Power Doppler imaging: initial evaluation as a screening examination for carotid artery stenosis

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
Power Doppler imaging (PDI) as a screening examination for carotid artery stenosis in patients routinely referred for carotid artery imaging.

Type of intervention
Screening and diagnosis.

Economic study type
Cost-utility analysis.

Study population
Patients routinely referred for carotid artery imaging at a large, private, multispecialty clinic.

Setting
Hospital. The economic analysis was carried out in Canada.

Dates to which data relate
Effectiveness data in the principal pilot study corresponded to patients examined between April and September 1997. Effectiveness data in the validation pilot study corresponded to patients examined between May and October 1997. Some effectiveness data were based on assumptions from two studies published in 1995 and 1997. Resource consumption data were based on a survey, the date of which was not reported. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the final outcomes was based on a single study and assumptions made by the authors (as conservative assumptions or assumptions based on another published study).

Link between effectiveness and cost data
Costing was performed based on a survey of informed radiologists regarding the resources consumed by the power Doppler imaging relative to duplex Doppler imaging. The comparison largely involved time. The analysis of time included set-up and clean-up times rather than merely the time to obtain images.

Study sample
Power calculations were not used to determine the sample size. The study sample in the principal pilot study (comparison between PDI and DDI) consisted of 100 patients with an average age of 66 years (range: 40-89) and 200
vessels. No patients refused to participate in the study. The study sample in the validation pilot study (comparison between PDI and digital subtraction angiography (DSI)) comprised 20 patients with an average age of 72 years (range: 46-87) and 40 vessels.

Study design
This was a prospective, blinded, cohort, pilot study, carried out in two centres:

(1) Ochsner Clinic, New Orleans - initial pilot study using duplex doppler; and

(2) teaching hospital, Pittsburgh - second, validation pilot study using angiography.

The duration of the follow-up appears to have been until the establishment of a diagnostic examination. Loss to follow-up was not reported. PDI was used only to demonstrate flow in the vessel and to assess the degree of stenosis. Each of the two imaging studies was performed independently by a different technologist and was interpreted offline by a different radiologist, without knowledge of the results of the other study. The degree of stenosis on the PDI images was estimated visually by the interpreting radiologist. In the validation pilot study, a prospective, blinded comparison of PDI with DSA, the reference-standard method, was conducted at a teaching hospital. The degree of stenosis depicted on the PDI and DSA images was determined by means of measurement with a ruler.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been intention-to-treat. The accuracy outcomes were the percentage of diagnostic-quality images produced, sensitivity, specificity, the area under the receiver operating characteristic (ROC) curve ($A(z)$), and positive and negative predictive values (PPV and NPV). These accuracy measures were calculated for each of two definitions of disease:

- stenosis of 60% or greater but no occlusion (based on the Asymptomatic Carotid Atherosclerosis Study (ACAS));
- and stenosis of 40% or greater but no occlusion (a definition based on the possibility of clinical trials broadening the suggested indications for surgery and the possibility of short-interval re-examination for patients near disease threshold).

Effectiveness results
PDI produced diagnostic-quality images in 89% of patients. Based on the ACAS disease definition the following results were achieved:

When the images of the patients with non-diagnostic examinations were regarded as positive, PDI had an $A(z)$ value of 0.87, sensitivity of 70%, specificity of 91%, PPV of 50%, and NPV of 95.8%.

Based on the second definition, sensitivity was 82%, specificity 81%, PPV 46%, and NPV 96%. The validation results were very similar.

Clinical conclusions
Overall, these research results indicate that power Doppler imaging seems to be a good screening examination for carotid artery stenosis; this proved to be true from the standpoints of both diagnostic accuracy and speed.

Modelling
A previously constructed and reported Markov model was re-run, with some modifications, to estimate costs and effects associated with each screening strategy. The model assumed that screening was applied to a general population of 65-year-old men.
Methods used to derive estimates of effectiveness
Authors’ conservative assumptions or assumptions based on another two published studies.

Estimates of effectiveness and key assumptions
It was assumed that there was an 80% risk in patients with stenosis genuinely 60% or greater. Other assumptions made based on two studies published in 1995 and 1997 were as follows: DDI sensitivity of 85% and specificity of 94%; conventional angiography sensitivity of 100% and specificity of 100%; MR angiography sensitivity of 67% and specificity of 95%.

Measure of benefits used in the economic analysis
The measure of benefits used was Quality-adjusted life-years (QALYs). The methods used to valuate utilities were not reported.

Direct costs
Costs were discounted. Some quantities were reported separately from the costs and some cost items were reported separately. The cost analysis covered the life-time expenditure for stroke-related health care and costs of screening procedures. The perspective adopted in the cost analysis was not explicitly specified. Costs for items of care were based on 60% of billed charges. Costs of the screening procedures were based on 125% of the national average Medicare payment. The price year was not specified.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
A series of one-way and two-way sensitivity analyses was performed based on regarding non-diagnostic PDI examination as negative, elimination of non-diagnostic PDI examinations, lower costs of PDI, and using more selective screening (prevalence of stenosis equal or greater than 60%).

Estimated benefits used in the economic analysis
In the base case, without an intervention consisting of screening and, if indicated, a definitive diagnosis and endarterectomy, the average member of the model cohort of 65-year-olds could look forward to slightly more than 11 QALYs. The intervention increased the number of QALYs by approximately 0.01 when the reference-standard method was DDI. The QALY gains associated with the intervention when the reference-standard method was MR angiography were 0.0085 and when it was conventional angiography (CA), 0.0070. QALYs were discounted at 3%.

Cost results
The discount rate was 3%. In the base case, without an intervention, life-time expenditure for stroke-related health care was $5,671. The intervention was associated with an increase in costs of $522 when the reference-standard method was DDI. The incremental costs associated with the intervention when the reference-standard methods were MR angiography and CA were $478, and $655, respectively.

Synthesis of costs and benefits
The incremental cost per QALY gained with PDI was $47,000 when the reference-standard method was DDI. The
corresponding values when the reference-standard methods were MR angiography and CA were $56,000 and $94,000, respectively. The sensitivity analyses identified multiple strategies for reducing the cost-effectiveness ratios to approximately $30,000-$40,000 per QALY.

**Authors’ conclusions**
The A(z) value for power Doppler imaging compares well with that for mammography, a generally accepted screening examination, and with most other imaging examinations. Power Doppler imaging is likely to be a reasonably accurate and cost-effective screening examination for carotid artery stenosis in asymptomatic populations.

**CRD COMMENTARY - Selection of comparators**
The strategy of using DDI, as the reference-standard method, was regarded as the comparator. MR angiography and conventional angiography were other reference-standards used in the cost-effectiveness comparisons. You, as a database user, should consider whether these are widely used health technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness results are likely to be internally valid given the prospective nature of the study design, and the validation study conducted. However, although the sample size appears to have been adequate, it was not justified by means of power calculations. Most of the effectiveness data incorporated in the Markov model were based on assumptions (conservative assumptions or assumptions based on the literature) the validity of which cannot be objectively assessed due to lack of sufficient information. The study sample appears to have been representative of the study population.

**Validity of estimate of measure of benefit**
Estimation of benefits was modelled using a Markov model. The instrument used to derive a measure of health benefit (techniques used to valuate preferences (utility values)) was not specified. For details the authors referred to another study published in 1997.

**Validity of estimate of costs**
Some quantities were reported separately from the costs. Adequate details of methods of cost estimation were not given. The price year, the perspective adopted in the cost analysis, and the sources of cost data were not reported. The components of the cost analysis were not reported in detail or in a systematic fashion. As a result, it is not possible to assess whether all cost components were included in the total cost analysis. The effects of alternative procedures on indirect costs were not addressed. Costing was based on a survey and not on the same patient sample as that used in the effectiveness analysis. The generalisability of the cost results was enhanced by the fact that charges were converted to costs and other relevant features of the analysis were given.

**Other issues**
The authors’ conclusions appear to be justified given the sensitivity analyses performed to address uncertainties in the data and the relative strengths of the pilot study design and validation analysis. The issue of generalisability to other settings was not addressed, although appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was addressed; the authors noted that the study had a population of 71% asymptomatic subjects and 88% of the vessels had less than 60% stenosis, making it immune to the type of bias arising from the inclusion of “the sickest of the sick”.

**Implications of the study**
The study tried to establish the merits of a much larger, and therefore much more expensive, multicentre trial in a purely screening population to evaluate definitively the value of PDI in screening.
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None stated.

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