Health Policy Advisory Committee on Technology

Technology Brief

Screening for coronary artery disease using CT calcium scoring

December 2015
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This brief was prepared by Jacqueline Parsons and Benjamin Ellery from Adelaide Health Technology Assessment, University of Adelaide.
Summary of findings

There is evidence that CT calcium scoring can accurately predict cardiovascular events in asymptomatic individuals, and it has been shown to perform better than traditional risk factor assessment, although the magnitude of that difference in clinical terms is not clear. What has not been tested is whether screening for CAD using CT calcium scoring has an impact on health outcomes, namely cardiovascular events. The risk associated with CT scanning from the radiation dose needs to be considered, as this is equivalent to approximately 50 chest x-rays. In addition, the impact on downstream tests and treatments (both increases and decreases) if this test is made widely available as a screening tool should also be taken into account.

HealthPACT Advice

The use of CT calcium scoring in symptomatic patients is not justified. Although CT calcium scoring is in widespread use for testing/screening asymptomatic patients in private clinical practice, it is of unproven clinical benefit or utility. A calcium score result will rarely change patient management; rather, patients with asymptomatic heart disease should be counselled in respect to behaviour modification and risk factor management. Therefore, HealthPACT does not support the use of CT calcium scoring in clinical practice at this time for screening asymptomatic patients. However, CT calcium scoring may have a role in identifying those patients deemed to be at intermediate risk of coronary artery disease, specifically for those patients in whom there is doubt as to whether or not to commence lipid lowering medication.
Technology, Company and Licensing

Register ID  WP227
Technology name  Computed tomography (CT) calcium scoring for screening for coronary artery disease
Patient indication  Asymptomatic patients undergoing screening for coronary artery disease

Description of the technology
CT calcium scoring, an established technology, measures the degree of calcification in the coronary arteries using computed tomography. The amount of calcification in the arteries gives an indication of the amount of atherosclerosis and therefore the risk of a heart attack or stroke.\(^1\)

CT calcium scoring works by detecting calcified lesions based on the relative brightness of pixels, measured in Hounsfield units (HU).\(^2\) Where a lesion has two or three pixels with a HU above 130, it is considered calcified. A weighting density factor is also added. The individual scores from each of the four main coronary arteries are then totalled to give an overall coronary artery calcium (CAC) score. The scores are then used to categorise the level of risk, with a score of 0 being normal, 1-10 minimal, 11-100 mild, 101-399 moderate and ≥400 severe. A score above 100 is the best predictor of the presence of coronary artery disease (CAD).\(^2\)

Company or developer
CT calcium scoring is already widely available in private imaging facilities.

Reason for assessment
An increase in referrals by general practitioners (GPs) and cardiologists for CT calcium scoring as an initial screening test for coronary artery disease was observed by the Department of Veterans’ Affairs.

Stage of development in Australia
☐ Yet to emerge  ☒ Established
☐ Experimental  ☐ Established but changed indication or modification of technique
☐ Investigational  ☐ Should be taken out of use
☐ Nearly established

Licensing, reimbursement and other approval
CT calcium scoring is not listed on the MBS. It is available privately in Australia and costs patients $125-$150.
Australian Therapeutic Goods Administration approval

☐ Yes  ARTG number (s)
☐ No  Various
☐ Not applicable

Technology type  Diagnostic
Technology use  Diagnostic

Patient Indication and Setting

Disease description and associated mortality and morbidity

Coronary artery disease (CAD), also known as coronary heart disease or ischaemic heart disease, is a common condition in Australia and New Zealand.\(^3\) CAD can lead to heart attack which can be fatal, or angina. The Australian Institute of Health and Welfare (AIHW) estimates that in 2011-12, around three per cent of the Australian population, or about 590,000 people, had CAD.\(^4\) The condition is not evenly distributed, with the prevalence twice as high in males as females and increasing in prevalence with increasing age. The AIHW also reported that acute coronary events (heart attacks and unstable angina) occurred at the rate of 200 per day in 2012, although the rate of events declined 24 per cent between 2007 and 2012. CAD was responsible for 31 per cent of all hospitalisations related to cardiovascular disease (CVD) as a primary diagnosis, and over 224,000 hospitalisations where CAD was the primary and/or additional diagnosis in 2013-14.\(^5\) Again, hospitalisation for CAD was not evenly distributed, with males outnumbering females in every age group, and the number of hospitalisations increasing with age. CAD was responsible for 14 per cent of deaths in 2012, making it the single largest cause of death in Australia; approximately half of these deaths are from acute myocardial infarction.\(^6\) The death rate from CAD has fallen dramatically since the 1980s (from 412 to 96 per 100,000 for males and 280 to 54 per 100,000 for females), mainly due to reductions in risk factors such as smoking, high blood pressure and high cholesterol, and to improvements in medical and surgical techniques.

In New Zealand, diagnosed CAD affected 4.6 per cent of the population in 2013-14, with the rate higher in males and older people.\(^7\) As in Australia, the prevalence of CAD had reduced over time, down from 5.3 per cent in 2006-7. There were 5,339 deaths from ischaemic heart disease in 2012.\(^8\) There were also 23,841 publicly-funded hospital discharges for ischaemic heart disease in 2012-3, with nearly twice as many discharges for men as women.\(^9\)

Although CAD itself is not curable, there are many modifiable risk factors that are known to increase the chances of a cardiovascular event and subsequent morbidity and mortality.\(^10\) These risk factors include smoking, hypertension, high total cholesterol, obesity, lack of physical activity, diabetes and depression. Management of these risk factors can reduce the
risk of further heart problems and relieve symptoms; thus, identifying individuals with CAD is important. The Australian Absolute Risk Calculator, produced by the National Vascular Disease Prevention Alliance (www.cvdcheck.org.au) is a tool clinicians can use to estimate the likelihood of a patient getting CVD in the next five years.\textsuperscript{11} Based on the Framingham Risk Equation (FRE), it includes age, gender, blood pressure, cholesterol, smoking and diabetes information. Australian guidelines on this subject suggest that all people aged 45-74 years and without a prior diagnosis of CVD or known high risk of CVD should have their absolute risk assessed using the FRE, and appropriate treatment initiated according to the level of risk.\textsuperscript{12} In this NHMRC-endorsed guideline, no imaging is included in the diagnostic or treatment pathway for assessing the risk of CVD.

It is important to note that the diagnosis of and treatment for CAD is based on risk. CT calcium scoring is a measure of risk of a cardiovascular event. Whilst there are treatments available for patients in whom the risk of a cardiovascular event is very high, such as coronary artery bypass grafting and revascularisation, the treatment for most patients involves modification of risk factors, regardless of how their risk has been evaluated. Much research has been done to identify the best way to assess risk for CAD, acknowledging that risk factors measured at one moment in time do not necessarily accurately reflect the lifetime contribution to atherosclerosis; this is why there has been considerable work done on imaging modalities and other indicators like serum biomarkers to try and improve the predictive ability of risk assessment.\textsuperscript{13}

**Number of patients**

The pool of patients who may be eligible to be screened for CVD is large; indeed all people aged over 45 years (or over 35 years in the Indigenous population) who are not known to already have CAD or to be at high risk. The prevalence of CAD increases with age, and according to AIHW, the prevalence for 45-54 year olds is approximately three per cent, leaving a potential pool of 97 per cent of this age group eligible for screening; the same applies for the other age groups with declining proportion of eligible people and higher prevalence of existing CAD.\textsuperscript{14}

<table>
<thead>
<tr>
<th>Speciality</th>
<th>Cardiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology setting</td>
<td>General hospital; private community setting</td>
</tr>
</tbody>
</table>

**Impact**

**Alternative and/or complementary technology**

Additive or complementary technology: New technology is used alongside the current technology, in combination with but not replacing them.
**Current technology**

The diagnosis of CAD often occurs when a cardiovascular event takes place. As prevention is important, and the risk factors for CAD are modifiable, screening patients before a cardiovascular event is recommended using the FRE. However, other tests may be used in the diagnosis of CAD including electrocardiogram (ECG) or stress ECG (exercise test), echocardiogram or angiogram. Imaging is not part of the risk assessment endorsed in the Guidelines for the Management of Absolute Cardiovascular Disease Risk. However, the Heart Foundation notes that these tests may be used to diagnose CAD; the interaction between risk assessment using standard risk factors and using imaging is not elucidated in the guidelines.

**Diffusion of technology in Australia**

CT calcium scoring is widely available in private imaging facilities.

**International utilisation**

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Many international observational studies</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Cost infrastructure and economic consequences**

CT calcium scoring is not currently listed on the MBS. Patients pay for their own tests at private imaging clinics. Ethical, cultural, access or religious considerations

Access to CT calcium scoring is limited by the location of CT scanners, the personnel to operate them and specialist physicians to interpret the findings; these limitations are the same for all types of CT scan. However, should CT calcium scoring become a routine test for asymptomatic people, the demand for CT services would be greatly increased, with implications for accessibility, particularly waiting times.

**Evidence and Policy**

It should be noted that the use of CT calcium scoring for predicting CAD risk is a widely debated area in which a plethora of opinion is available, some of which is based on evidence and some which is not. A good example of the fervour with which this topic is approached can be found in the documentary, The Widowmaker (http://widowmakerthemovie.com/). Addressing all of this information is not within the scope of the brief; thus we have attempted to look at a snapshot of the evidence to assess the effectiveness of the test with relation to the appropriate comparator, and much of the research in this field simply does not adequately answer this question.
Safety and effectiveness

The safety of CT scanning has been established and it is considered a very safe test, especially given its non-invasive nature. Although it is associated with a radiation dose, the dose in a single test is not deemed to be harmful by some proponents and is estimated to be the equivalent to exposure to three years background radiation.\(^{15}\) Another review suggested that CT scans were associated with a small but measurable increase in cancer risk, and also with a potential increase in unnecessary downstream testing and treatment.\(^{16}\) In the Multi-Ethnic Study of Atherosclerosis, a large cohort study conducted in the US, each participant received a mean dose of one millisievert from their CT calcium scoring procedure.\(^{17}\) This radiation does is equivalent to about 50 chest x-rays. No studies were identified that considered the relative safety of CT calcium scoring with risk-factor based assessment; however it is acknowledged that this limited search may have missed such information.

The primary question about the effectiveness of calcium scoring for diagnosing CAD (that is, the risk of a cardiovascular event) in a screening population is if it performs better than other tools in clinical practice; namely, risk-factor based assessment. It is important to emphasise that a screening population is one where asymptomatic patients are offered a test or assessment to identify if they are at sufficiently high risk to justify further testing or treatment.\(^{18}\) Other imaging techniques are also used for diagnosing CAD, such as ECG and stress testing; however it is likely these tests would only be used in patients where a clinician judges a patient to be at high risk of CAD, rather than in a screening population.\(^{10}\) These tests are therefore not considered as comparators. Importantly, any change in management as a result of using calcium scoring needs to be considered.

Many review and opinion articles were located in the search for evidence; given the time constraints of a Technology Brief, not all the evidence could be considered. Thus the highest levels of evidence (systematic reviews) were sought, in order to provide a snapshot of the evidence related to this technology, and the majority of the research in this area- the large observational studies- has not been considered in full.

The highest level of evidence located (level 1 evidence) was from The American College of Cardiology (ACC). The ACC produced evidence-based guidelines for the assessment of cardiovascular risk in 2014.\(^{19}\) They investigated whether calcium scoring (among other markers) contributed to risk assessment, and considered systematic reviews and meta-analyses in their assessment. Only two such studies considering calcium scoring were included. The guideline authors concluded that calcium scoring was “likely to be the most useful approach to improving risk assessment among individuals found to be at intermediate risk after formal risk assessment.” Their formal recommendation, based on expert opinion, not on evidence, was that if formal quantitative risk assessment resulted in uncertainty about treatment, then calcium scoring could be considered to inform treatment
decisions. They noted that calcium scoring had not been tested as a screening instrument in RCTs with clinical events as outcomes, and that issues of cost and radiation exposure added to uncertainty about widespread population-based calcium scoring; hence the recommendation only for patients in whom uncertainty over risk remained.

A systematic review of guidelines (level 1 evidence) for imaging for asymptomatic CAD considered 14 guidelines which addressed various forms of imaging, including CT calcium scoring. This 2011 review was comprehensive and assessed the quality of the guidelines using the AGREE instrument. Quality varied greatly, from a low rigor score of 21 per cent to a high score of 93 per cent, with a median of 57 per cent. Ten out of 14 guidelines included a recommendation about calcium scoring as an improvement on traditional risk factor assessment, and among those, four stated there was sufficient evidence for consideration of its use and one recommended its use, but solely in an intermediate risk population. Three other guidelines stated there was insufficient evidence to recommend calcium scoring in intermediate populations. All guidelines were unanimous in not recommending calcium scoring for low CAD risk individuals or people with known CAD.

To further investigate the claim that calcium scoring is better at predicting cardiovascular events that risk factor assessment, some of the largest, most recent studies were assessed in more depth.

The MESA study (Multi-ethnic Study of Artherosclerosis) was a large cohort study (level II prognostic study) of asymptomatic people aged 45-84 years of white, African American, Hispanic or Chinese ethnicity living in multiple centres in the US. There have been a plethora of publications from this study, and the actual results comparing the prognostic ability of calcium scoring versus risk factor assessment using the Framingham risk index or Reynolds risk score to predict cardiovascular events were difficult to find, particularly at longer follow-up points. The article that was located with the best description of the results was published in 2008 and included n=5,878 participants with a median follow up of 5.8 years. There were 209 events during the follow up period. A risk model comprising the Framingham risk factors was compared to the model including calcium scores. The area under the ROC curve for the risk factors alone was 0.76 (95% CI 0.72, 0.79) compared to 0.81 (95% CI 0.79, 0.84), which, although a statistically significant difference, may not be a clinically significant difference. Using a five-year risk estimate, the addition of calcium score to the model resulted in reclassification of 26 per cent of the sample, with n=728 participants reclassified to a higher risk category and n=814 reclassified to a lower risk category. Overall, 5.1 per cent of the sample was reclassified to high risk and 16.4 per cent of these experienced events. Of the 12.7 per cent who were reclassified as low risk, 2.3 per cent experienced events. Amongst the intermediate risk, 16 per cent were reclassified as high risk and 39 per cent as low risk, with 41 per cent of events in the intermediate group among individuals reclassified as high risk, and 13 per cent among those reclassified as low
risk. The authors concluded that the intermediate group benefit the most from the addition of calcium score to the risk assessment, specifically in those patients where there is doubt whether or not to commence lipid lowering medication. The authors also acknowledged that this study, despite its large size and robust design, could not determine whether screening for subclinical disease with calcium scoring improved patient outcomes.25

The Rotterdam study was a large observational cohort study of people aged over 55 years in Rotterdam, the Netherlands, which began in 1990 (level II prognostic study).26 Data informing the comparison of calcium scoring with risk assessment came from n=3,678 participants followed for a median of 5.5 years, reported in 2012. Statistical methods (parametric Weibull proportional hazards regression model) were used to extrapolate data to ten years follow-up, which is the timeframe for the Framingham Risk Score assessment. The mean age of participants was 69.1 years and 59 per cent were female. There were 347 first coronary heart disease events. The study found that a significant proportion of people in each risk group according to the Framingham Risk Score were reclassified when the calcium score was added, based on the outcomes measured in the study. The results are shown in Table 1. The authors concluded that although calcium screening made a difference to the risk classification of subjects, it is still unclear if it makes a difference to clinical outcomes, and that a full evaluation of the costs, risks and benefits of a population-wide program for calcium scoring need to be further investigated.26

A third large study, the St Francis Heart Study, included n=4,903 asymptomatic individuals aged 50 to 70 years (mean 59±6 years) in a prospective cohort study (level II prognostic study), although only n=1,293 had their risk factors (hypertension, cholesterol etc) measured.27 It is not clear in this paper, published in 2005, which patients are included in which analyses. The cohort was followed up for a mean of 4.3 years and there were 119 cardiovascular events. Limited data were presented on the comparison of calcium scoring to the Framingham risk index, however the area under the ROC curve was 0.79 ± 0.03 for calcium scoring compared to 0.68 ± 0.03 for Framingham, a statistically significant difference. Again, the clinical significance of this finding was not discussed. Despite the limited data presented for the superiority of calcium screening over risk assessment, the authors strongly proclaimed “coronary calcium score predicted atherosclerotic cardiovascular disease events, including nonfatal MI and coronary death, independently of and more accurately than standard coronary risk factors”.27

More broadly, there is general agreement amongst authors that calcium scoring does accurately predict cardiovascular events over the short term and is about equivalent to the assessment using risk factors such as the Framingham Risk Score.21,22 However, the radiation risk of widespread calcium scoring in a population has generally not been addressed or dismissed as minor, and should be considered in view of some cardiologists requesting annual calcium scores. A narrative review by Weber et al (2015) showed the
results of a selection of large studies where a higher calcium score was strongly predictive of a cardiovascular event compared to a lower score. The authors also claimed that calcium scoring was considerably better than risk factors alone for predicting CAD, however did not provide any data to this end, short of mentioning results from one trial (the MESA study).

Another recent review (2015) strongly supports the superiority of calcium scoring over risk factor assessment alone. In this narrative review, the large percentage of patients reclassified from the Framingham risk index category into a different category based on the calcium score and cardiovascular outcome is given as evidence of the accuracy of calcium scoring. In the three large studies considered (n=2028, 4487 and 5878), with follow-up of between five and 9.2 years, a large proportion of patients (between 52% and 65%) in the intermediate category of the Framingham Risk Score were reclassified. However, the direction of the reclassification was not reported; thus, the question about whether calcium scoring actually changes management is not answered by these results. Moreover, the author acknowledges that there are no studies that demonstrate clinical benefit. Other reviews have also noted that screening for coronary calcium has not demonstrated a reduction in cardiovascular events or benefits to other health outcomes.

Considerations of treatment adherence

To address the issue of lack of research data on the impact of calcium scoring on health outcomes, an argument has been made that a patient that knows their calcium score is more likely to adhere to their lifestyle modification and medications for CAD. A systematic review (level I evidence) addressing this question was published in 2014. The review included three RCTs which had mixed results on the impact of calcium scoring on risk factor modification; one trial found a significant improvement in risk factors in the no-scan group and no change in the scan group; one trial found an improvement in the scan group; and one found no difference between groups. The review also included 12 cohort studies (non-comparative) which assessed outcomes of lifestyle and behavioural modification, medication adherence, risk perception and psychosocial factors. The results varied widely, both within and between studies. Studies that considered diet found that calcium scores improved beneficial dietary changes, but the effect for smoking and exercise was inconsistent, with only two of the studies showing a positive impact on smoking with known calcium scores. Results for risk perception were also inconsistent. However, nearly all the studies showed a relationship between higher calcium score and better medication adherence. The mixed results from this review led the authors to conclude that further research was necessary to fully understand any effect calcium scoring has on risk factor modification.
Table 1  Reclassification of risk category with calcium scoring from the Rotterdam study

<table>
<thead>
<tr>
<th>Base model</th>
<th>Base model + CAC score</th>
<th>Reclassified as higher risk*</th>
<th>Reclassified as lower risk*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;10%</td>
<td>10-20%</td>
<td>&gt;20%</td>
</tr>
<tr>
<td>Persons with event, n</td>
<td>71</td>
<td>50</td>
<td>4</td>
</tr>
<tr>
<td>Persons without event, n</td>
<td>2015</td>
<td>315</td>
<td>16</td>
</tr>
<tr>
<td>Total persons, n</td>
<td>2086</td>
<td>365</td>
<td>20</td>
</tr>
<tr>
<td>Observed risk [95% CI]</td>
<td>0.03 [0.02, 0.05]</td>
<td>0.14 [0.10, 0.19]</td>
<td>0.21 [0.06, 0.60]</td>
</tr>
<tr>
<td>10-20%</td>
<td></td>
<td></td>
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<tr>
<td>Persons with event, n</td>
<td>19</td>
<td>75</td>
<td>55</td>
</tr>
<tr>
<td>Persons without event, n</td>
<td>262</td>
<td>364</td>
<td>144</td>
</tr>
<tr>
<td>Total persons, n</td>
<td>281</td>
<td>439</td>
<td>199</td>
</tr>
<tr>
<td>Observed risk [95% CI]</td>
<td>0.07 [0.04, 0.12]</td>
<td>0.17 [0.13, 0.22]</td>
<td>0.28 [0.20, 0.37]</td>
</tr>
<tr>
<td>&gt;20%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons with event, n</td>
<td>0</td>
<td>9</td>
<td>62</td>
</tr>
<tr>
<td>Persons without event, n</td>
<td>17</td>
<td>60</td>
<td>140</td>
</tr>
<tr>
<td>Total persons, n</td>
<td>17</td>
<td>69</td>
<td>202</td>
</tr>
<tr>
<td>Observed risk [95% CI]</td>
<td>0.00 [0.00, 0.00]</td>
<td>0.13 [0.06, 0.27]</td>
<td>0.31 [0.23, 0.40]</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Persons with event, n</td>
<td>90</td>
<td>134</td>
<td>121</td>
</tr>
<tr>
<td>Persons without event, n</td>
<td>2294</td>
<td>739</td>
<td>300</td>
</tr>
<tr>
<td>Total persons, n</td>
<td>2384</td>
<td>873</td>
<td>421</td>
</tr>
</tbody>
</table>

CAC=coronary artery calcium; NA=not applicable

*Numbers (percentages) of person with or without and even who are reclassified to a higher or lower risk category after the base model is extended with CAC score. They are based on the results from the parametric Weibull proportional hazards regression model, estimating the individual 10-year predicted risk for coronary heart disease from the available median follow-up of 5.5 years.
Other considerations

Several reviewers noted that calcium screening was effective at identifying people with no artherosclerosis, which has important implications for downstream testing and treatment. Several large studies are cited where a calcium score of zero has been associated with a very low risk of events. The authors suggest that this ‘power of zero’ finding is very important for targeting appropriate testing and treatment, especially with regard to the use and dose of statins, where side effects are a consideration.

Economic evaluation

The cost effectiveness of calcium scoring in a screening population is an important consideration given the potential demand for this service. However, evidence for this is sparse. A systematic review of the cost-effectiveness of coronary computed tomography for coronary artery disease assessment was published in 2014. This review considered three studies that used CT calcium scoring as an index test. The first was an RCT that showed comparable downstream medical testing and costs in the scan and no-scan groups, but increasing downstream resource utilisation and cost with increasing calcium score. Another study constructed a decision tree to look at the marginal cost per additional patient of using calcium scoring in addition to the Framingham Risk Index. They found the marginal cost per quality adjusted life year (QALY) is highly sensitive to the gain in life expectancy from early intervention when calcium scoring is included in the assessment, however also found that using calcium scoring in a population at low risk and with no symptoms is expensive, even with favourable assumptions. Two other prospective cohort studies did not compare risk assessment strategies and their impact on cost effectiveness could not be determined. The authors noted that the cost effectiveness of calcium scoring as an index test is yet to be established.

Ongoing research

No studies of calcium scoring were identified, however numerous studies using computed tomography angiography are in process, and these may also include calcium scoring results. One study comparing standard CT with ultra-low dose CT for calcium scoring was also located on ClinicalTrials.gov; it is not yet recruiting (NCT02458352).

Other issues

The systematic review of guidelines for imaging for asymptomatic CAD mentioned earlier noted that 11 out of the 14 guidelines reported a relationship with industry.

It is worth noting that the US Choose Wisely campaign has three items concerning coronary artery calcium scoring:
* Don’t order coronary artery calcium scoring for screening purposes on low risk asymptomatic individuals except for those with a family history of premature coronary artery disease.

* Don’t order coronary artery calcium scoring for preoperative evaluation for any surgery, irrespective of patient risk.

* Don’t use coronary artery calcium scoring for patients with known coronary artery disease (including stents and bypass grafts).

**Number of studies included**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies: 13

Total number of Level I studies: 4

Total number of Level II studies: 3

**Search criteria to be used (MeSH terms)**

Coronary calcium scoring, screening

Text: cost effectiveness

**References**


