Cost-effectiveness and clinical effectiveness of catheter-based renal denervation for resistant hypertension

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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.

CRD summary
The study examined the cost-effectiveness of catheter-based renal denervation in resistant hypertensive patients with no prior cardiovascular events. The authors concluded that renal denervation was likely to be a cost-effective alternative to standard of care as it resulted in lower cardiovascular morbidity and mortality. The analysis used a conventional cost-effectiveness framework that considered various aspects of uncertainty. The authors’ conclusions appear appropriate.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The study examined the cost-effectiveness of catheter-based renal denervation in resistant hypertensive patients with no prior cardiovascular events.

Interventions
Renal denervation plus standard of care (three or more hypertensive medications) was compared to standard of care alone.

Location/setting
USA/Hospital.

Methods
Analytical approach:
The analysis was based on a state-transition Markov model with two time horizons: 10 years and lifetime. The authors stated that a societal perspective was adopted.

Effectiveness data:
Clinical inputs were based on evidence taken from systematic searches of literature catalogued in PubMed. Treatment effect and patients characteristics were obtained from the randomised Simplicity HTN-2 trial which compared renal denervation plus standard of care with standard of care in patients resistant to hypertensive drugs. Transition probabilities were calculated on the basis of published large-scale cohort studies such as the Framingham Heart Study. Mortality was based on USA estimates. Reductions in systolic blood pressure were key inputs of the model.

Monetary benefit and utility valuations:
Utility valuations were taken from published studies but details were not provided.

Measure of benefit:
Quality-adjusted life-years (QALYs) and life-years were used as summary benefit measures and were discounted at an annual rate of 3%.

Cost data:
The economic analysis included costs of stroke, myocardial infarction, heart failure, angina pectoris, end-stage renal disease, hypertension and renal denervation. Costs were presented as macro-categories (no breakdown of items provided). All economic data (including cost and cost-effectiveness analyses) were taken from published sources.
obtained from a review of the literature (no details on these studies were reported). Costs were in US dollars ($) and were discounted at a yearly rate of 3%. The price year was 2010.

Analysis of uncertainty:
Various approaches were used to deal with the issue of uncertainty. One-way sensitivity analyses varied all parameters. Ranges were based on the authors’ opinions or published sources. Alternative assumptions about baseline systolic blood pressure and other model pathways were considered. Threshold analyses were performed to identify how large changes to individual inputs needed to be to exceed the conventional threshold of $50,000 per QALY. A comprehensive probabilistic sensitivity analysis was conducted using distributions based on published sources or expert opinions.

Results
Renal denervation increased costs by $2,013 over a lifetime compared to standard of care. Life-years were 17.07 with standard of care and 18.37 with renal denervation. QALYs were 12.07 with standard of care and 13.17 with renal denervation. The incremental cost per life-year gained with renal denervation over standard of care was $2,715 and the incremental cost per QALY gained was $3,071.

Sensitivity analyses showed the robustness of base case findings to plausible variations in model inputs. The most influential inputs were renal denervation-associated systolic blood pressure reduction, baseline systolic blood pressure and costs for renal denervation therapy. Only wide variation of these parameters made the renal denervation not cost-effective using the $50,000 per QALY threshold. Even assuming an annual decrease in treatment effect, renal denervation remained cost-effective unless the decrease in systolic blood pressure reduction was greater than 3.0mmHg/year.

Probabilistic sensitivity analysis produced a 95% credible interval that ranged from cost-saving (renal denervation was dominant) to $31,460 per QALY. The incremental cost per QALY was below the threshold of $30,000 in 97% of the simulations and below $50,000 per QALY in 99.6% of the simulations.

Authors’ conclusions
The authors concluded that renal denervation was likely to be a cost-effective alternative to standard of care as it resulted in lower cardiovascular morbidity and mortality.

CRD commentary
Interventions:
The selection of comparators was appropriate as the proposed intervention was compared to the conventional pattern of care for these patients.

Effectiveness/benefits:
Clinical inputs were obtained from published sources selected by means of a systematic review of the literature that should have identified relevant studies. Treatment effect was appropriately taken from a randomised controlled trial that was likely to have high internal validity. Transition probabilities were taken from well-known observational studies. Assumptions on long-term treatment effect were made but varied in the extensive sensitivity analysis.

Use of QALYs was appropriate given the impact of disease on mortality and morbidity. No details of sources of utility weights were provided.

Costs:
The authors stated that a societal perspective was adopted but the whole economic analysis was not clear as most details of the analysis were not reported. The cost categories included in the analysis were stated explicitly and costs were presented as macro-categories associated to the health states considered in the model. This made it unclear whether both direct and productivity costs were included. Costs were taken from published sources that were likely to be representative of the USA setting but these were not described. The price year was reported clearly but overall the economic analysis was not reported transparently.

Analysis and results:
The study results were presented selectively as the projected costs were not reported clearly. An incremental approach
was appropriate to synthesise costs and benefits of the various strategies. Model results were validated using real-world data. Appropriate approaches were used to investigate the issue of uncertainty and the findings were clearly illustrated (especially in the online appendix). The authors acknowledged some limitations of their analysis mostly related to the need for some simplification and assumptions. Study findings were specific to the USA setting and did not appear to be directly transferable to other jurisdictions.

Concluding remarks:
The analysis used a conventional cost-effectiveness framework that considered various aspects of uncertainty. The authors’ conclusions appear appropriate.

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