Rescue percutaneous thrombectomy system provides better angiographic coronary flow and does not increase the in-hospital cost in patients with acute myocardial infarction

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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
The use of a rescue percutaneous thrombectomy system (Rescue PT; Boston Scientific) in patients with acute myocardial infarction (AMI) was investigated. The Rescue PT system removes thrombus by using a vacuum pump system.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with AMI who arrived at hospital within 24 hours of the onset of symptoms. AMI was diagnosed when there was at least 30 minutes of symptoms consistent with AMI, in association with either ST segment elevation of more than 1 mm in at least 2 contiguous leads or left bundle branch block. Patients were excluded if percutaneous coronary intervention (PCI) was not the initial reperfusion therapy, or a thrombolytic agent (tissue-type plasminogen activator or urikonase) or abciximab was administered before or during PCI. They were also excluded if successful dilation at the culprit lesion (defined as <50% stenosis by visual estimation) was not achieved on the final angiogram.

Setting
The setting was secondary care. The economic analysis was carried out in Japan.

Dates to which data relate
The patients in the intervention group (i.e. Rescue PT system) were recruited from October 1999 to June 2001. These patients were compared with patients who had been treated by other means before August 2000. The price year was not reported.

Source of effectiveness data
The effectiveness data were 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
No power calculations, to determine the sample size, were reported. In addition, no specific sample size was planned. From October 1999 to June 2001, 106 consecutive patients with AMI arrived at the hospital. Of these, 41 patients were excluded. The remaining 65 patients underwent Rescue PT as the primary treatment after August 2000, when the treatment became available at the hospital. These 65 patients (RT group) were compared with 66 patients who were treated by other means before August 2000 (control group). There were 52 (80%) males in the RT group and 55 (83%) males in the control group. The mean age of the patients was 64 (+/- 13) years in the RT group and 66 (+/- 11) years in the control group.

Study design
The study was a comparative study with historical controls, which was carried out in a single centre. The patient groups were followed up until they were discharged from hospital (i.e. 19.0 +/- 9.9 days for the RT group and 19.7 +/- 9.3 days for the control group). There was no loss to follow-up.

Analysis of effectiveness
All the patients included in the study were accounted for in the analysis. The outcomes used were:

- the occurrence of death from any cause,
- heart failure,
- reinfarction,
- emergency bypass surgery,
- target lesion revascularisation,
- angiographic coronary flow,
- the incidence of life-threatening arrhythmia,
- acute or sub-acute closure of the target lesion after leaving the catheterisation laboratory, and
- the maximum serum value of creatine kinase within 24 hours of the completion of the PCI.

Angiographic-impaired coronary flow (slow flow phenomenon) was defined as a reduction of antegrade blood flow (< TIMI 3) in the final coronary angiogram that was not associated with abrupt closure, spasm or significant stenosis of the culprit lesion. The groups were shown to be comparable in terms of age, gender and prognostic features. A multiple logistic regression analysis of all significant univariate variables was performed to determine the independent predictors of the development of slow flow phenomenon (< TIMI 3) after the procedure.

Effectiveness results
The incidence of slow flow phenomenon (< TIMI 3) in the RT group (3.1%) was significantly lower than in the control group (19.7%), (p=0.01). It was still lower in the RT group after excluding patients who showed spontaneous recanalisation before PCI (3.4% versus 26.1%, p=0.003).

Reperfusion time, Rescue PT use and direct stenting were all found to correlate with slow phenomenon on univariate logistic regression analysis, (p<0.1). However, multiple logistic analyses indicated that reperfusion time was the only independent variable, (p=0.044). The use of Rescue PT showed a trend toward reducing slow flow phenomenon, but it did not reach statistical significance, (p=0.084).

The mean, maximum serum creatine kinase value in the 24 hours after PCI was lower in the RT group (3,444 +/- 2,218 IU) than in the control group (4,182 +/- 3,010IU), (p<0.05). However, the ejection fraction at discharge did not differ between the groups.
There were no significant differences between the groups in terms of the incidence of death, heart failure, nonfatal infarction, and life-threatening arrhythmia or target lesion revascularisation.

Clinical conclusions
The most important result of the present study was that final TIMI 3 flow was achieved more frequently in patients treated with the Rescue PT system than in those who did not undergo that treatment.

Measure of benefits used in the economic analysis
No summary measure of benefit was derived. The study was, in effect, a cost-consequences analysis.

Direct costs
The resource quantities and the costs were reported separately. The direct costs included in the analysis were those of the hospital. These comprised the costs of the initial procedure, such as balloon catheter, stent, IVUS, guide wire, diagnostic catheter, guiding catheter, sheath, contrast medium, Rescue PT and other minor equipment. When PCI was performed for lesions other than the culprit lesion, the cost was included in the procedural cost. When intra-aortic balloon pumping or percutaneous cardiopulmonary support was used during the first day, the cost of the device and the procedural fee of the first day were included in the initial procedural cost. Other costs included in the analysis were those for the entire hospitalisation, the procedure time, and the coronary care unit and ward length of stay. The costs were derived from the procedural fee of the PCI and the price of resources used during the procedure. Discounting was not relevant since all the costs were incurred during a short time. The study reported the mean cost for both groups. The price year was not reported.

Statistical analysis of costs
The costs and resource use were treated stochastically. An unpaired Student's t-test was used to compare the mean values. A probability value of less than 0.05 was considered statistically significant.

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

Currency
Japanese yen (Y).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The initial procedural cost was Y1,224,680 (+/- 381,013) for the RT group and Y1,000,067 (+/- 325,687) for the control group, (p=0.12).

The total in-hospital cost was Y3,083,939 (+/- 1,649,336) for the RT group and Y3,113,215 (+/- 1,348,491) for the control group, (p=0.81).
Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
During acute myocardial infarction (AMI), thrombectomy with the Rescue PT system prior to mechanical dilation of the culprit lesion was safe and feasible, even in the emergency clinical setting, and provided better angiographic coronary flow after the procedure. The authors also concluded that the therapeutic strategy facilitated direct stenting and did not increase the cost of a percutaneous coronary intervention (PCI).

CRD COMMENTARY - Selection of comparators
The Rescue PT system was compared with other treatments used in the authors' setting before August 2000. The authors did not provide any information on the strategies used in the treatment of AMI before August 2000.

Validity of estimate of measure of effectiveness
The study was a comparative study with historical controls. The authors pointed out that the period of time when the procedures were undertaken differed between the groups. Hence, factors such as new types of stent becoming available, improved medical technologies, better health care delivery, new management styles, and other such trends taking place over time, might have biased the authors' results. However, the authors believed that this difference did not affect their results. The study sample was representative of the study population and the patient groups were shown to be comparable at analysis. Appropriate statistical analyses were undertaken to test for statistically significant differences in outcomes between the two patient groups.

The authors reported that important selection bias occurred in their study, as 34 AMI patients treated after August 2000 were excluded because they were not treated by the Rescue PT system. According to the authors, this implied that the operators tended to avoid using the Rescue PT device when they considered it would not be useful, because the amount of thrombus in the culprit lesion was small or the territory of infarcted myocardium was narrow. The authors could not deny that this selection bias had some effect on their results. Further, the number of patients was relatively small and, therefore, the clinical impact on this new therapy could not be evaluated adequately. The authors also reported that the TIMI flow was a relatively subjective measure with large inter-observer variability, which was not considered for in this study.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
If the perspective adopted in the economic analysis was indeed that of the hospital, all the categories of cost were included in the analysis, as were all relevant cost items. The costs and the quantities were reported separately, which will enhance the generalisability of the authors' results. Appropriate statistical techniques were used to test for statistically significant differences between the two groups, both for cost and resource use. It was unclear where the authors derived their unit costs from, although it would appear that these were derived from the authors' settings. Since all the costs were incurred during a short time, discounting was unnecessary. The price year was not reported, which will hamper any possible inflation exercises.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively, and they clearly and exhaustively reported all the limitations of the study. The authors' conclusions reflected the scope of the analysis.
Implications of the study
The authors recommended that the Rescue PT device should be considered as a routine adjunctive therapy for patients with AMI. They also reported that a randomised prospective study with a larger population and longer follow-up period was needed to determine the impact of the new device on the short- and long-term clinical outcomes.

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None stated

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Other publications of related interest


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