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Title: Hybrid cardiac imaging: insights in the dilemma of the appropriate clinical management of patients with suspected coronary artery disease

Article Type: Original Research Article

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the diagnostic performance of cardiac SPECT/MPI and CTCA alone in order to act as more accurate gate keeper to further investigation invasive or not.
Methods and Results: Twenty five patients were subjected to SPECT /MPI and CTCA within a period of one month without any medical treatment modification. Cardiac
SPECT studies were performed on a dual-head cardiologic gamma-camera and CTCA studies on a 64-slice CT scanner. A fusion software package was used for cardiac SPECT-CTCA image fusion. Semiquantitative analysis was performed for cardiac SPECT, CTCA and SPECT/MPI-CTCA fusion images. Patients were classified in 2 groups according to the clinical decision for further investigation: group A: clear
decision for further investigation, group B: no further investigation. In classifying patients to groups A and B, statistically significant differences were observed when
SPECT/MPI-CTCA fusion images were used instead of cardiac SPECT alone ($p<0.05$). No statistically significant differences were observed comparing CTCA alone to
SPECT/MPI-CTCA fusion images ($p=0.25$)
Conclusion: In patients suspected for coronary artery disease, cardiac SPECT/MPICTCA fusion imaging was found to considerably alter the clinical decision for referral
to further investigation derived from SPECT/MPI.
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Introduction

Non-invasive tests often fail to precisely detect which lesions are responsible for myocardial ischemia in patients with multi-vessel disease.[1] Conventional coronary angiography (CCA) remains the method of choice for assessing vascular lesions and determining approaches to revascularization. In daily practice as well as in clinical trials, lesions with a stenosis exceeding 50% are commonly considered for revascularization.[2] However, CCA may result in both underestimation and overestimation of a lesion's severity.[3] In addition, CCA is often inaccurate in predicting which lesions cause ischemia when compared with the Functional Flow Reserve (FFR).[3] Moreover, the decision to revascularize the culprit lesions should be guided by the presence of myocardial ischemia and not always by the degree of stenosis.[4,5]

Taking into account the invasive nature of CCA, non invasive methods with high ability to identify ischemia and vascular stenosis, are increasingly used for diagnosis and management of patients with CAD.[6]

All approaches used for the noninvasive assessment of CAD have benefits and limitations.[7] Myocardial perfusion SPECT imaging (MPI) is nowadays the most commonly used non invasive method to determine the hemodynamic significance of CAD.[7] However, its diagnostic accuracy is affected by several limitations such as diaphragmatic or breast attenuation, scatter and blur.[6,8] Besides, computed tomographic coronary angiography (CTCA) has been validated as a possibly non-invasive tool in patients with low and intermediate probability for CAD.[9,10] Limitations such as overestimation of stenoses, motion artifacts and blooming artifact associated with heavy calcifications shortened its value in patients with suspected CAD.[11-13]

Hybrid imaging from SPECT/MPI and CTCA fusion may provide valuable additional information, combining anatomic and functional features.[6] The potential of SPECT/ MPI-CTCA fused images to aid clinicians accurately identify patients with suspected CAD who need further management should be investigated.[14] The aim of this study was to investigate the effect of the additional clinical information offered by hybrid cardiac imaging in patients suspected for CAD regarding the clinical decision for further evaluation invasive or not.

Materials and Methods

Study population

Data from SPECT/MPI (1789 patients) and from CTCA (320 patients) acquired during a 6-month period were retrospectively retrieved. From these patients, only those who were referred for both tests within a period of 30 days were included in this study. Patient's double referral was done due to the mismatch between the clinical status and the supposed diagnosis from the first imaging test, being either SPECT/MPI or CTCA. The second imaging modality was additionally performed to assist the final clinical decision. From this subgroup, patients with irreversible defects in SPECT/MPI, cardiac events, changes in medical treatment and intervention in the period between the two examinations were excluded.

Twenty five patients (7 females, 19 males) fulfilled all of the above criteria. Patients were divided in two groups. Group A: patients with abnormal findings on SPECT/MPI or/and CTCA, requiring further investigation, and Group B: patients with normal or equivocal imaging findings not definitely requiring further management. Data from SPECT/MPI and CTCA alone were compared with SPECT/MPI-CTCA hybrid fusion imaging. The study was approved by the institutional review board.

SPECT/ MPI study

All patients underwent a one day stress/rest SPECT/MPI according to the protocol of the European Association of Nuclear Medicine.[12] Doses of 12 and 25 mCi (444MBq and 925MBq) Tc-99m tetrofosmin (TF) were injected at peak stress using the Bruce protocol and at rest, respectively. Images were acquired with the patient in a supine position. Planar image acquisition in prone position was additionally performed in some patients in order to minimize the diaphragmatic and breast artifacts. Tomographic images were obtained 60 min after intravenous injection of the radiotracer using a dual head dedicated γ-camera (Optima NX, General Electric, Milwaukee, WI, USA). SPECT images were reconstructed with an iterative algorithm (OSEM, ordered-subsets expectation maximization). Transaxial slices were reoriented to obtain short, vertical long and horizontal long axis slices encompassing the entire left ventricle.

CTCA study

CTCA was performed using a 64-slice scanner (LightSpeed VCT, GE Healthcare, Milwaukee, WI, USA), with a pitch of 0.2, a tube voltage of 120 kV, and a tube current of 300–600mA, depending on patient size and ECG (Smart mA, ECG Dose Modulation GE Healthcare). The electrocardiogram was digitally recorded during data acquisition and was archived with the unprocessed CT data set. Eighty millilitres of iodinated contrast agent (Optiray [ioversol], Covidien; 350 mg I/ mL) were continuously injected into the right antecubital vein via an 18-gauge catheter with an infusion rate of 5 mL/sec, followed by a saline flush of 50 ml with an infusion rate of 5 mL/sec. Automated peak enhancement detection in the ascending aorta was used for timing of the bolus using a threshold of +130 Hounsfield units. The data acquisition was performed during an inspiratory breath hold of approximately 10 s. Using retrospective electrocardiographic gating, all data set was reconstructed in 5% increments across the RR cycle, with a slice thickness of 0.625 mm. Beta blockers (Brevibloc [esmolol], 100mg VIAL, Baxter,) were injected IV in patients with heart rates exceeding 65 beats per minute in a Dosage of 0.5mg/kg, unless beta blocker medication was contraindicated. All patients included in the study achieved acceptable heart rates between 50 and 62 beats per minute.

Cardiac Fusion imaging

Integration of SPECT/MPI with CTCA images was performed on a designated workstation using the CardIQ Fusion software package (Advantage Workstation 4.4, GE Healthcare, Milwaukee USA). Introduced by Gaemperli et al [10], this software provides analysis and review of CT morphologic information and SPECT/MPI functional information. The myocardial vascular territories were individually co-registered using the SPECT/MPI-CCTA and not using the standardized myocardial territories thus allowing us to avoid a disagreement in all segments.[15]

Image analysis

Semiquantitative analysis was performed independently for the SPECT/MPI and the CTCA images. Results were compared with the fused SPECT/MPI-CTCA images.

SPECT/MPI interpretation

SPECT/MPI was evaluated by consensus of two experienced nuclear medicine physicians using a dedicated workstation (Xeleris Workstation, Myovation software,GE Medical Systems, Milwaukee, Wis). Tomographic slices were divided in 17 segments as previously proposed.[16] Each of the 17 segments in every patient was assigned to one of the major vascular territories.

Semiquantitative analysis was performed. A polar map was created and the left ventricle was divided into: 6 basal and 6 middle (anterior, anterolateral, inferolateral, basal inferior, inferoseptal, anteroseptal) segments, 4 apical (anterior, lateral, inferior and septal) plus the apex. Segments were scored for radiotracer uptake with a 5 point score system. Score 0: normal uptake of the radiotracer, score 1: equivocal, score 2: moderately reduced, score 3: severely reduced, score 4: no uptake. Patients were classified in group A: score ≥2 (clear decision for further investigation) and group B: score 0 and 1 (no further evaluation).

CTCA interpretation

The data sets were analyzed by two experienced radiologists by consensus, blinded to the results of gated SPECT, using an Advantage Workstation 4.4 (GE Healthcare, Milwaukee, USA). Image quality was determined on the basis of the presence of motion artifacts and vessel calcifications. Results were documented separately for all coronary segments using a modified American Heart Association classification as described by Kuettner[17]. Sections containing an intracoronary stent were included. All lesions leading to luminal narrowing by as well as lesions with blockage of contrast material were registered and located to the coronary segments described above. For coronary stenosis quantification segments were scored with a 5 point score. Score 0: normal, no lesion, score 1: 0-50% stenosis, score 2: 50-75% stenosis, score 3: ≥75% stenosis, score 4: occlusion). Stenoses ≥50% were defined as significant. Patients with scores 0 and 1 were included in group B (no further evaluation) and patients with scores 2-4 in group A (clear decision for further investigation).

Cardiac Fusion imaging interpretation

The 3D volume rendered fused images are generated by superimposing the constructed coronary tree on the SPECT/MPI images. The evaluation was based on the relation between the SPECT/MPI perfusion defect and the corresponding CTCA coronary artery stenosis classified as match when a superposition was observed. These images provide a volume rendered view of the myocardium, the regional myocardial perfusion and the coronary artery tree, eliminating uncertainties in the relationship of perfusion defects and disease coronary arteries.[10] **Figure 1** shows the steps for cardiac fusion imaging interpretation.

The evaluation was based on the high negative predictive value of both methods. All lesions depicted in the CTCA which superimposed to perfusion defects were classified as hemodynamically significant (Group A). On the other hand, lesions on the CTCA without underlying perfusion defect were classified as not significant (Group B). Perfusion defects that were seen without any lesion in the feeding vessel were categorized as artifacts or limitations of the SPECT/MPI study and therefore further investigation was considered unnecessary (Group B).

Patients were categorized in group A (i.e clear decision for further investigation) or group B (no further evaluation). The final diagnosis was obtained by consensus between the radiologists and the nuclear medicine physicians.

Statistical Analysis

Statistical analysis was performed using the statistical software package Origin 7.0 (Origin Lab Corporation, Northampton, MA, USA). The McNemar test was used to compare patient classification to groups A and B obtained from SPECT/MPI analysis and CTCA analysis to the corresponding classification obtained from cardiac hybrid imaging. A p value <0.05 was required to consider a test statistically significant.

Results

On SPECT/MPI, from a total of 425 segments (25 patients x 17 segments), 79/425 (18.6%) were evaluated with perfusion defects (score 1-4), mostly on the inferior wall, based on the extent and severity of perfusion abnormalities and also to attenuation artifacts. Seventeen out of 25 patients (68%) were classified in group A. The rest 8/25 (32%) were classified in group B.

From CTCA imaging 253 out of the 425 segments were evaluated as score 0 i.e. no stenosis observed. The rest 172/425 were scored as score 1-4 based on the percentage of the vessel stenosis. Nine out of 25 patients (36%) were classified in group A and were introduced for further investigation for CCA. The rest 16/25 were classified in group B (64%).

The final decision for the clinical management based on SPECT/MPI-CTCA data was taken on the hybrid fusion imaging, allowing modifications on our interpretations. Six out of 25 patients (24%) were classified in group A. The rest 19/25 (76%) were classified in group B. Table 1 shows the grouping of 25 cases according to the SPECT/MPI, CTCA and fused SPECT/MPI-CTCA images.

In the determination of the group of patients requiring further investigation i.e. group A, statistically significant differences were observed when SPECT/MPI-CTCA fusion images were used instead of cardiac SPECT/MPI alone ($p<0.05$).A p value=0.25 was found for CTCA alone vs SPECT/MPI-CTCA fusion imaging (no statistically significant).

Discussion

SPECT/MPI is established as a first line non invasive method for assessing of the hemodynamic significance of stenosis in patients with CAD in order to select those requiring further evaluation.[7] CTCA is a new diagnostic tool providing information on stenosis location and size. CTCA has been also proposed as a possible non-invasive method to exclude or confirm CAD, particularly in intermediate risk patients with equivocal findings at SPECT/MPI, in order to avoid unnecessary CCA.[18,19] Cardiac

SPECT/MPI-CTCA fusion from independent SPECT/MPI and CTCA studies has been reported to provide additional clinical information vs side by side analysis.[20] For this reason we avoided in our study the side by side analysis of both imaging methods and we proceeded directly to hybrid analysis.

In the current study, hybrid cardiac image analysis was performed to evaluate the potential role of software SPECT/MPI-CTCA fusion imaging in improving the diagnostic value of either SPECT/MPI or CTCA alone. Based on SPECT/MPI alone and CTCA alone, 68% and 36% of examined patients were respectively identified as candidates for further evaluation. By using the SPECT/MPI-CTCA fused imaging, 24% of examined patients were identified to require further investigation. This may be attributed to potentially increased sensitivity for discrimination of haemodynamically significant stenoses offered by SPECT/MPI-CTCA fusion image analysis. Images of a patient with a treated filiform stenosis of the distal RCA are shown in Figure 2 a and b.

In the same examination a 50% LCX stenosis (Fig 2c) was classified as not significant and was not invasively treated. Eight months later the patient was again symptomatic.

The CTCA alone (Fig 2d) revealed the same 50% stenosis in the LCX without any significant stenosis in the other territories. The fused hybrid image (Fig 2f) showed a perfusion defect in the distribution territory of the LCX and identified LCX stenosis as functionally relevant lesion.

Current results indicate that cardiac SPECT/MPI-CTCA fusion imaging may provide additional clinically relevant information vs SPECT/MPI alone to appropriately tackle the dilemma regarding the management of patients with suspected CAD. On the other hand, no significant statistical differences were observed comparing patient classification to groups A and B obtained from CTCA analysis to corresponding classification obtained from cardiac hybrid imaging. Further evaluation is essential possibly due to the small number of patients.

Previously reported data are in agreement with the results of the current study.[6,10,20] Santana and coworkers[6] mentioned that SPECT/MPI-CTCA fusion imaging has considerable diagnostic potential over SPECT/MPI and CTCA alone reducing the number of misinterpretations and improving sensitivity and particularly specificity compared to MPI alone. SPECT/MPI-CTCA fusion was also reported by Gaemperli et al[10] to be straightforwardly implemented into clinical practice, providing complementary information on culprit lesions. Thus, hemodynamically non-significant lesions may be identified with higher efficiency resulting in the avoidance of several unnecessary interventional procedures.[10,20] Figure 3 presents an example of the ability of hybrid imaging to overcome several misinterpretations of SPECT/MPI alone, such as diaphragmatic attenuation. SPECT MPI study shows a perfusion defect on the posteroseptal wall (a). CTCA revealed no plaques in the LCX (Fig 3c) and in the RCA (Fig 3d). Fused images were very helpful to evaluate the possible lesion on the posteroseptal wall by identifying the LCX and RCA as draining vessels. The final decision was that the perfusion defect was due to attenuation artifact and the patient was classified on group B instead the initial decision of group A avoiding the CCA.

Figure 4 illustrates an excentric stenosis in the proximal LCX with mild plaques in the proximal and distal segments (Fig 4a). Fused SPECT/MPI-CTCA allocate perfusion defect in the posterolateral wall in the distribution territory of the LCX identifying the stenosis as probably hemodynamically significant (Fig4b).

Our study has limitations. The population was automatically preselected due to the mismatch between clinical and imaging findings. Only a small number of the patient cohort underwent both examinations within a month. Although the number of the patients included is relatively small to extrapolate the conclusions to any other population, the results seem to be promising. Another limitation of the current study originates from the absence of CCA and FFR data. Such CCA/FFR results for the participants would be used as reference standard and provide the ultimate proof that changes in the clinical decision for CCA referral or not are towards improving specificity of cardiac SPECT or CTCA alone as gate-keepers for CCA.[2] Future studies with a larger patient population for which CCA/FFR results would be available are necessary to establish the role of cardiac SPECT/MPI-CTCA fusion imaging in identifying high risk for CAD patients that require further evaluation with CCA.

Conclusion

The current study provides evidence for the promising role of fusion cardiac imaging vs SPECT/MPI and CCTA alone in gate-keeping for further investigation with invasive methods. Fusion image analysis may improve the efficiency of the non-invasive discrimination of haemodynamically significant lesions and may contribute to a more accurate clinical management of patients with suspected CAD.

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Figure Legends

Figure 1.

a: vertical long axis slice of Stress SPECT study, **b:** Source axial image of CCTA (Coronary CT Angiograpy), **c:** Fused SPECT and CCTA source image, **d:** Fused 3D SPECT/CCTA

Figure 2.

a: CCA revealed a filiform stenosis in the distal RCA, **b:** RCA after angioplasty, **c:** 50% stenosis of the LCX was not treated, **d:** CTCA revealed the same 50% stenosis in the LCX, **e:** Fused 3D SPECT/CCTA showed a perfusion defect in the distribution territory of the LCX . The LCX stenosis seemed to be hemodynamically significant.

Figure 3.

a: Short axis slices of Stress SPECT study indicate posteroseptal perfusion defect. **b:** Fused 3D SPECT/CCTA identify RCA and LCX as both draining vessels of the posteroseptal wall, **c:** Curved MIP/ MPR of 64slice CCTA show absence plaques in the LCX, **d:** Curved MIP/ MPR of 64slice CCTA show absence plaques in the RCA. The perfusion defect seemed to be due to attenuation artifact of the region.

Figure 4.

a: Curved MIP/ MPR of 64slice CCTA show mild excentric stenosis in the proximal LCX with mild plaques in the proximal and distal segments, **b:** Fused 3D SPECT/CCTA allocate perfusion defect in the distribution territory of the LCX in the posterolateral wall.

Table 1. Classification of the 25 patients according to SPECT MPI, CTCA and fused SPECT- CTCA image analysis

Group	SPECT/MPI	CTCA	SPECT/MPI-CTCA
A (pts)	17 *	9	6
B (pts)	8 *	16	19

* statistically significant differences from SPECT/MPI-CTCA classification ($p<0.05$)

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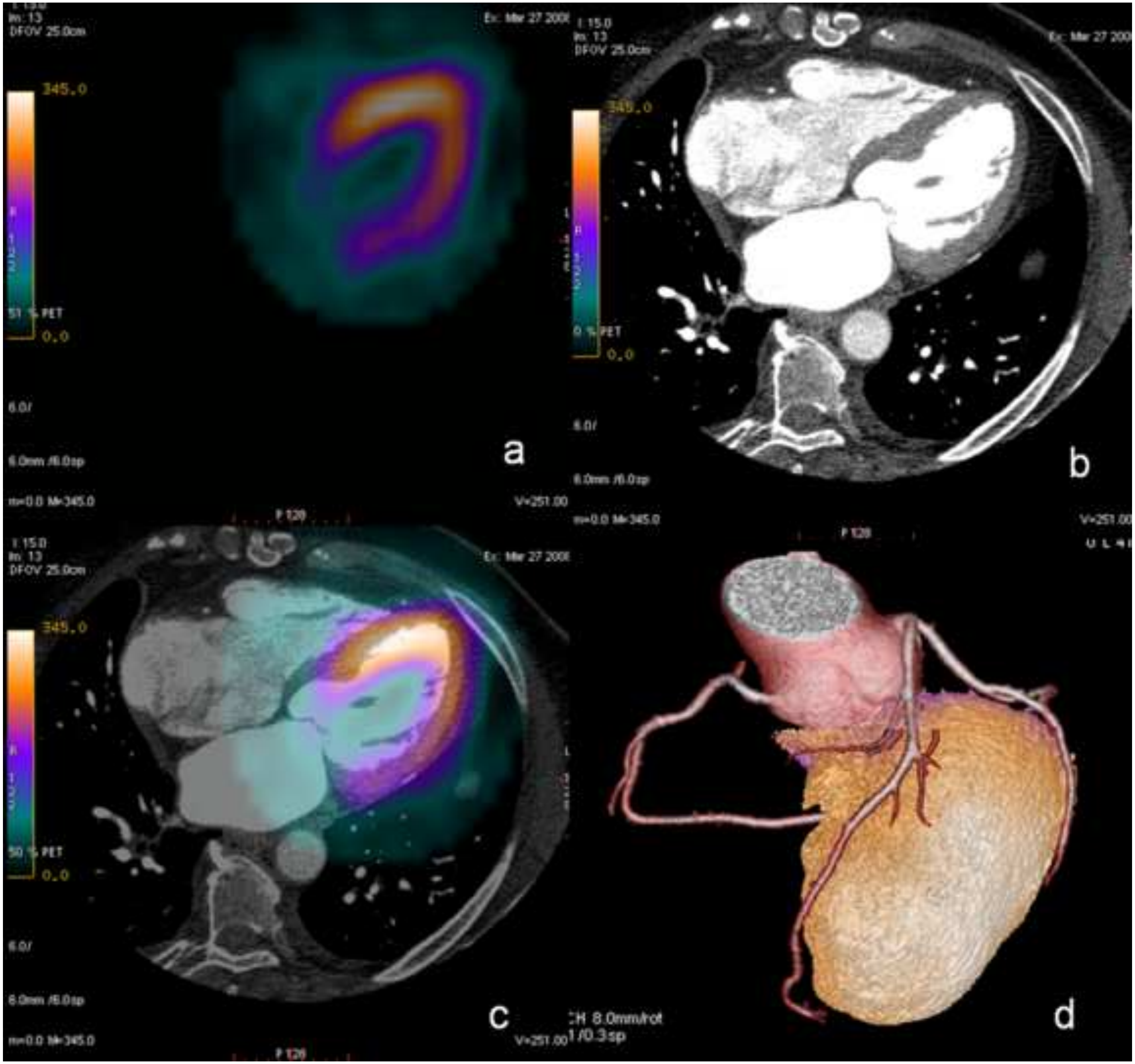

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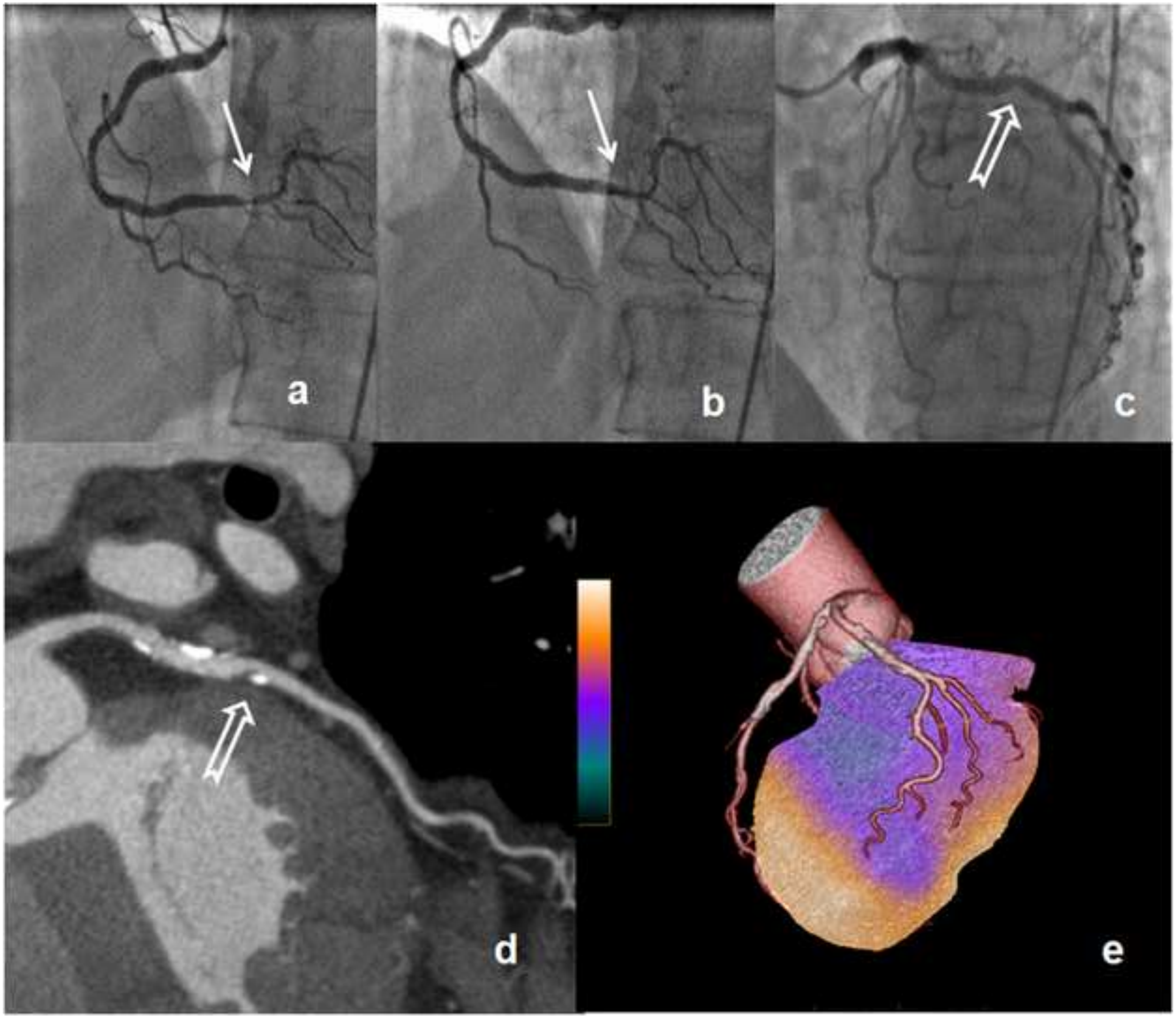

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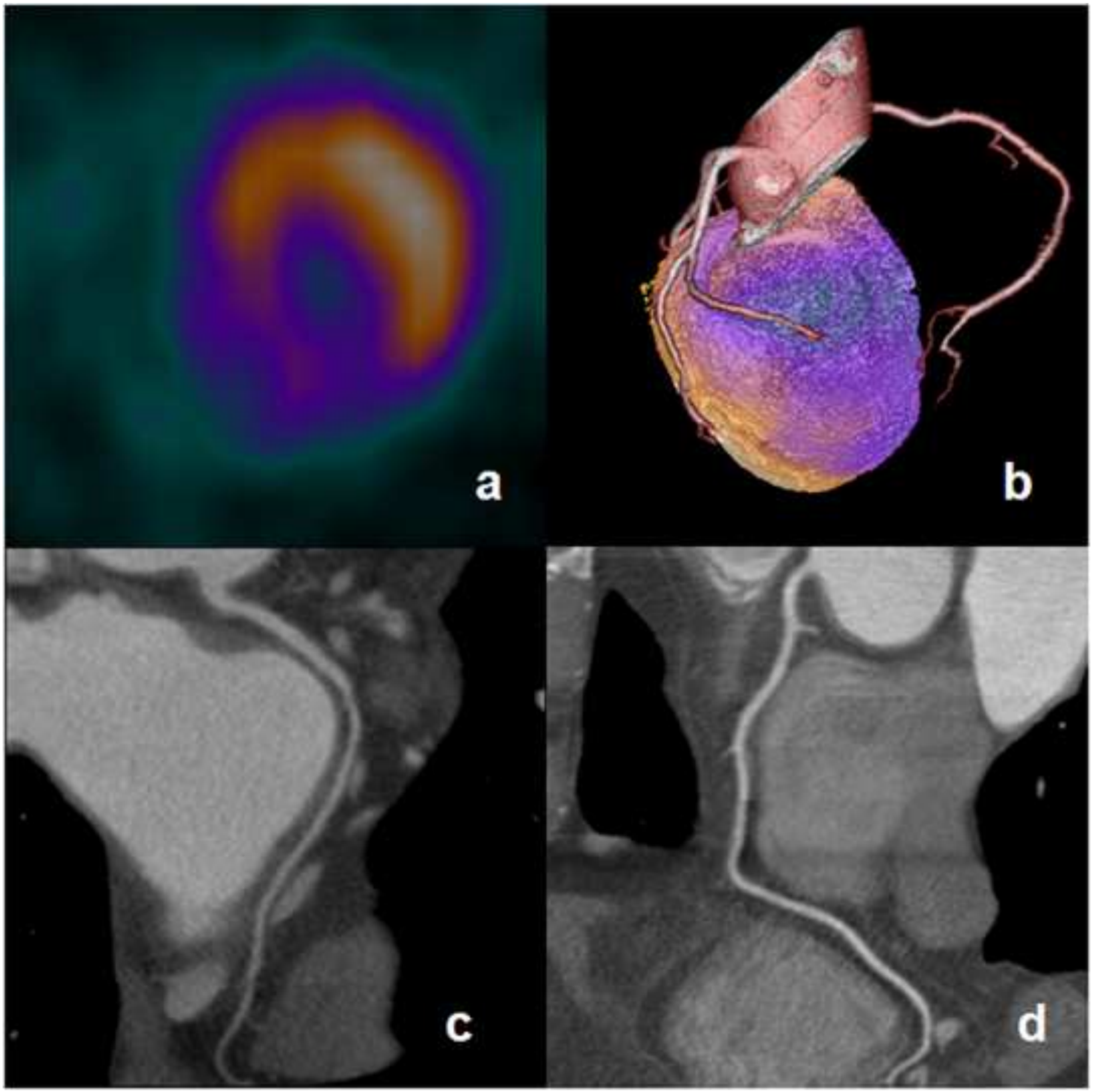

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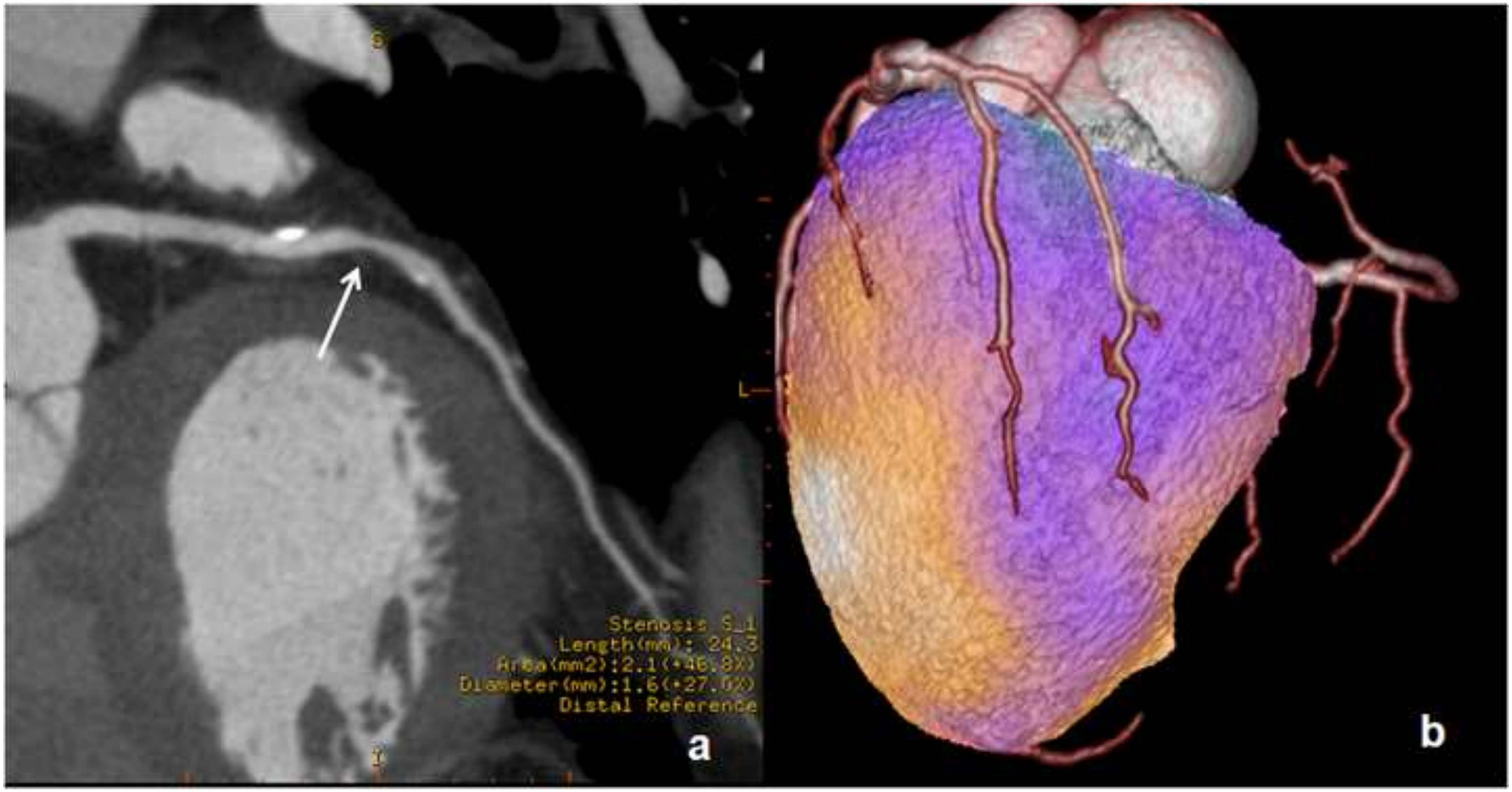

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