

Title:	Multi-slice computed tomography coronary angiography in the visualisation of coronary arteries	
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AIM

To assess the safety, effectiveness and cost-effectiveness of multi-slice computed tomography coronary angiography (MSCTCA) in the visualisation of coronary arteries for the following four clinical indications:

1. Evaluation of patients with symptoms consistent with coronary ischaemia (including evaluation of coronary bypass graft patency and coronary artery stent stenosis or patency);
2. Exclusion of coronary artery anomaly or fistula;
3. Evaluation of coronary arteries in patients with cardiomyopathy; and
4. Evaluation of coronary arteries in patients undergoing non-coronary cardiothoracic surgery.

CONCLUSIONS AND RESULTS

MSCTCA is a non-invasive procedure used in the visualisation of coronary arteries. It involves the administration of contrast material and subsequent acquisition of multiple images of the coronary tree by means of a spiral CT scanner. The technique combines the use of x-rays with computerised analysis of the images. From the various types of CT scanners developed over time, only the most recent have the technical characteristics which allow the task of non-invasive visualisation of the coronary arteries. Consequently, the current report analysed only scanners with 16 slices or more.

Safety

29 studies (with a total of 2,060 patients) reported on the primary safety outcomes assessed with 16-slice, 32-slice or 64-slice MSCTCA for the investigation of symptoms consistent with coronary ischaemia, follow-up of patients with coronary artery bypass grafts or stents, or exclusion of coronary fistula or anomalies. Complications may occur from MSCTCA as a result of the contrast media administered to allow visualisation of the coronary arteries. These were found to occur rarely (0.24 per cent of patients) and at a likely similar rate to the comparator, coronary angiography (CA), as it also uses contrast media. There is a theoretical risk from radiation exposure, which is considerably higher in patients who undergo MSCTCA than CA, although the difference in radiation exposure is greatly reduced through the use of dose-modulation protocols. As MSCTCA avoids invasive catheterisation, patients are less likely to have severe adverse events such as a stroke, death or infection which occur in a small percentage of patients who undergo CA (although no complications from CA were identified in the literature included in this systematic review). Thus, overall MSCTCA is likely to have improved safety when compared to the diagnostic gold standard of CA.

Effectiveness

Indication 1 – Evaluation of patients with symptoms consistent with coronary ischaemia

A large body of evidence assessed the diagnostic accuracy of MSCTCA. For the 64-slice MSCTCA studies, pooled sensitivity and specificity in the per patient analyses were estimated to be 98 per cent (95% CI: 95%, 100%) and 94 per cent (95% CI: 89%, 99%) respectively compared to CA. Due to its high negative predictive value, MSCTCA appears to be useful in clinical practice to rule out significant coronary artery disease (CAD). This may optimise the investigation of patients with low to intermediate risk of CAD in whom initial stress tests has been non-diagnostic or inconclusive. It is well established that the treatment currently available for CAD has a beneficial effect on patients' health. In contrast, the available literature offers very limited evidence in relation to the impact of MSCTCA on patient management.

Indication 2 – Exclusion of coronary anomaly or fistula

No studies meeting the inclusion criteria were found to assess the diagnostic effectiveness of MSCTCA in this patient group. A considerable number of case reports describing various anatomical presentations in patients with these conditions suggest that MSCTCA is increasingly used in clinical practice for this particular indication.

Indication 3 – Evaluation of coronary arteries in patients with cardiomyopathy

No literature was identified that assessed the effectiveness of MSCTCA in patients with cardiomyopathies.

Indication 4 – Evaluation of coronary arteries in patients undergoing non-coronary cardiothoracic surgery

Limited but good quality evidence suggests that MSCTCA has the ability to rule out CAD in patients awaiting valve surgery. This represents a large subgroup of patients awaiting non-coronary cardiothoracic surgery.

Cost-effectiveness

A cost–utility analysis was performed for Indication 1 comparing MSCTCA±CA to CA. The results of the analysis indicate that different levels of pre-test likelihood of CAD in a patient will result in different levels of cost-effectiveness. For an individual pre-test risk of CAD of 65 per cent or below, the modelled economic analysis predicts MSCTCA±CA to be the less costly strategy. Above 65 per cent pre-test risk of CAD, there is a trade-off, with every health-related quality of life gain from MSCTCA±CA incurring additional costs to the Australian society. The point at which MSCTCA±CA ceases to be cost-effective depends on the willingness to pay of the Australian society. For example, at a hypothetical willingness to pay of between \$30,000/QALY and \$70,000/QALY and given the base case estimate of total costs of MSCTCA, the MSCTCA±CA clinical strategy can be seen to be cost-effective up to approximately 70 per cent pre-test risk of CAD in a patient. These findings were stable in all employed sensitivity analyses with the exception of pre-test risk of CAD and the costs associated with MSCTCA.

For a potential scenario of substitution (ie every patient at low to intermediate pre-test risk of CAD would receive MSCTCA before being referred to invasive CA, conditional on the MSCTCA result), the weighted average was calculated across the point estimates of incremental cost-effectiveness ratios (ICER) for between 10 per cent and 90 per cent pre-test risk of CAD. The result suggests approximately \$28,367/QALY as the weighted average across the ICER point estimates. However, this result is constrained by uncertainty around the estimate for the distribution of patients across the different pre-test risk levels of CAD.

The financial incidence analysis for Indication 1 suggests that, given the assumptions made, there will likely be additional costs of approximately \$10.2 million to Medicare when considering the number of patients diagnosed in the private sector and given the availability of MSCTCA to patients with a pre-test risk of CAD of up to 70 per cent. In addition, it was estimated that there are additional costs from the perspective of the Australian society, at the above threshold, of approximately \$0.2 million.

Lack of evidence hindered an assessment of the use of MSCTCA to exclude coronary artery anomaly or fistula (Indication 2), and to evaluate coronary arteries in patients with cardiomyopathy (Indication 3). Thus, it was not possible to conduct an economic evaluation for these indications.

Cost-minimisation analysis found that MSCTCA is less costly than CA when used to evaluate the coronary arteries of patients undergoing valve surgery. These patients form a large subgroup of those patients undergoing non-coronary cardiothoracic surgery (Indication 4). The base-case analysis indicated that use of MSCTCA±CA compared to CA alone in this population results in savings to the public hospital system of approximately \$8.4 million per year, and costs to Medicare of approximately \$1.6 million per year. Thus, the result is a net saving of \$6.8 million per year to the Australian society.

Recommendations

‘Based on the available evidence, the MSAC finds that multi-slice computed tomography coronary angiography (MSCTCA) is safer than coronary angiography (CA) by avoiding the risks associated with an invasive procedure.

The MSAC has considered the safety, effectiveness and cost-effectiveness for MSCTCA compared with invasive CA for the following indications:

Indication 1

The MSAC finds that MSCTCA is as effective as CA in ruling out significant coronary artery disease in

patients with symptoms consistent with coronary ischaemia, with a high negative predictive value allowing CA to be avoided if MSCTCA reveals no significant disease.

The MSAC finds that, in patients at low to intermediate risk of coronary artery disease, MSCTCA is cost-effective; however, in patients at high risk, MSCTCA is not cost-effective. If applied generally to patients with stable symptoms consistent with coronary ischaemia, but whose pre-test likelihood of disease is low to intermediate, MSCTCA appears to be cost-effective.

Based on the available evidence, the MSAC recommends that public funding is supported for MSCTCA on specialist referral of patients with stable symptoms consistent with coronary ischaemia who have a low to intermediate risk of coronary artery disease and are being considered for CA.

Indication 2

There is limited evidence supporting the effectiveness of MSCTCA in the assessment of coronary anomaly or fistula, given that these conditions are rare and there has been no appropriate comparator.

On the basis of limited evidence of effectiveness, the MSAC recommends that public funding is supported for MSCTCA based on specialist referral of patients requiring exclusion of coronary artery anomaly and fistula.

Indication 3

No evidence was identified to assess the effectiveness of MSCTCA in the evaluation of coronary arteries in patients with cardiomyopathy.

On the basis of insufficient evidence of effectiveness, the MSAC recommends that public funding is not supported for MSCTCA in the evaluation of coronary arteries in patients with cardiomyopathy.

Indication 4

Limited but good quality evidence suggests that MSCTCA is as effective as CA in ruling out coronary artery disease in patients prior to non-coronary cardiac surgery.

Cost-minimisation studies suggest that MSCTCA is less costly than CA in ruling out coronary artery disease in patients prior to non-coronary cardiac surgery.

The MSAC recommends that public funding for MSCTCA is supported in patients undergoing non-coronary cardiac surgery.'

The Minister for Health and Ageing accepted this recommendation on 11 April, 2008.

METHOD

Systematic literature reviews were conducted to assess the safety and effectiveness of MSCTCA for the four clinical indications given above. Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched from when MSCTCA was first described in the literature (2002) until August 2006. Specific journals were handsearched and reference lists perused. Studies were included in the reviews using pre-determined PICO selection criteria. Study quality was appraised and data extracted in a standardised manner. Meta-analyses were conducted where relevant. A linked evidence approach was used – linking evidence of test accuracy to likely impact on patient management and ultimately patient health outcomes. Methods of economic analysis for Indications 1 and 4 are provided in the discussions of cost-effectiveness above.