Contrast-enhanced cardiac computed tomographic angiography for coronary artery evaluation

BlueCross BlueShield Association

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Citation

Authors' objectives
The objective of this Assessment is to evaluate the clinical effectiveness of contrast-enhanced cardiac computed tomographic angiography (CTA), for coronary artery evaluation. CTA may be performed using either electron beam computed tomography (EBCT) or multidetector-row computed tomography (MDCT); although most recent technical developments have been focused on MDCT.

Authors' conclusions
Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether CTA for screening or diagnostic evaluation of the coronary arteries meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental bodies.

CTA can be performed using either multidetector-row CT (MDCT) or electron beam CT. Multiple manufacturers have received FDA 510(k) clearance to market MDCT machines equipped with at least 16 detector rows and at least two models of EBCT machines have been cleared through FDA 510(k) clearance. Intravenous iodinated contrast agents used for CTA have also received FDA approval.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The available evidence does not permit conclusions on the effect of CTA on health outcomes, and thus, the second criterion is not met. All studies included in this Assessment used MDCT with 16 detector rows or EBCT with slice thickness of 1.5 mm or less. However, in practice, MDCT is being improved with newly available scanners offering 3264 or more detector rows, and it is hoped that emerging technology will provide improvements in technical and diagnostic performance. At this writing, no published full-length studies were identified using MDCT with 32 or more detector row technology.

A total of 22 eligible studies (16 MDCT, 6 EBCT; total N=1,016) were included in the review of evidence, with 15 of these studies (total N=809) addressing CTA for diagnosis of non-acute CAD. Invasive coronary angiography was used as the standard of reference in all but 1 study. Most of these studies were prospective and CTA was interpreted without knowledge of invasive angiography results, however, some overlap may be possible between subjects included in different reports of studies from the same co-authors and institutions.

The main weakness of this literature is that most studies used individual coronary vessels or vessel segments as the unit of analysis while only 4 studies reported the more clinically relevant analysis of diagnostic performance measures using the patient as the unit of analysis. While vessel/segment-based analyses might be useful in determining treatment
decisions about single vessels, these calculations are not relevant when making treatment decisions about the patient as a whole. When deciding whether or not to perform invasive angiography, the negative predictive value of CTA for the patient is most relevant since missing the significant lesion on CTA could result in misdiagnosis if invasive angiography were avoided. Furthermore, sensitivity and negative predictive values calculated from the number of vessels or segments are artificially inflated compared with patient-based analyses because a large number of true-negative segments are added into the denominator for the calculation of NPV, which will dilute the mathematical effect of the false-negative segments.

To illustrate this problem, if a hypothetical study enrolled 10 patients (n=10), each patient could be counted as having 12 segments (total study n=120 segments). If 3 of these patients truly have single-vessel segment disease, but all 10 patients receive negative CTA results, the NPV calculated by vessel segments would be 97.5% (117/120), but the NPV calculated by patients would be 70% (7/10). Finally, these studies were conducted in populations with a prevalence of CAD ranging from 5383% of patients and 937% of vessels/segments. This relatively high patient prevalence is dissimilar to the low-risk population for which CTA use is proposed.

Technical Performance Results. A high technical success rate for CTA is desirable since subjects who undergo CTA and receive unevaluable results have undergone the CTA procedure with its associated risks from intravenous contrast and radiation but have derived little or no benefit from its results and would still require invasive angiography. The best reported information examines technical success using the patient as the unit of analysis. One such study found only 74% of subjects had all vessels evaluable on MDCT; while a different study using EBCT reported 91% of subjects had all arteries evaluable. This implies that approximately one-fourth of subjects undergoing MDCT may have at least some technical limitation in the visualization of the coronary arteries. Other studies that analyzed the proportion of evaluable vessels/segments reported a range of 79% to 93% for MDCT and 77% to 95% for EBCT.

Furthermore, several studies analyzed and reported diagnostic performance of CTA only in vessels/segments that were evaluable, which means vessels that were not well seen due to blurring or dense calcification were excluded from the analysis of results. This would favorably bias reported diagnostic performance since missed lesions would not be counted against CTA if the lesion was not visible due to blurring. Finally, most studies limited analysis to vessel segments at least 1.5 to 2 mm in diameter but this may be of only minor concern given that lesions in smaller caliber vessel segments are not amenable to revascularization procedures.

Diagnostic Performance Results. Among 11 MDCT reports (total N=622), 4 studies (total N=289) reported patient-based analyses on all diagnostic performance characteristics without excluding unevaluable segments. These studies found CTA achieved 85100% sensitivity, 75-86% specificity, 8197% positive predictive value (NPV), and 82100% negative predictive value (PPV). Three other MDCT studies reported very limited results based on analysis of patients, and 1 additional study analyzed results by patient but excluded unevaluable vessels from the analysis. Vessel- or vessel segment-based analyses reported 6395% sensitivity, 8698% specificity, 6487% PPV, and 9699% NPV with prevalence of stenotic vessels ranging from 937%; however, as previously discussed, the NPV based on vessel/segments is not clinically relevant as decisions about whether to undergo invasive angiography are not made independently on a vessel-by-vessel basis but made based on all cardiac vessels in the patient as a whole.

Among the 4 studies using EBCT (total N=187), diagnostic performance was reported based only on vessels or segments and no study provided patient-based analysis. Sensitivity range was 7090%, specificity was 9195%, NPV was 9596%, and PPV was 7084%. One of these studies also reported partial results according to a patient-based analysis and found that CTA found at least one significant stenosis in 49 of 53 patients (92%).

No eligible studies were identified using CTA as a screening test for CAD. Included studies addressing the use of CTA for diagnoses other than non-acute CAD were all small and frequently did not address prospectively defined populations or provide explanation of how CTA would be used to guide management. These studies did not permit conclusions on the effects of CTA on health outcomes.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

The evidence is insufficient to determine whether the use of CTA improves net health outcome or whether it is as
beneficial as any established alternatives.

5. The improvement must be attainable outside the investigational settings.

Whether the use of CTA improves health outcomes has not been established in the investigational settings.

Therefore, the use of contrast-enhanced cardiac CT angiography for screening or diagnostic evaluation of the coronary arteries does not meet the TEC criteria.

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