Percutaneous stenting of incidental unilateral renal artery stenosis: decision analysis of costs and benefits

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 prophylactic percutaneous transluminal angioplasty with stent placement (PTA-S) for patients with renal artery stenosis (RAS). This was compared against therapeutic PTA-S being delayed until symptoms worsen. No "do nothing" option was considered.

Type of intervention
Treatment for RAS, and the prevention of worsening of symptoms.

Economic study type
Cost-utility analysis.

Study population
The target study population was hypothetical patients, aged 61 years, with RAS. No inclusion or exclusion criteria were stated.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were gathered from studies published between 1993 and 2000, although one study was undertaken in 1984. The cost data were taken from national sources that were published at the time of the study. The price year was 1999.

Source of effectiveness data
The effectiveness data were derived from a number of published studies.

Modelling
A Markov-style decision analysis model was developed to predict the future health pathways of the patient. The model consisted of several distinct health states. It was based upon the clinical characteristics of a prospectively identified cohort.

Outcomes assessed in the review
The parameters used in the Markov model included:
state transition probabilities for RAS progression, contralateral RAS progression, bilateral RAS progression to end-stage
renal disease (ESRD), developing ESRD with chronic renal failure, and developing ESRD with uncorrected bilateral RAS;

mortality rates;

incidence of non-RAS hypertension;

incidence of non-RAS renal insufficiency;

the sensitivity and specificity of magnetic resonance angiography; and

the sensitivity and specificity of diagnostic angiography.

Estimates were also provided for the success rates of hypertension medication, surgery and stenting, and the rates of azotemia stabilised or improved by surgery or stenting.

Study designs and other criteria for inclusion in the review
The authors developed a decision analysis model, using Markov techniques, to predict the health pathways of patients with RAS, following PTA-S or delayed PTA-S. The parameters for the model were populated using findings from published literature. The authors did not state any exclusion or inclusion criteria.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The effectiveness data were derived from 17 studies. The cost data were taken from three published studies, as well as Professional Reimbursement databases.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The values of the parameters used in the Markov model were as follows.

The state transition probabilities were:

for RAS progression, 12% (range: 5 - 20);

for contralateral RAS progression, 5% (range: 2 - 10);
for bilateral RAS progression to ESRD, 3% (range: 1 - 5);
for developing ESRD with chronic renal failure, 0.6% (range: 0.2 - 0.8); and
for developing ESRD with uncorrected bilateral RAS, 3% (range: 2 - 5);

The mortality rates were 3% (range: 2 - 5) for moderate or high-grade RAS, 12% (range: 5 - 15) with bilateral RAS, and 29% (range: 2 - 40) with ESRD.

The incidence of hypertension and high-grade RAS was 72% (range: 50 - 95).

The incidence of renal insufficiency and bilateral RAS was 50% (range: 30 - 80).

The incidence of non-RAS hypertension was 4.5% (range: 1 - 10).

The incidence of non-RAS renal insufficiency was 0.9% (range: 0.4 - 1.0).

The sensitivity of magnetic resonance angiography was 93% (range: 88 - 100) and the specificity was 83% (range: 70 - 100).

The sensitivity of diagnostic angiography was 99% (no range given) and the specificity was 99% (no range given).

Mortality was 5% (range: 4 - 17) in surgery and 1% (range: 0 - 1) in stenting.

The success rates of hypertension medication were 90% (range: 60 - 95) in moderate RAS and 50% (range: 40 - 60) in high-grade RAS.

The utility associated with living with hypertension was 0.826.

The quality of life estimate for living with ESRD was 0.462.

**Measure of benefits used in the economic analysis**
The main measure of benefit used in the study was the quality-adjusted life year (QALY). The QALY estimates were taken from a published study in which the QALY values were derived from the expert opinion of 17 health care workers, using the time trade-off method.

**Direct costs**
The direct costs measured in the study were surgery, angioplasty or stenting, magnetic resonance angiography, diagnostic angiogram, antihypertensive medication (controlled and uncontrolled), azotemia medication, initiating antihypertensive medication, and dialysis. The costs were based on a combination of existing databases and expert opinion. The costs and the quantities were reported separately. All the costs were discounted at a rate of 3% per annum, and were reported for the price year 1999.

**Statistical analysis of costs**
No statistical analysis of the costs was undertaken.

**Indirect Costs**
No indirect costs were included in the study.

**Currency**
US dollars ($).
Sensitivity analysis
A one-way sensitivity analysis was carried out on all parameters within the model. The ranges were chosen arbitrarily, but they appear to have represented the ranges observed in the literature reviews. A two-way sensitivity analysis was undertaken on the most important parameters.

Estimated benefits used in the economic analysis
The authors stated that prophylactic PTA-S was associated with greater life expectancy than delayed therapeutic PTA-S (11.3 years compared with 10.8 years).

QALYs gained for the two strategies were 10.9 (prophylactic PTA-S) and 10.3 (delayed PTA-S), respectively. Therefore, prophylactic PTA-S was associated with 0.6 more QALYs per patient than delayed therapeutic PTA-S. The outcomes were measured over the remainder of the patient's lifetime.

Cost results
Prophylactic PTA-S was associated with greater costs (discounted at 3% per year) over the remainder of the patient's lifetime than delayed therapeutic PTA-S ($23,664 compared with $16,558).

Therefore, the incremental cost was $7,106. The cost of adverse events was not considered in the analysis.

Synthesis of costs and benefits
The authors combined the incremental costs and effectiveness to produce an incremental cost-effectiveness ratio (ICER). The ICER was $12,466 per QALY gained for prophylactic PTA-S compared with delayed therapeutic PTA-S.

The authors showed that the findings of the model findings remained robust to the variations investigated in the sensitivity analysis. The parameters with the greatest impact on the ICER were the cost of stents, the probability of ipsilateral stenosis progression from moderate to high-grade, the probability of the contralateral artery progressing from normal to moderate stenosis, and the frequency of restenosis after PTA-S.

The ICER exceeded $50,000 per QALY at only the extreme points of the two-way sensitivity analysis.

For the one-way sensitivity analysis, only lowering the incidence of contralateral artery RAS progression to less than 2% (base-case value was 5%) meant that the ICER exceeded $50,000.

Authors' conclusions
Prophylactic percutaneous transluminal angioplasty with stent placement (PTA-S) was both more effective and more costly than delayed therapeutic PTA-S. However, the incremental cost-effectiveness ratio (ICER) showed that prophylactic PTA-S was a cost-effective option. Nevertheless, the authors cautioned against using these findings for policy-making, until rigorous support for the long-term effects is found.

CRD COMMENTARY - Selection of comparators
Prophylactic PTA-S was compared against delayed therapeutic PTA-S. The authors justified their choice of the comparators by citing recent evidence of the effectiveness of both methods. No "do nothing" option was included in the review.

Validity of estimate of measure of effectiveness

Validity of estimate of measure of benefit
The authors reported the benefits as QALYs. QALYs are an appropriate summary benefit measure and allow for meaningful comparisons with other studies. The QALYs were measured using an appropriate technique (the time trade-off approach). However, the estimates were taken from expert clinicians rather than the patients themselves. There is considerable debate as to which source is more appropriate, therefore you should consider the usefulness of this approach for your own purposes. The authors do not appear to have reported the benefits in a selective manner.

Validity of estimate of costs
The costs were calculated from the perspective of the health care provider only (i.e. only direct costs were included, rather than indirect costs such as lost productivity due to time off work). The costs included in the analysis appear to have been reasonably representative of the true costs associated with each intervention strategy. All the costs were appropriately discounted.

Other issues
The authors acknowledged some limitations of their study, such as the lack of evidence for the long-term effects of each intervention strategy. It was also noted that, in the "real world", other factors may affect the effectiveness of each intervention. For example, the diameter of the renal arteries, or the presence of accessible renal arteries, will have an important impact on the decision for treatment. The authors offered little in comparison with published studies, although they stated that this was due to the lack of existing studies in this area.

Implications of the study
Although prophylactic PTA-S appears to have been cost-effective, it was recommended that firm conclusions should only be drawn when more rigorous evidence on the long-term effects of each treatment strategy becomes available.

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