Review

Executive summary

A systematic literature review of spiral and electron beam computed tomography: with particular reference to clinical applications in hepatic lesions, pulmonary embolus and coronary artery disease

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Health Technology Assessment NHS R&D HTA Programme

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Objectives

The aim of this review was to identify publications relating to the use of spiral and electron beam computed tomography (CT), in order to draw conclusions about the effectiveness of latest generation CT devices. The Fineberg evaluative framework was used, with publications sought for all clinical applications at the levels of health economics, patient outcome and therapeutic impact. For diagnostic impact and diagnostic performance, specific clinical uses were selected: the investigation of liver lesions using spiral CT (SCT); the investigation of pulmonary embolism (PE) using SCT; and the diagnosis and prediction of coronary artery disease (CAD) using electron beam CT (EBCT).

Methods

Data sources

MEDLINE and BIDS-ISI formed the basis of the literature search. Other electronic resources searched included the Cochrane Library, EMBASE, Inside Information Plus, the System for Information on Grey Literature, and FirstSearch. Bibliographic listings of all retrieved articles were handsearched. In addition, manufacturers were contacted with a request for unpublished information.

Study selection

Study selection was a three-stage process using predefined inclusion and exclusion criteria. Non-English language papers were excluded. In the assessment of health economics, patient outcome, therapeutic impact and diagnostic impact, important validity criteria were identified and study compliance noted, but studies were not excluded on this basis. For studies of diagnostic performance, a checklist approach was used to record the risk of bias and methodological differences. Quantitative synthesis was performed only in the case of EBCT for CAD. The results of the checklists were incorporated into the data synthesis to assess the influence of biases and factors on the reported diagnostic performance.

Data extraction

Data extraction forms were used. Numerical values for the completion of 2×2 contingency tables were extracted when possible. Descriptive summaries were prepared for the other types of study when quantitative analysis was not feasible.

Data synthesis

Qualitative synthesis was used for the studies of health economics, patient outcome, therapeutic impact and diagnostic impact.

The results of studies of diagnostic performance for one out of three clinical applications were synthesised into summary receiver operator characteristic (SROC) curves. Study validity was investigated by using regression techniques to incorporate biases and factors into the quantitative analysis. For each bias or factor found to be significant (p < 0.05) its influence on the diagnostic performance was illustrated with SROC curves.

Results

- There was very little health economics evidence relating to either SCT or EBCT. Only one study approached acceptable standards for economic evaluation.
- Patient outcome or therapeutic impact was adequately addressed by nine studies: three for SCT and six for EBCT.
 - The indications from three studies on EBCT that addressed patient outcome are that EBCT (as opposed to no EBCT) may improve outcome in a variety of clinical scenarios, but results are by no means conclusive.
 - Insufficient information was found for qualitative synthesis regarding the therapeutic impact of the use of SCT and EBCT. It is likely that results will depend upon the clinical application and the comparator investigation.
- No studies were identified that were designed specifically to address the diagnostic impact of either modality.
 - The included studies that compared the detection performance of SCT for liver lesions with conventional CT found that SCT performed better, but disagreed about the size of lesion that was best detected.
 - There were conflicting findings when comparing SCT for the detection of liver lesions with alternative modalities other than conventional CT.
 - Insufficient information was found for qualitative synthesis that compared results from other modalities with SCT in PE, and with EBCT in CAD.

- From 1515 articles that satisfied the preliminary inclusion criteria on diagnostic performance in the three clinical application areas, 49 satisfied the inclusion criteria for the qualitative review, and 7 for quantitative analysis.
 - Four articles were included that measured the diagnostic performance of SCT applied to liver lesions against a gold standard, but no conclusions could be drawn from them because there was great variation among the individual studies. Those that compared performance with conventional CT showed an increase in the number of lesions detected by SCT of the order of 10%.
 - SCT detection performance for PE is better for the central vessels alone than for both central and peripheral vessels together.
 - Insufficient information for qualitative synthesis was found regarding the prediction of asymptomatic CAD by using EBCT.
 - Six studies on the diagnosis of symptomatic CAD using EBCT had a low specificity (high false-positive rate). The most likely role for EBCT is in excluding obstructive CAD in the older population.
 - Interobserver and intraobserver reproducibility of EBCT for CAD is acceptable, but interexamination reproducibility is not.
- A total of 11 studies of radiation dose were included in the review.
 - Of four studies comparing SCT dose with that of conventional CT, the general agreement was of an insignificant increase in dose over conventional CT, with SCT offering the potential for reducing the dose by increasing pitch.
 - Insufficient information for qualitative synthesis was found regarding the radiation dose in EBCT.

Conclusions

- MEDLINE and BIDS-ISI are comprehensive sources of references in this subject area.
- There is no strong evidence about any aspect of the use of latest generation CT at the health economics, patient outcome or therapeutic impact levels.
- SCT detects liver lesions that are not seen with conventional CT.
- EBCT has a low specificity when applied to the diagnosis of symptomatic CAD.
- While the evidence suggests EBCT use for population studies, it does not support its use to track CAD progression in individuals.
- The introduction of SCT will not cause a significant increase in radiation dose compared

with similar examinations performed with conventional CT.

Recommendations for research

Methodological:

- methodological research into the effect of searching only the major electronic databases and into factors that make publication bias less likely
- continued collaboration between reviewers in fields that are lacking in randomised controlled trials regarding the assessment of study quality
- further research into SROC methodology when applied to tests requiring unequal sensitivity and specificity
- horizon scanning to identify developments such as SCT that may rapidly become accepted before assessment has been performed
- the encouragement of imaging scientists both to perform better designed studies and to ensure that descriptions published in the literature are comprehensive.

Topic related:

- updating of this review, especially with regard to long-term follow-up of EBCT in asymptomatic individuals, and for SCT in PE
- a multicentre study of SCT for liver lesions, using a group of affected patients to investigate optimum automatic protocols, and with careful control of intrinsic factors
- studies on the reduction of contrast medium dose, using automatic injection protocols, concentrating on the detectability of liver lesions rather than maximal parenchymal enhancement
- a systematic literature review on the clinical relevance of subsegmental PE
- after the review of subsegmental PE, research using decision analytical modelling to compare a variety of diagnostic strategies including ventilation/perfusion, SCT, magnetic resonance imaging and pulmonary angiography
- new studies designed specifically to measure diagnostic impact, therapeutic impact and patient outcome
- the use of decision-modelling techniques to combine outcome and cost data from a variety of sources and new studies.

Publication

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Diagnostics and Imaging Panel and funded as project number 94/28/01.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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Copies of this report can be obtained from:

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