Renal artery stenosis: cost-effectiveness of diagnosis and treatment

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 study examined five strategies of diagnosis and/or treatment of renal artery stenosis. These were digital subtraction angiography (DSA), computed tomographic (CT) angiography, magnetic resonance (MR) angiography, immediate tentative percutaneous revascularisation, and medical therapy (antihypertension medication).

In the DSA strategy, diagnostic DSA and subsequent revascularisation were carried out on different days.

In both the CT and MR angiography strategies (minimally invasive options), a revascularisation procedure was scheduled only if the diagnostic studies depicted stenosis. No further diagnostic tests were performed in the case of negative results.

In the strategy based on immediate tentative percutaneous revascularisation, all patients suspected of having renovascular hypertension underwent percutaneous revascularisation.

Finally, in the medical therapy option, patients did not undergo any imaging work-up for renal artery stenosis.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-utility analysis

Study population
The study population comprised a hypothetical cohort of patients suspected of having renovascular hypertension. Suspicion of renovascular hypertension was based on a diastolic blood pressure of 95 mmHg or higher and one or more clinical signs suggestive of renovascular hypertension. The typical patients were 50 years of age. Male and female patients were considered separately. Alternative age cohorts were considered in the sensitivity analysis.

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

Dates to which data relate
The clinical data were derived from studies published between 1987 and 2004. Resource use was based mainly on data reported in a study published in 2004. The price year was 2000.

Modelling
A Markov model was constructed in a hypothetical cohort of patients using published evidence. A schematic representation of the model structure was provided. The time horizon of the model was lifetime. First-order Monte-Carlo simulations were performed in order to account for variability within patient groups. An initial standard decision tree incorporated the outcomes associated with true and false positive and negative diagnostic test results, and patients then moved on to health states on the basis of their condition. The cycle length was not explicitly reported, but it might have been 1 year.

Study designs and other criteria for inclusion in the review
The clinical data used as model inputs were:

prevalence of disease,

the sensitivity and specificity of diagnostic procedures,

the rates of complications associated with some procedures, and

follow-up data such as mortality rates, risk of myocardial infarction, major stroke and dialysis.

**Sources searched to identify primary studies**

Most of the clinical data were derived from the Renal Artery Diagnostic Imaging Study in Hypertension (RADISH), a multi-centre trial that was carried out in The Netherlands. Details of this study were provided in an appendix. Some data were based on personal communications from a university hospital in The Netherlands. Complications after revascularisation were taken from a literature review. The remaining clinical estimates were derived from published studies, the design of which was unclear, other than that one was a large Dutch study.

**Methods used to derive estimates of effectiveness**

The approach used to identify the primary studies was not explicitly described. The authors did not report the details of a review of the literature. The authors extracted information from the RADISH when available, and used other published sources only when data were not identified from this pivotal trial.

**Measure of benefits used in the economic analysis**

The summary benefit measure used was the number of quality-adjusted life-years (QALYs). These were estimated using the decision model approach. Utility weights required to adjust life expectancy were obtained from the RADISH, which employed the EuroQol-5D instruments to elicit patient preferences for specific health conditions. Missing utility values were obtained from the literature. Temporary disutility from procedures and treatments were also incorporated into the model, using measurements based on a visual analogue scale (again, from the RADISH). Future benefits were discounted at an annual rate of 3%.

**Direct costs**

The analysis of the costs was carried out from a societal perspective. It included the direct costs of procedures and laboratory tests such as personnel, materials and equipment. Specifically, the analysis considered the costs of hospital stay, outpatient visits, travel expenses, home care, medications and general practitioner visits. Overhead and housing expenses were also included as a percentage of the total costs. The unit costs were presented in the appendix, but there was little information on resource use. Much of the data on resource consumption appear to have been derived from the RADISH. Procedural and laboratory costs were available from the University Hospital Maastricht, while medication costs were taken from official Dutch price lists. The costing was performed in accordance with Dutch guidelines using official national sources. Discounting was relevant, as long-term costs were evaluated, and an annual rate of 3% was applied. The price year was 2000.

**Statistical analysis of costs**

The costs and quantities were treated deterministically.

**Indirect Costs**

The cost analysis also included indirect costs such as time spent by family and friends in providing informal care, and patient time costs arising from the inability to perform usual activities. The cost of informal care and housekeeping was derived by using a shadow price corresponding to an hourly wage rate of a cleaner. Productivity losses were estimated from national wages in the labour market and using the friction cost approach. Resource use appears to have been based on data from the RADISH. As in the analysis of the direct costs, the annual discount rate was 3% and the price year was 2000.

**Currency**

Euros (EUR). The exchange rate from US dollars ($) was $1 = EUR 1.08.
Sensitivity analysis
A deterministic univariate sensitivity analysis was carried out to address the issue of uncertainty. Key clinical and economic model inputs were varied. Ranges of values appear to have been derived from the literature, although this was not explicitly stated. Alternative patient populations such as 60-year-old men and 40-year-old women were also considered. The authors stated that the model results were based on first-order Monte Carlo simulations, but only point estimates for total costs and benefits were presented.

Estimated benefits used in the economic analysis
For a 50-year-old man, the expected discounted QALYs were 11.866 with medical therapy, 12.088 with MR angiography, 12.163 with CT angiography, 12.195 with DSA and 12.265 with immediate tentative revascularisation (most effective strategy).

For a 50-year-old woman, the expected discounted QALYs were 13.381 with medical therapy, 13.731 with MR angiography, 13.749 with CT angiography, 13.902 with DSA and 13.937 with immediate tentative revascularisation (most effective strategy).

Cost results
For a 50-year-old man, the expected discounted costs were EUR 60,841 with medical therapy, EUR 56,890 with MR angiography, EUR 55,191 with CT angiography, EUR 55,570 with DSA and EUR 54,415 with immediate tentative revascularisation (least costly strategy).

For a 50-year-old woman, the expected discounted costs were EUR 70,980 with medical therapy, EUR 66,731 with MR angiography, EUR 63,970 with CT angiography, EUR 63,079 with DSA (least costly strategy) and EUR 63,329 with immediate tentative revascularisation.

Synthesis of costs and benefits
Incremental cost-utility ratios were calculated in order to combine the costs and benefits of the alternative strategies.

The incremental analysis showed that, for a typical 50-year-old man, immediate tentative revascularisation was the dominant strategy, as it was the most effective and the least expensive.

In a typical 50-year-old woman, DSA was the reference strategy, and the incremental cost per QALY gained with immediate tentative revascularisation was EUR 7,143. The remaining strategies were all dominated (less effective and more expensive).

The strategy of immediate tentative revascularisation also dominated the other diagnostic options in the two alternative patient populations (60-year-old men and 40-year-old women).

The results of the sensitivity analysis basically confirmed the base-case findings, with some exceptions. For male patients, the results were sensitive to variations in the prior probability of renal artery stenosis and the sensitivity of MR and CT angiography. Immediate tentative revascularisation was the dominant strategy if the prior probability of renal artery stenosis was greater than 11%, and if the sensitivity of MR angiography ranged from 88 to 94%. For a sensitivity of greater than 95% for MR angiography, immediate tentative revascularisation remained the preferred strategy, with an incremental cost per QALY gained of EUR 6,379. Similar conclusions were achieved for female patients.

Authors' conclusions
The authors concluded that, under most scenarios for both male and female patients, immediate tentative revascularisation was the most cost-effective strategy for suspected renal artery stenosis. The unfavourable results associated with minimally invasive diagnostic procedures such as computed tomographic (CT) angiography and magnetic resonance (MR) angiography were due to the poor accuracy of these techniques. The analysis revealed that improving the accuracy of these diagnostic approaches would make them more cost-effective from a societal perspective.
CRD COMMENTARY - Selection of comparators

The rationale for the choice of the comparators was clear. DSA represented the reference test for the diagnosis of renal artery stenosis, while minimally invasive strategies have been recently proposed. Medical therapy and immediate tentative percutaneous revascularisation were also included to cover all possible options for the management of the patient population considered in the study. You should decide whether these are valid comparators in your own setting.

Validity of estimate of measure of effectiveness

The analysis of clinical estimates was based on published values, but the approach used to derive these estimates was not clear. The authors did not state whether a systematic review of the literature was undertaken to identify these studies. Most of the evidence came from a large clinical trial that was not described in detail but that should, in principle, have provided valid estimates, given the nature of the study. There was little information on the other sources of data, which limits the possibility of assessing the robustness of the clinical inputs. Some data were based on the opinions of a Dutch expert. The authors pointed out the uncertainty surrounding some clinical estimates. However, the robustness of key clinical assumptions was investigated in the sensitivity analysis.

Validity of estimate of measure of benefit

The use of QALYs as the summary benefit measure was appropriate in that they capture the impact of the diagnostic interventions on both quality of life and survival, which are both relevant dimensions of health for patients suspected of having renal artery stenosis. Details of the sources of the utility weights and the instruments used to elicit these values were reported and were appropriate. Discounting was performed, in accordance with international recommendations for estimation of future benefits. QALYs can be compared with the benefits of other health care interventions.

Validity of estimate of costs

The analysis of the costs was carried out from a broad perspective, and all the relevant categories of costs appear to have been included. A breakdown of the cost items was provided in the online appendix. The approaches used to derive costs were explicitly reported and were consistent with the Dutch setting. Resource use was mainly based on data observed in a large clinical trial conducted in the authors' setting. Statistical analyses of the costs were not performed, but key cost estimates were varied in the sensitivity analyses. The price year was reported, which will facilitate reflation exercises in other time periods. Currency exchange rates were reported.

Other issues

The authors stated that comparisons with published economic evaluations were difficult because of differences in the model assumptions, perspective of the study and types of comparators. However, when comparisons could be made, conclusions similar to those published in the current study appear to have been reached. The bulk of the information on the cost-effectiveness analysis was presented in an online appendix, where all clinical and economic data together with their sources were presented. The issue of the generalisability of the study results to other settings was explicitly addressed and the authors stated that, although differences in health care systems might limit the external validity of the current analysis, the robustness of the study conclusions suggested that these results could be extrapolated to other countries such as the USA.

Implications of the study

The study results support the use of immediate tentative revascularisations for the diagnosis and treatment of suspected renal artery stenosis. However, in patients for whom there is a low suspicion of disease, less invasive procedures such as CT angiography might be considered the most cost-effective approach.

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