VIEWPOINT

Can the published cost analysis data for delivery of an efficient primary angioplasty service be applied to the modern National Health Service?

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Despite the clinical benefits and safety profile of primary percutaneous coronary intervention (PCI), the health care system in the UK has been slow to adopt this strategy as first line management for ST segment elevation myocardial infarction. The cost implications of a 24 hour a day, seven days per week primary PCI service and the absence of an existing efficient working model within the National Health Service (NHS) framework are two of the major deterrents for provision of such a service. The existent cost effectiveness data for primary PCI is critically reviewed, with particular reference to the NHS.

mended the setting up of primary PCI models to explore the unanswered financial questions.¹

THE EXISTING EVIDENCE

Europe

A number of studies from the Netherlands have addressed the cost effectiveness of primary PCI.^{2–4} The first was the Zwolle trial where STEMI patients were randomised to receive either streptokinase or primary PCI and followed up for a minimum of 12 months.² Although the final calculations demonstrated that thrombolysis was cheaper in the acute setting, this difference had disappeared over a 12 month period (cost per patient at 12 months: thrombolysis \$16 681 and primary PCI \$17 316; $p = 0.22$). Furthermore, the cost effectiveness ratio (average cost per event-free survivor) of primary PCI at \$25 431 per patient was significantly less than the \$36 798 accrued for each thrombolysis patient. Similarly, indirect costs such as the bill for pharmacological agents were also significantly lower for primary PCI (primary PCI \$695 and streptokinase \$854 per patient; $p = 0.01$).²

Other groups from the Netherlands have addressed the cost of stent usage in the context of primary PCI, by randomising STEMI patients to balloon angioplasty alone (POBA) or balloon angioplasty followed by stent deployment (stent).^{3,4} The results mimicked those obtained in the Zwolle trial.^{3,4} For example, in the study by Suryapranata and colleagues, stent deployment incurred higher initial costs, but by 24 months the cumulative costs between the two groups were comparable.³ The mean cost effectiveness ratio (as calculated in one of the two studies) also favoured stenting (Dfl 37 408) over POBA (Dfl 53 117; $p < 0.001$). The investigators attributed the comparable cost of the two treatment modalities to the better clinical outcome of patients who had received stents, resulting in lower repeat revascularisation rates (target vessel revascularisation: 12% stent *v* 34% POBA; $p < 0.001$) and recurrent cardiac events (cardiac event free survival: 84% stent *v* 62% POBA; $p < 0.001$).³

Abbreviations: NHS, National Health Service; PCI, percutaneous coronary intervention; PAMI, primary angioplasty in myocardial infarction; POBA, plain old balloon angioplasty; rt-PA, recombinant tissue plasminogen activator; STEMI, ST elevation myocardial infarction; QALY, quality adjusted life-year

The past three decades have witnessed considerable evolution in the treatment of acute ST segment elevation myocardial infarction (STEMI). Over the years, introduction of coronary care units, β blockade, aspirin, and reperfusion treatment (thrombolysis or primary percutaneous coronary intervention (PCI)) have all contributed positively to the management of STEMI patients. In recent years trial evidence has specifically scrutinised the effectiveness of the two clinically acceptable reperfusion strategies, demonstrating that both short and long term outcomes are superior in patients undergoing primary PCI.

However, despite the clear benefits and safety profile of primary PCI the health care system in the UK has been slow to adopt this strategy as first line management for STEMI. The cost implications of a 24 hour a day, seven days per week primary PCI service and the absence of an existing efficient working model within the National Health Service (NHS) framework appear to have become two of the major deterrents for provision of such a service.

The evidence (as outlined below) from both North American and European health economic models of primary PCI demonstrates that in the medium to long term primary PCI is at the best more cost effective, or at the worst cost neutral compared with thrombolysis. However, critics of primary PCI in the UK remain sceptical and continue to question the applicability of these models to the NHS. The National Service Framework for coronary artery disease has acknowledged the unresolved “implications of introducing and maintaining a 24/7 primary angioplasty” service and in turn has recom-

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North America

Despite major differences in the delivery of health care between Europe and North America, the cost effectiveness data from primary PCI studies appear to be broadly similar.⁵⁻⁷ A major difference between North American and European studies is the substitution of hospital charges for actual costs incurred by the health service. Breakdown of hospital charges indicates that professional fees (which is not a feature of most national health care systems in Europe) form a significant component of the overall charge and can in some cases exceed the actual costs borne by the health service.

The Mayo Clinic trial randomly compared thrombolysis with recombinant tissue plasminogen activator (rt-PA) with primary PCI.⁵ In the short term there was a non-significant trend towards lower costs in the primary PCI patients (total charge per patient: rt-PA \$28 600, PCI \$24 900; $p = 0.15$). However, when all indirect measures of cost, including late procedures and re-admissions were accounted for, primary PCI was clearly more cost effective. Breakdown of costs in the PAMI (primary angioplasty in myocardial infarction) trial also replicated previous findings, where per patient hospital charges (excluding professional fees) were significantly lower in primary PCI patients.⁶ The PAMI investigators demonstrated that the greatest cost reduction with primary PCI was achieved in the low risk (as defined by TIMI (thrombolysis in myocardial infarction) criteria) subgroup of patients (a mean saving of \$4365 per patient), who were discharged on average 1.3 days earlier than the thrombolysis group. In the high risk subgroup of patients there was only a non-significant trend towards a lower overall cost with primary PCI. The strongest predictor of cost in this study was the duration of hospital stay. The more recently published Canadian STAT study, which randomised acute STEMI patients to primary stenting (stent) or rt-PA, also demonstrated significantly lower costs for the initial hospitalisation (stent \$6354 $\pm$ \$6382, rt-PA \$7893 $\pm$ \$4429; $p = 0.001$), as well as at six months (stent \$7100 $\pm$ \$7111, rt-PA \$9559 $\pm$ \$6933; $p = 0.001$) in the invasive arm of the study.⁷

Table 1 summarises the five major publications discussed.

Models of primary PCI

Health economists have also produced complex “decision analytic models” to complement the cost effectiveness data generated from actual primary PCI trials. Unlike randomised trials with highly selective inclusion criteria, these models have utilised health outcome information from a broad selection of sources to create balanced hypothetical scenarios in order to provide a comparison of the costs between primary PCI and thrombolysis.

In the model proposed by Lieu and colleagues for 10 000 STEMI patients, projections demonstrated a significant reduction in overall cost and quality adjusted life-years (QALYs) saved in favour of primary PCI.⁸ The cost per life saved was \$11 000 for primary PCI and \$14 000 for thrombolysis. The model also accounted for the increased cost of using stents for primary PCI, demonstrating that over a 12 month period an estimated 20% increase in overall cost per patient would be balanced by significant reduction in continued costs—for example, repeat procedures, admissions, and the cost for pharmacological agents.⁸

The authors of this model outline important prerequisites for the running of an efficient cost effective primary PCI programme, including: (1) use of an existent cardiac catheterisation laboratory; (2) a throughput of at least 200 cases per annum; (3) a long term view of providing a primary PCI service (at least six years); and (4) utilisation of existent on call technical/nursing staff and cardiothoracic support teams. In the proposed model the cost effectiveness of the primary PCI programme was highly dependent on the volume of work and the length of time for which the service

Table 1 A summary of cost effectiveness data from five major primary percutaneous coronary intervention publications

Study name	Setting	Design	Initial costs measured	Follow up costs measured	Results
Reeder <i>et al</i> 1994 ⁵	USA	Randomised to either t-PA or primary angioplasty; n = 99	Hospital stay, all diagnostic or therapeutic procedures	Costs over 12 months including indirect costs such as lost employment days	No significant difference in initial or follow up costs. Trend towards fewer late in-hospital procedures and shorter hospital stay in the primary angioplasty group
de Boer <i>et al</i> 1995 ²	Netherlands	Randomised to either streptokinase or primary angioplasty; n = 301	Hospital stay, angiography, angioplasty, coronary bypass surgery, thrombolysis	Costs over 12 months, additional hospital stay and cardiac procedures, cardiac medication only	Higher in-hospital costs with primary angioplasty but no significant difference in costs at 12 months
Stone <i>et al</i> 1997 ⁶	USA	Randomised to either t-PA or primary PCI; n = 358	Hospital charges from index admission, professional, cardiology and cardiac surgery fees	2 year resource consumption was approximated by tabulating hospital readmissions and major clinical events	Trend towards lower initial charges associated with primary PCI. Significantly lower if professional fees excluded
Suryapranata <i>et al</i> 2001 ³	Netherlands	Randomised to either primary stenting or balloon angioplasty; n = 227	Hospital stay, all diagnostic or therapeutic procedures	Costs over 24 months. Limited to cardiac hospital admissions and cardiac outpatient visits and diagnostic tests	Higher initial costs with stenting but no difference at 24 months
Le May <i>et al</i> 2003 ⁷	Canada	Randomised to either t-PA or primary stenting; n = 123	Hospital stay, all diagnostic or therapeutic procedures	6 month follow up, subsequent hospital stay and all diagnostic and therapeutic procedures	Significant reduction in costs of initial hospitalisation and costs at 6 months in favour of primary stenting

was provided. Costs increased exponentially if the number of patients treated fell below 100 cases per annum and if the service was run for less than six years.^{8,9}

THE NHS IN 2005

The fundamental question is whether primary PCI data from other healthcare systems and health economical models can be applied to the NHS? To answer this very question the Department of Health has pledged in excess of £1 million to set up a number of investigative primary PCI programmes around the country. While actual cost effectiveness data are awaited we have critically analysed the applicability of the existent information to the NHS.

Although the broad concepts from existent primary PCI studies remain applicable to the NHS, the information on outcome and cost effectiveness are outdated and are in need of further scrutiny. Since the publication of the majority of the primary PCI cost effectiveness data in the mid 1990s, interventional cardiology has undergone significant changes. Novel techniques, equipment, designs, and adjuvant treatments (such as the antiplatelet agents clopidogrel and abciximab) over the past decade have all contributed to major improvements in both acute and long term outcomes with reductions in repeat revascularisation, readmission, and mortality rates. Furthermore, in this period the UK has witnessed a major increase in the number of coronary interventional procedures leading to a substantial reduction in the cost of PCI. Therefore, re-evaluation of any one of the models we have described using current price tags and projected outcomes should in theory increase effectiveness of primary PCI in comparison to thrombolysis. It is also vital to note that thrombolysis has undergone minimal change during the same time frame. Second and third generation tissue plasminogen derivatives, which are now increasingly used by health care trusts in the UK, remain expensive and their mid to long term clinical outcome inferior to that of primary PCI.

It is also important to note that all cost analyses data to date are derived from randomised controlled trials with stringent inclusion and exclusion criteria. Therefore, information from a real world primary PCI service is vital in order to have a meaningful analysis of the cost of running a comprehensive primary PCI service.

Adherence to the four criteria as proposed by Lieu and colleagues on volume of workload and the use of existent cardiac facilities are vital and highly applicable to the NHS.^{8,9} Primary PCI programmes within the NHS must make use of existing facilities and there is a need to explore more efficient systems by optimising the volume and concentration of expertise in designated regional STEMI centres. Furthermore, the use of these facilities, which already have complex staffing arrangements to provide round the clock catheterisation and cardiothoracic services, should prevent the spiralling of staffing costs. However, the applicability of such models to the rural parts of the country remains questionable, where alternative reperfusion strategies such as pre-hospital thrombolysis and/or a hybrid thrombolysis-PCI programme may be of greater value.

Do we have a possible future model for an efficient NHS primary PCI programme?

The North-West London Primary PCI Programme has been set up to investigate some of the outstanding issues regarding the cost effectiveness of primary PCI within the framework of the NHS. The programme utilises the principles outlined in previously published health economic models.^{8,9} It is based on a dynamic "hub and spoke" model, with one established central tertiary cardiac centre and three high volume district general hospitals. The London Ambulance Service is used for rapid direct and/or inter-hospital transfer of acute STEMI patients. Since its inception in October 2003 the service has been rolled out in a stepwise manner to surrounding hospitals and represents the first comprehensive regional 24/7 primary PCI service. Currently it treats on average a minimum of one patient every day.

Meticulous cost analysis, including information on the cost savings achieved with reductions in length of hospital stay, re-admission and repeat procedure rates, as well as information on medium to long term complications should over the next two years provide accurate information on the viability of this model as a 24/7 urban NHS primary PCI programme. Furthermore, these data will be the first "real world, non-trial" evidence of outcomes and costs for a comprehensive primary PCI programme.

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