Contrast-enhanced MR angiography and digital subtraction angiography in living renal donors: diagnostic agreement, impact on decision making, and costs

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 authors studied contrast-enhanced magnetic resonance angiography (MRA) and digital subtraction angiography (DSA). MR images were obtained using a 1.5-T MR scanner (Signa CV/I, GE Healthcare) with a torso phased-array coil. Digital subtraction images were obtained using a 38-cm field of view and an image matrix of 1,024 x 1,024 pixels (Integris V3000, Philips Medical Systems; or Angiostar Plus, Semaens Medical Solutions).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised potential living renal donors. The inclusion criteria specified that individuals were renal donor candidates without contraindications found during the routinely performed work-up for kidney donation. Donors were excluded if there were contraindications for undergoing MR imaging (e.g. pacemaker) or angiography, or for receiving iodine contrast medium.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness and resource use data were collected for patients enrolled between May 2000 and September 2001. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
There was no report of power calculations being carried out to estimate the impact of chance on the results. The authors recruited their convenience sample by including consecutive patients presenting at the study setting, who met the inclusion and exclusion criteria. Of the 52 potential living renal donors, 42 were included in the study. The full
reasons for their exclusion were reported. Such reasons encompassed refusals to undergo one or other of the diagnostic tests, cancellations unrelated to the anatomy, problems with the scanner, and foreign metallic bodies in the patient that precluded scanning. The mean age of the sample was 48 years (standard error 2 years).

Study design
The authors designed a diagnostic case series analysis using both diagnostic techniques on all patients. The diagnostic techniques were performed on the same day to ensure fair comparisons. Two reviewers examined all the MR images, while a different set of two reviewers examined the DSA images. The two reviewers worked together and formed a consensus about parenchymal abnormality, duplication or obstruction of the collecting systems, number and localisation of renal arteries, presence of renal artery stenosis, any findings suggestive of fibromuscular dysplasia, and the number and localisation of renal veins. The reviewers were blinded to the series of images that they were not reviewing and to the extensive workup for kidney donation. The study was conducted at a single tertiary referral centre. Separate evaluations of the images were made for decision-making purposes, and again the reviewers were blinded. When reviewing the MR images, the evaluators assessed whether a further subtraction diagnosis would have been required.

Analysis of effectiveness
The analysis was based on the opinions of the individuals who reviewed the angiography images. The primary outcomes were the diagnostic agreement between the reviewers of the images and the decision-making outcomes. The decision-making outcomes were which side should be chosen for nephrectomy and the reasons for that choice, and the necessity of and reasons for an additional DSA examination after MRA. A weighted kappa analysis was used to determine agreement between the conclusions drawn for each technology of interest.

Effectiveness results
The authors reported that no complications from contrast-enhanced MRA or DSA were found.

Agreement between the images was reported as "excellent" (weighted k = 0.82) for the detection of supernumerary arteries and "moderate" (k=0.41) for the presence of arterial stenosis.

A decision could be made in 95% of cases for contrast-enhanced MRA and 88% of cases for DSA.

The overall difference between decisions (whether a decision was possible and from which side to harvest) based on the two techniques was not statistically significant, (p=0.07).

Additional DSA after contrast-enhanced MRA was requested in 10 cases (24%), of which five provided new information.

Clinical conclusions
The authors concluded that "contrast-enhanced MRA was superior to DSA in detecting renal vascular abnormalities and depicting parenchymal abnormalities and did not lead to a significantly different choice of kidney for harvesting”.

Measure of benefits used in the economic analysis
The authors did not estimate a summary measure of health benefits. Therefore, the study was categorised as a cost-consequences analysis.

Direct costs
The costs were estimated from the perspective of the hospital, with the aim of establishing the differences in the use of resources and costs of diagnostic tests for each of the technologies. The authors collated information concerning "all relevant items of health care in the preoperative evaluation of potential renal donors". This included the costs of the
imaging tests, hospital costs after the imaging tests, and costs incurred because of test procedure complications. The cost of the imaging test encompassed personnel, supplies such as film, investment cost for equipment, equipment servicing, construction, supporting departments, renting hospital floor space and overheads. The costs seem to have been estimated directly from the study hospital, although this was not explicitly stated. In addition, although a timeframe was not explicitly reported, the analysis seems to have focused on the immediate costs associated with diagnosis and, therefore, discounting was not required. The price year was 2000. The authors aimed to estimate the costs of the three diagnostic strategies: contrast-enhanced MRA, DSA, and contrast-enhanced MRA followed by DSA only if necessary. The latter strategy took the number of additional DSA procedures necessary after inconclusive MR findings into consideration.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
Indirect costs estimating the broader economic impact of the technologies were not estimated and were not relevant to the perspective adopted.

**Currency**
Euros (EUR) converted to US dollars ($). The conversion rate was EUR 1.00 = $1.24 at 15th July 2004.

**Sensitivity analysis**
There was no report that sensitivity analyses were carried out.

**Estimated benefits used in the economic analysis**
Not relevant. See the 'Effectiveness Results' section.

**Cost results**
The cost of contrast-enhanced MRA was EUR 346 ($429). It was driven principally by the large investment in scanning equipment and the cost of gadolinium.

The cost of DSA was EUR 435 ($539). This was driven principally by the costs of hospital stay for observation, personnel and materials.

The cost of contrast-enhanced MRA followed by DSA only if necessary was EUR 449 ($557).

**Synthesis of costs and benefits**
Not relevant.

**Authors’ conclusions**
Contrast-enhanced magnetic resonance angiography (MRA) alone was less expensive than digital subtraction angiography (DSA), while the strategy of contrast-enhanced MRA plus DSA if necessary was similar in expense. The outcomes were reported to be comparable between the two technologies.

**CRD COMMENTARY - Selection of comparators**
The authors compared DSA with contrast-enhanced MRA. The former (DSA) seems to have been standard practice in the authors' setting. The latter (contrast-enhanced MRA) was a relatively newly available technology which, despite
favourable evidence in terms of its effectiveness, has had an uncertain impact on decision-making. The authors hoped to increase the body of evidence relating to decision-making. Readers would need to assess for themselves whether these are relevant comparators in their own setting.

Validity of estimate of measure of effectiveness
The authors designed a case series diagnostic study. They took every step to maintain the internal validity of this study, in particular by ensuring that the patients received both imaging techniques on the same day and that the reviewers were completely blinded. Statistical analyses were used to compare the similarity in results between the diagnostic images and resulting clinical decisions.

Validity of estimate of measure of benefit
The authors did not estimate a summary measure of health benefit. The study was therefore categorised as a cost-consequence analysis. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The authors clearly set out the perspective of their analysis and estimated costs relevant and appropriate to this perspective. Further to presenting the results, they also identified the key cost-drivers for each treatment strategy. The analysis might have been improved by considering costs as stochastic variables and employing sensitivity analyses to assess the impact of differences in cost over time and between settings. In addition, a breakdown of the total cost might have given readers a better understanding and enabled them to form their own conclusions. The price year was reported but, as the period for analysis extended for longer than one year, the costs observed in other years should have been reflated to 2000 using an appropriate measure.

Other issues
The authors were able to make comparisons between their own work and that already carried out, and suggested that their results "support previous published findings". The issue of generalisability was not considered, but it is limited by several factors. For instance, the use of institution-specific costs, the deterministic nature of the costs, and not carrying out some form of sensitivity analysis. Nevertheless, readers might be able to use the outline of methods to estimate costs in their own setting. The results were presented thoroughly and it should be noted that only a summary has been provided in this abstract; readers are referred to the original paper. The conclusions are an accurate reflection of the results presented and are appropriate to the authors' aims and objectives.

The authors noted several limitations were noted. For instance, not considering a strategy of all patients receiving both technologies, a possible bias toward MRA caused by the reviewers, the plan to assume kidneys were harvested laparoscopically, and the hospital rather than societal perspective adopted. The authors discussed these limitations and also described attempts to circumvent them and address their implications.

Implications of the study
The authors reported that their "results suggest that living renal donors should initially be evaluated with contrast-enhanced MRA". Further work to improve the quality of imaging pictures was implied, as was a longer term analysis of the outcomes.

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