GFR determined by nonradiolabelled iothalamate using capillary electrophoresis

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
Non-radiolabeled iothalamate using capillary electrophoresis (CE) in the measurement of glomerular filtration rate (GFR) in renal function assessment. The dose for the cold iothalamate was 300 mg (Cornay dye) for patients larger than 20 Kg given subcutaneously in the upper outer arm.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients attending a renal laboratory for GFR measurement by 125I-iothalamate. No further details were given.

Setting
Renal laboratory (clinic/outpatient). The economic study was carried Rochester, MN, USA.

Dates to which data relate
The main effectiveness data were derived from a single study conducted in 1997. Resource and cost data were taken from 1997 sources. The price year was not stated.

Source of effectiveness data
The estimates of the correlation rate of GFR between isotopic iothalamate and the CE-determined clearance and the coefficient of variation for the control GFRs over 20 days were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
One hundred patients attending a renal laboratory for GFR measurement by 125I-iothalamate were included in the analysis for measurement of GFR using cold iothalamate and 125I-iothalamate. Thirty-one additional patients were recruited after the initial data set was evaluated and a minor technical change in the sample handling was performed. The age range was 23 to 82 years. Pregnant or lactating women were not used for this study because of the standard isotopic techniques used. Power calculations to determine the sample size were not undertaken.
Study design
This was a cohort study in which all patients in the sample were tested using both the intervention and the comparator. The aim was to determine the degree of correlation between the two methods by means of regression analysis. The duration of the follow-up was not given. The loss to follow-up was not stated.

Analysis of effectiveness
The analysis of effectiveness was based on the whole sample and most closely represents the intention to treat method. The primary health outcomes were the correlation rate of GFR between isotopic iohexol and the CE-determined clearance and coefficient of variation for the control GFRs over 20 days.

Effectiveness results
The correlation coefficient of GFR measured by CE compared with 125I-iothalamate was 0.978. The mean GFR was 58 mL/min/1.73 m² by the CE method and 54.4 mL/min/1.73 m² using the isotope methodology. Additionally, 10 patients with relatively large increases in the GFR using the CE were analysed by vortexing the sample after filtration before analysis. The plasma iohexol levels were higher after vortexing so that the CE/125I-iothalamate clearance ratio decreased from 1.15 to 1.00. The correlation rate of GFR between isotopic iohexol and the CE-determined clearance was 0.99 and the means were 62 mL/min and 61 mL/min, respectively for the two methods. The coefficient of variation for the control GFRs over 20 days was 2.85%.

Clinical conclusions
This study shows an excellent correlation between standard 125I-iothalamate and cold iohexol measured by CE.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the analysis and as such the benefits are considered to be the same as the outcome measures. The implicit benefits intimated by the authors would be the avoidance of drug interference and the avoidance of complications and costs associated with isotopic materials.

Direct costs
Equipment costs using CE apparatus (clearance for the analyzer and injected materials and bladder monitoring) and 125I-iothalamate (iothalamate, gamma counter and isotope bladder probe) were included in the analysis. The quantities were not reported separately from the prices. The quantity/cost boundary adopted was the hospital. Discounting was not undertaken. The price year was not stated.

Statistical analysis of costs
Not undertaken.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
The correlation coefficient of GFR measured by CE compared with 125I-iothalamate was 0.978. The mean GFR was 58 mL/min/1.73 m2 by the CE method and 54.4 mL/min/1.73 m2 using the isotope methodology. Additionally, 10 patients with relatively large increases in the GFR using the CE were analysed by vortexing the sample after filtration before analysis. The plasma iothalamate levels were higher after vortexing so that the CE/125I-iothalamate clearance ratio decreased from 1.15 to 1.00. The correlation rate of GFR between isotopic iothalamate and the CE-determined clearance was 0.99 and the means were 62 mL/min and 61 mL/min, respectively for the two methods. The coefficient of variation for the control GFRs over 20 days was 2.85%.

Cost results
The amortized cost of the equipment over 5 years included a $1.64 cost/clearance for the analyzer and injected materials and $0.50 for bladder monitoring (11,000 clearance/5 years, $45,000 for CE apparatus and $5,000 for ultrasound probe). The cost of comparable studies using 125I-iothalamate were: $20 for the injected isotope and $3 for measuring the isotope and bladder monitoring ($750/mCi iothalamate, $28,000 for gamma counter and $5,000 for the isotope bladder probe). This resulted in savings of more than $20 per patient or $50,000 per year for the study's laboratory.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
GFR using cold iothalamate is cost-effective and allows the avoidance of exposure to isotopes as well as problems such as the disposal and short shelf life of isotopes. This technology could allow for replacement of 125I-iothalamate as a marker for GFR.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. Non-radiolabeled iothalamate has several advantages over standard methodologies for measuring GFR. However, several other potential comparators exist that use a variety of techniques for measuring GFR which were not included in the analysis of this study. You, as a user of this database, should consider if the intervention and comparator are relevant health technologies in your own setting.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis and as such the benefits are considered to be the same as the outcome measures. The data have not been used selectively but a full economic evaluation using one benefit measure would be required to assure greater validity.

Validity of estimate of costs
Resource quantities were not reported separately from the prices. As costs were only briefly addressed it is not possible to assess the implications of the cost-effectiveness analysis beyond the perspective of the laboratory addressed here.

Other issues
The authors' conclusions are likely to be justified for the technologies examined, given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. However, appropriate comparisons were made with other studies in terms of results obtained using different techniques for measuring GFR.

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None stated.
Bibliographic details

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Other publications of related interest
As the authors acknowledge the existence of other alternative techniques, which were not examined in this study, a more rigorous and inclusive economic evaluation is required to validate these results.

Indexing Status
Subject indexing assigned by NLM

MeSH
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