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 angioplasty versus thrombolysis with tissue-type plasminogen activator for acute myocardial infarction.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with acute myocardial infarction of less than 12 hours duration were randomised to undergo t-PA or primary PTCA.

Setting
Hospital. The economic study was carried out at 11 centres in the USA.

Dates to which data relate
Effectiveness and resource data related to the period June 1990 to April 1992. The price year was not stated.

Source of effectiveness data
Evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The total sample included 395 patients. Cost data were not available for 37 patients, and 358 patients were therefore randomised to treatment with t-PA (181 patients, 128 males) or primary PTCA (177 patients, 130 males). The mean age in the PTCA group was 59.7 and in the t-PA group was 60.1 years. Given the number of patients enrolled, the study had only 31% power to detect a difference in total hospital charges. With the differences observed, p values <0.05 would have been reached if 99 more patients had been enrolled. Patients were excluded based on the absence of ST segment elevation or the presence of left bundle branch, cardiogenic shock, standard risk factors known to predispose to increased bleeding risk after thrombolytic therapy or the inability to give informed consent.
Study design
This was a randomised controlled trial carried out at 11 US centres. The duration of the follow-up period for the two groups was, respectively, 2.2 (+/- 0.7) years and 2.1 (+/- 0.7) years, (p=0.27). Follow-up data were available for 340 of 341 patients discharged alive.

Analysis of effectiveness
The analysis of the clinical study was based on the intention to treat principle. The primary health outcomes used in the study included the rate of in-hospital mortality, rate of recurrent ischemia and stroke, rate of non-protocol catheterization, rate of non-protocol PTCA, number of CABG or CHF, cardioversion of defibrillation, IABC, intubation, major bleeding, blood transfusion, vascular surgical repair, number of catheterization procedures per patient, number of PTCA procedures per patient, predisharge exercise test, length of hospital stay, postdischarge events and the number of patients alive and free of discharge at late follow-up. There were no significant differences in baseline demographic or clinical features on presentation between the two patient groups. These features included age, gender, history of diabetes mellitus, hypertension or hypercholesterolemia, cigarette smoking, previous myocardial infarction or congestive heart failure, time from symptom onset to randomisation, anterior myocardial infarction, admission Killip class >2, admission systolic blood pressure and admission heart rate.

Effectiveness results
Compared with the t-PA group, patients treated with primary PTCA exhibited lower rates of in-hospital death (4 versus 13, p=0.03), rate of reinfarction (5 versus 13, p=0.06), rate of death or nonfatal reinfarction (9 versus 24, p=0.008), rate of recurrent ischemia (20 versus 52, p<0.0001), rate of stroke (0 versus 9, p=0.02), rate of non-protocol catheterization (23 versus 114, p<0.0001), rate of non-protocol PTCA (11 versus 65, p<0.0001), number of catheterization procedures per patient (0.96 +/- 0.37 versus 0.41 +/- 0.59, p=0.0001) and hospital stay (7.6 +/- 3.3 days versus 8.4 +/- 4.7 days, p=0.04).

Events during the follow-up period occurred with similar frequency in patients initially assigned to t-PA and PTCA, although trends were present for a greater late incidence of non-elective hospitalisation and late bypass surgery in PTCA patients. For the two groups, hospital stay after discharge was 60 versus 42 days, (p=0.06), and the number of CABGs was 22 versus 11, (p=0.06) respectively.146 of 177 PTCA patients and 134 of 180 t-PA patients were alive and free of reinfarction at the end of the follow-up period. For the non-high risk patients, PTCA resulted in discharge 1.3 days earlier (hospital stay of 7.0 days +/- 3.1 versus 8.3 +/- 4.5, p=0.03) and lowered the rate of recurrent ischemia (9 versus 27, p=0.0007), the number of non-protocol catheterisations (7 versus 55, p<0.0001) and the number of non-protocol PTCA (4 versus 33, p<0.0001). In high-risk patients, PTCA markedly reduced in-hospital mortality rates (2 versus 10, p=0.01), rate of recurrent ischemia (11 versus 25, p=0.01), rate of stroke (0 versus 6, p=0.03), the number of non-protocol catheterisations (16 versus 59, p<0.0001) and the number of non-protocol PTCA (7 versus 32, p<0.0001).

Clinical conclusions
If patients with AMI present at centres with skilled PTCA operators, primary PTCA can be expected to save lives and lower the incidence of non-fatal reinfarction and stroke compared with treatment with thrombolytic therapy.

Measure of benefits used in the economic analysis
No explicit measure of benefit was put forward. Primary benefit measures include the rate of in-hospital mortality, recurrent ischemia, stroke, hospital stay and the number of patients alive and free of reinfarction at late follow-up.

Direct costs
Three categories of costs were assessed: hospital charges, professional cardiology and cardiac surgery fees, and post-discharge follow-up resource consumption. Costs were not discounted. Costs and quantities were not reported separately. The quantity/cost boundary adopted was that of the hospital. The estimation of costs and quantities was based on actual data. For the case of follow-up costs, late resource consumption was approximated by tabulating hospital readmissions and major clinical events during the first 2 years after discharge. Hospital and physician bills
were obtained from the patients. Summary ledger forms and detailed itemised bills were available for all patients. The date of the price data was not stated.

**Statistical analysis of costs**
Categorical variables were compared by chi-square analysis or the Fisher exact test. Continuous variables were compared using the Student t test or Mann-Whitney U test. Median charges were reported, with 90% confidence intervals. Univariate correlates of increased hospital charges were determined. A forward stepwise multiple regression analysis was carried out to determine the independent correlates of increased hospital charges. Three analyses were performed: the first involving only demographic features, the second including the randomisation arm and the third including all variables. A p value <0.05 was considered significant.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
Compared with the t-PA group, patients treated with primary PTCA exhibited lower rates of in-hospital death (4 versus 13, p=0.03), rate of recurrent ischemia (20 versus 52, p<0.0001), rate of stroke (0 versus 9, p=0.02), and hospital stay (7.6 +/- 3.3 days versus 8.4 +/- 4.7 days, p=0.04). 146 of 177 PTCA patients and 134 of 180 t-PA patients were alive and free of reinfarction at the end of the follow-up period.

**Cost results**
Per patient in-hospital charges were significantly lower (p=0.04) in patients treated with PTCA: $23,468 (+/- $13,410; 90% CI: $12,586 -38,346) compared to t-PA $26,904 (+/- $18,246; 90% CI: $12,893 -49,612). For the non-high risk group, the PTCA group exhibited lower in-hospital charges (p=0.025): $22,038 (+/- $12,896) compared to the t-PA group $26,403 (+/- $16,104). In-hospital charges for the high risk group were similar across the two groups. Professional fees were higher in the PTCA group: $4,185 (+/- $3,183) versus $3,322 (+/-$2,728),(p=0.001). Total charges were similar in both groups: $27,653 (+/- $13,709) versus $30,227 (+/- $3,183), (p=0.21).

By multivariate analysis, the only baseline variables that correlated with increased hospital charges were advanced age, previous myocardial infarction and previous heart failure. When the randomisation arm was entered into the model, age, previous myocardial infarction and previous heart failure retained significance, but the randomisation arm did not. The global multivariate analysis showed that the primary determinants of hospital charges were adverse in-hospital events, including a prolonged hospital stay, need for intra-aortic balloon counterpulsation, non-protocol PTCA, intubation, stroke and bypass surgery. Angioplasty did not have a significant independent effect on costs.

**Synthesis of costs and benefits**
Costs and benefits were not combined into a cost-effectiveness ratio.

**Authors’ conclusions**
Compared with t-PA, reperfusion by primary PTCA improves clinical outcomes with similar or reduced costs.
CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear.

Validity of estimate of measure of benefit
All relevant benefit measures seem to have been included. However, future studies should preferably include life expectancy and quality adjusted life years (QALYs).

Validity of estimate of costs
One limitation to this study is the substitution of charges for true costs. This method overestimates the costs of both procedures since hospital charges are significantly greater than absolute costs. This makes comparisons with other studies or the applicability of the results to other countries more difficult.

Other issues
No sensitivity analysis was carried out, so it is somewhat difficult to assess the robustness of the results. A sensitivity analysis may have been omitted because of the use of charges.

Implications of the study
Future studies should examine further cost reductions for the PTCA procedure. Another issue is how to make this therapy more widely available in a cost-effective manner to patients presenting at hospitals without interventional facilities, whether by altering ambulance triage strategies or investing in new infrastructure.

Source of funding
None stated.

Bibliographic details

PubMedID
9120173

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Angioplasty, Balloon, Coronary /economics; Female; Hospital Charges; Humans; Male; Middle Aged; Plasminogen Activators /economics /therapeutic use; Prospective Studies; Thrombolytic Therapy /economics; Tissue Plasminogen Activator /economics /therapeutic use