

INPLASY

INPLASY202530008

doi: 10.37766/inplasy2025.3.0008

Received: 1 March 2025

Published: 1 March 2025

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Accuracy of photon-counting detector computed tomography angiography for the diagnosis of significant coronary artery disease: a Bayesian meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No financial support.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202530008**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 March 2025 and was last updated on 1 March 2025.

INTRODUCTION

Review question / Objective What is the diagnostic accuracy of photon-counting detector computed tomography angiography (PCD-CCTA) as an index test, as compared to the gold standard of invasive coronary angiography (ICA) as the reference standard, in terms of pooled sensitivity, specificity, negative likelihood ratio (LR), and positive LR?

Rationale PCD-CCTA is a new computed tomography (CT) imaging modality which comprises improved spatial resolution, reduced radiation dose, and enhanced tissue characterization as compared to conventional energy-integrating detector (EID) CT. As coronary artery disease (CAD) remains a leading cause of morbidity and mortality worldwide, non-invasive imaging techniques that offer high diagnostic accuracy while reducing procedural risks are of great clinical importance. Currently, ICA is considered the gold standard for diagnosing CAD. However, it is associated with procedural risks

such as bleeding, contrast-induced nephropathy, and radiation exposure. If PCD-CT can demonstrate comparable diagnostic accuracy to ICA in detecting significant CAD, it may offer a safer, more accessible alternative for CAD assessment, with improved diagnostic accuracy.

Condition being studied

Patients with either:

- Suspected or known coronary artery disease, which can range from stable disease, to acute coronary syndromes.
- An indication for cardiac surgery, while being screened for potentially significant CAD, in their pre-operative work-up.

METHODS

Search strategy Our predefined search strategy was composed of the following criteria:

- Patient-/disease-associated terms: 'Coronary artery disease' and all possible alternative spellings.

- Index-associated terms: 'Photon-counting detector computed tomography angiography' and all possible alternative spellings.
- Reference-associated terms: 'Invasive coronary angiography', and all possible alternative spellings.
- Outcome-associated terms: 'Diagnostic accuracy, sensitivity, specificity, NPV, PPV, likelihood ratio', etc., and all possible alternative spellings.

Participant or population Patients with either suspected or known coronary artery disease, which can range from stable disease, to acute coronary syndromes, or patients with an indication for cardiac surgery, while being screened for potentially significant CAD, in their pre-operative work-up.

Intervention The index-test is coronary computed tomography angiography (CCTA), and specifically by use of the new photon-counting detector (PCD) modality.

Comparator The reference test, the gold standard, is invasive coronary angiography, which can be analyzed through quantitative coronary analysis (QCA) or three-dimensional (3D) QCA.

Study designs to be included All types of study designs are being considered.

Eligibility criteria All types of studies that reported diagnostic accuracy data using PCD-CCTA as an index test, and ICA as a reference test, were eligible for inclusion. If true positive (TP), false positive (FP), true negative (TN), and false negative (FN) rates were not available, these were recalculated from measures such as disease prevalence, sensitivity, specificity, negative predictive value (NPV), or positive predictive value (PPV). If these measures were insufficiently reported, the study was excluded.

Information sources A comprehensive search was conducted through PubMed, EMBASE, and Cochrane Library.

Main outcome(s) The primary outcomes are the following diagnostic measures:

- Pooled sensitivity
- Pooled specificity
- Pooled positive likelihood ratio
- Pooled negative likelihood ratio
- Pooled diagnostic odds ratio (DOR).

Quality assessment / Risk of bias analysis A standardized risk of bias assessment will be

performed by use of the QUADAS-2 tool, focusing both on 'risk of bias' and 'applicability'.

Strategy of data synthesis We aim to perform a Bayesian diagnostic meta-analysis, as this methodology is particularly recommended in the event of expected small sample sizes. Given the recent advent of PCD-CT, a relatively low number of eligible studies was foreseen, and a Bayesian approach was consequently prespecified. Compared to the frequentist approach, Bayesian methods offer several potential advantages, which includes the use of Markov chain Monte Carlo (MCMC) sampling, which is restricted to positive values and explores the whole (posterior) distribution of the parameter and not just the mode. Hierarchical Bayesian meta-analysis was performed by using the TP, FP, TN, and FN rates of all studies, using a random-effects model. The prior settings for sensitivity and specificity were a mean of 0.5 and SD of 0.44, corresponding to a 95% credible interval (CrI) of 0.01-0.99, reflecting a weakly informative prior that assumes no difference between tests and a large distribution. The current Bayesian diagnostic accuracy test meta-analysis was performed using the 'MetaBayesDTA' packages and applications.

Subgroup analysis We performed subgroup analyses for:

- High resolution versus ultra-high resolution scanners
- Patients being analyzed in the context of (i) suspected/known CAD or (ii) pre-operative work-up before cardiac surgery

Furthermore, all analyses were performed on a patient-, vessel- and segment-level.

Sensitivity analysis We performed subgroup analyses for:

- High resolution versus ultra-high resolution scanners
- Patients being analyzed in the context of (i) suspected/known CAD or (ii) pre-operative work-up before cardiac surgery

Furthermore, all analyses were performed on a patient-, vessel- and segment-level.

Language restriction We did not apply any language restrictions.

Country(ies) involved Nederland.

Keywords Coronary artery disease; Coronary computed tomography angiography; CCTA, photon-counting detector; PCD; PCD-CT.

Dissemination plans We aim to publish our findings, irrespective of their results, in a peer-reviewed medical journal.

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