be discharged on day 3 in the absence of clinical contraindications such as arrhythmia, hypotension, chest pain, congestive heart failure (CHF), stroke, renal insufficiency, sepsis or any other condition requiring hospitalisation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with evidence of MI who were classified as low risk using catheterisation with primary PTCA. Low risk was defined as having an age less than or equal to 70 years, no persistent arrhythmias after reperfusion, one or two vessel disease (70% or more stenosis), left ventricular ejection fraction greater than 45% and successful PTCA of a native coronary artery.

Setting
Hospital. The economic study was conducted in the USA.

Dates to which data relate
Effectiveness and resource use data were collected for patients enrolled in the study between September 1993 and January 1995. The price year was not explicitly specified. Evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was prospectively performed on a subsample of the patient sample used in the effectiveness analysis.

Study sample
The sample size was designed to detect a 10% difference in primary end points with an alpha level of 0.05 and a power of 0.8 in a two tailed test. To achieve this a sample size of 400 was required. In total, 1,100 patients were enrolled for this and another study involving high risk patients. Of these 48 patients considered low risk were excluded because they were treated medically, another 144 with unstated risk levels were excluded without a reason being given and 437 were defined as high risk. 471 low risk patients were randomised to the accelerated care group (n=237) with a mean (SD) age
of 55 (10) years or to the traditional care group (n=234) with a mean (SD) age of 56 (10) years.

Study design
This was a multi-centred randomised controlled trial, conducted in 34 centres in 5 countries. The study sites were described as diverse and included rural and urban settings and both teaching and non-teaching hospitals. After identification of the low risk patients, they were randomised to the 2 treatment strategies. Duration of follow up was 6 months. Loss to follow up was 19 (4%). Research nurses at each of the 34 clinical centres prospectively collected data. Case report forms and medical records were randomly cross checked by an independent study coordinator.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The primary health outcome was the combined occurrence of "unsatisfactory" outcomes by 6 months: death, reinfarction, unstable ischemia, stroke or congestive heart failure. These unsatisfactory outcomes were also analysed individually. Groups were comparable in terms of age, sex, and prognostic features.

Effectiveness results
Of the 237 patients randomised to the early discharge protocol, designated contraindications were present in 59 (25%) by day 3 and of the remaining 178 only 142 (80%) were actually discharged on day 3. In the USA this proportion was higher, with 137 (92%) of 149 eligible patients being discharged on day 3. At 6 months none of the differences between groups were statistically significant. The combined occurrence of adverse events was 15.2% in the accelerated care group and 17.5% in the traditional care group, (p=0.49). Mortality was 0.8% versus 0.4%, (p=1.00). The rate of unstable ischemia was 10.1% versus 12.0%, (p=0.52). The rate of reinfarction was 0.8% versus 0.4%, (p=1.00). The percentage of stroke was 0.4% versus 2.6%, (p=0.07). The percentage with congestive heart failure was 4.6% versus 4.3%, (p=0.85). Patients randomised to receive accelerated care had no increase in the incidence of in-hospital adverse effects.

Clinical conclusions
This study confirmed that low risk patients treated with primary PTCA have excellent clinical outcomes. Given the low event rate, it was not surprising that elimination of the intensive care unit and non-invasive testing, with a day 3 hospital discharge strategy, did not adversely affect outcomes.

Measure of benefits used in the economic analysis
Since the clinical study showed no difference in effectiveness between the intervention and the comparator, the economic analysis was based on the difference in costs alone.

Direct costs
Costs were not discounted since the time frame of the study was restricted to a 6-month follow-up period. Quantities and costs were not analysed separately. Costs were obtained for the US centres only. Charges were abstracted from hospital bills and converted to hospital costs using each hospital’s Medicare charge/cost ratios. Charges were given separately for room and board, pharmacy, laboratory, diagnostic testing and other. The cost boundary was that of the hospital. The date of the price data was not explicitly specified.

Statistical analysis of costs
Costs were presented as the mean plus or minus the standard deviation and a p value was given. It was stated that for all comparisons in the study the t test was used for continuous variables and the Mann Whitney U test for continuous variables with non-normal distribution. However, it was not stated which of these was used for costs.
Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean cost per patient for the accelerated care group was $9,658 (+/- $5,287) versus $11,604 (+/- $6,125) for the traditional care group, (p=0.002).

Synthesis of costs and benefits
Costs and benefits were not combined since the use of the accelerated care process for the low risk patients was the dominant strategy (with equal efficacy and lower costs).

Authors' conclusions
Early identification of low risk patients with MI allowed safe omission of the intensive care phase and non-invasive testing, and a day 3 hospital discharge strategy, resulting in substantial cost savings.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparators is clear.

Validity of estimate of measure of benefit
The effectiveness results are likely to be internally valid given the use of a randomised design.

Validity of estimate of costs
Insufficient details of costs and resource use were provided. Costs should be reflated to a specific date and costs based on charges converted using Medicare charge to cost ratios are less informative than an estimate based on resource use and prices.

Other issues
The authors' conclusions seems to be reasonably justified given the randomized design used in the effectiveness analysis and charge/cost ratios used in the cost analysis. The issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with other studies.

Implications of the study
Wide application of this management strategy may result in substantial cost savings.
Source of funding
None stated.

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