Diagnostic accuracy of dual-source multi-slice CT-coronary angiography in patients with an intermediate pretest likelihood for coronary artery disease

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Aims The aim of the present study was to assess the clinical performance of a dual X-ray source multi-slice CT (MSCT) with high temporal resolution to assess the coronary status in patients with an intermediate pretest likelihood for significant coronary artery disease (CAD) without using negative chronotropic pretreatment.

Methods and results Dual-source CT (DSCT) angiography (Siemens Definition) was performed in 90 patients with an intermediate likelihood for CAD who were referred for invasive coronary angiography. DSCT generated data sets with diagnostic image quality in 88 of the overall 90 patients. In six of seven patients with atrial fibrillation and in 46 of 48 patients with heart rates (HR) ≤65 b.p.m. image quality was diagnostic. In 20 of 21 patients with at least one stenosis ≥50% (sensitivity 95%) were correctly identified by DSCT-angiography. In 60 of 67 patients, a lesion ≥50% was correctly excluded (specificity 90%; positive predictive value 74%). The accuracy to detect patients with coronary stenoses ≥50% (sensitivity 92 vs. 100%; specificity 88 vs. 91%) was not significantly different among patients with HR ≤65 b.p.m. (n = 46) and >65 b.p.m. The concordance of DSCT-derived stenosis quantification showed good correlation (r = 0.76; P < 0.001) to quantitative coronary angiography with a slight trend to overestimate the stenosis degree.

Conclusion DSCT is a non-invasive tool that allows to accurately rule out coronary stenoses in patients with an intermediate pretest likelihood for CAD, independent of the HR.

KEYWORDS
Dual-source CT; CT; Coronary artery disease; Multi-slice CT

Introduction
Multi-slice CT (MSCT) has gained acceptance as an accurate non-invasive tool to evaluate coronary arteries. In patients with fast heart rates (HR) and arrhythmias, image quality is frequently affected by motion artefacts, limiting its utility. Furthermore, little is known about the accuracy of MSCT in patient populations with an intermediate prevalence of coronary stenoses.

Recently, MSCT has emerged as a non-invasive technique that allows to reliably detect coronary stenoses. Because of restricted temporal resolution, the clinical utility of MSCT is limited by the frequent occurrence of motion artefacts in patients with HR above 65–70 b.p.m. Consequently, a negative chronotropic pretreatment is recommended, sometimes complicating the patient management. Because of the high negative predictive value (NPV), MSCT is gaining acceptance as a tool to rule out coronary stenoses in patients with a low to intermediate pretest likelihood and a class IIa recommendation for this specific indication was proposed in a recent scientific statement of the American Heart Association. However, so far the vast majority of MSCT validation studies were performed in high-risk cohorts with a prevalence of significant disease in more than 50% of patients1,2,6,7 and thus the performance of MSCT in an intermediate risk population remains somewhat unclear.

The present study aimed to evaluate the diagnostic accuracy of a newly introduced dual X-ray source MSCT with high temporal resolution (83 ms) to rule out coronary stenoses in a patient cohort with an intermediate likelihood for coronary disease without using HR-modulating premedication.

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gave informed consent to participate in the study. The institutional review board approved the study protocol and all patients received chronicotropic premedication prior to the scan. All dual-source CT (DSCT) scans were performed with rotation time 0.33 s, and pitch 0.2–0.44 adapted to the heart rate. Per full current between 30 and 80% of the cardiac cycle, the gantry was 120 kV for both tubes, current 560 mA with modulation, and the image slab can be acquired in half the time needed by a conventional scanner (Siemens Medical Solutions, Forchheim, Germany). CT-coronary angiography was performed using a Siemens Definition Dual Score-CT system (Quantcor, Siemens Medical Solutions, Forchheim, Germany). The transmission data required for the reconstruction of one segment (modified AHA-segment model, fusion of segment 14 and 15) was judged as non-stenosed (no stenosis, >50%), intermediate disease (50% to 75% diameter stenosis), or significantly diseased (>75% diameter stenosis).

### Methods

#### Patients

From mid-July 2006 until January 2007 we included 90 consecutive patients who were referred to our hospital for coronary angiography for various reasons. Inclusion criteria were negative or equivocal stress tests, no prior known coronary artery disease (CAD), intermediate pretest probability for CAD according to the scoring method of Morise et al.\(^\text{10}\) (9–15 points). Exclusion criteria were renal insufficiency, known allergy to iodinated contrast material, unstable clinical condition, clear evidence for ischaemia in any stress test and high pretest likelihood (>15 points), or low likelihood for CAD (<9 points). Further patient characteristics are given in Table 1.

An independent external cardiologist determined the indication for invasive angiography. All dual-source CT (DSCT) scans were done one day before invasive coronary angiography. No negative chronotropic premedication was used prior to the scan. The institutional review board approved the study protocol and all patients gave informed consent to participate in the study.

#### Dual-source CT

CT-coronary angiography was performed using a Siemens Definition scanner (Siemens Medical Solutions, Forchheim, Germany) that uses two X-ray sources for image generation. With two tubes and two detectors mounted at orthogonal orientation in the gantry, the transmission data required for the reconstruction of one image slab can be acquired in half the time needed by a conventional MSCT-system. A gantry rotation time of 0.33 s results in a temporal resolution of 82.5 ms. Tube voltage for CT-angiography was 120 kV for both tubes, current 560 mA with modulation, and full current between 30 and 80% of the cardiac cycle, gantry rotation time 0.33 s, and pitch 0.2–0.44 adapted to the HR. Per rotation 64 slices are generated with a collimation of 0.6 mm, leading to an isotropic voxel resolution of approximately 0.6 mm edge length and 0.2 mm\(^3\) volume. Before the scan, nitroglycerine was administered sublingually. A bodyweight adapted volume of 5 cm\(^3\)/s was applied to maintain a compact bolus.

Axial images were reconstructed with 0.75 mm slice thickness and 0.5 mm increment using a medium sharp convolution kernel (B26) and retrospective ECG gating. The reconstructions were performed in 5% steps over the entire R-R cycle using a single-segment algorithm that utilizes a quarter segment of projection data from both detectors. In atrial fibrillation (AF), data sets were reconstructed in 50 ms steps.

#### Dual score-CT image analysis

#### Coronary analysis

In the first step all reconstructed data sets were evaluated at different ECG-phases for diagnostic image quality and the optimal data set was then chosen for analysis. The DSCT datasets were evaluated by two independent investigators using a dedicated cardiac workstation (Siemens, Leonardo Circulation). After visually identifying coronary stenoses, a computerized quantitative analysis on the basis of a density-based lumen edge detection algorithm was done. For this purpose luminal diameters in disease-free proximal and distal reference segments, that were marked by the investigator, were automatically determined and were set into relation to the minimal diameter measured within the stenosis. This approach corresponds to the method used for quantitative coronary angiography (QCA). The coronary lumen was defined by using the density-based full width half maximum method, which means that the outer lumen contour is determined by the Hounsfield value that represents 50% of the maximum value measured within the lumen. In the case of vessel calcification, the automatized contour detection was manually edited, in order to exclude calcifications from the lumen contour. The analysis as well as the manual editing was based on curved multiplanar reconstructions and cross-sections of the vessel perpendicular to the centreline. Each coronary segment (modified AHA-segment model, fusion of segment 14 and 15) was judged as non-stenosed (no stenosis, >50%), intermediate diseased (>50 to <75% diameter stenosis), or significantly diseased (>75% diameter stenosis).

#### Invasive coronary angiography

Invasive coronary angiography was done applying the Judkins approach using 4F catheters acquiring standardized projections. Coronary stenoses were analysed offline using a well-validated commercially available software package (Quantcor, Siemens Medical Solutions, Forchheim, Germany).

#### Statistical analysis

All calculations were done using the Medcalc software package. The agreement to determine stenosis severity by DSCT and QCA was done using Bland-Altman Analysis and calculating the spearman correlation coefficient. Interobserver variability was calculated by the following formula: (Stenosis degree observer 1 − stenosis degree observer 2) / (0.5 × stenosis degree observer 1) + (0.5 × stenosis degree observer 2). By averaging the sum of numbers obtained from each individual, stenosis average variability was calculated. Confidence intervals were determined for sensitivity, specificity, and for negative (NPV) and positive predictive values (PPV) on a patient basis, because of the clustering and potential within patient effects no confidence intervals are given for the accuracy values on a segment basis. To test the performance of DSCT-angiography in patients with HR exceeding 65 b.p.m., the results for these patients were calculated separately and compared with those obtained in patients with HR below 65 b.p.m. We assumed significant

#### Table 1  Patient characteristics

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<tr>
<td>Male</td>
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<tr>
<td>Female</td>
<td>33</td>
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<tr>
<td>Age (years)</td>
<td>58 ± 8</td>
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<tr>
<td>Atypical chest pain</td>
<td>53</td>
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<tr>
<td>Typical angina pectoris</td>
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<td>Dyspnoea/chest discomfort</td>
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<td>Hypertension</td>
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<tr>
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<td>Smokers</td>
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<tr>
<td>Family history of premature coronary artery disease</td>
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<tr>
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<td>36</td>
</tr>
<tr>
<td>Permanent beta-blocker</td>
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differences between these two groups in the case of non-overlapping confidence intervals. To test the ability of DSCT to identify different degrees of stenosis severity, separate analysis were done for detection of lesions ranging from 50 to 75% and >75% stenosis. These values were chosen because a discrimination of these different groups is critical for clinical decision-making and patient management.

Results

DSCT-angiography could be performed in all 90 patients 1 day before coronary angiography without any complications. Image quality was graded sufficient for analysis in 88 of 90 patients. In these 88 patients, 1216 of potentially 1232 segments were available for comparison, three segments could not be visualized in coronary angiography due to a proximal vessel occlusion and in 13 cases only 13 instead of 14 segments could be identified by invasive angiography. In two patients not all coronary vessels could be visualized with diagnostic image quality, so that they were not included to the accuracy analysis. In one patient respiratory motion was the reason for poor image quality and in the other patient motion artefacts of the RCA occurred (HR 112 b.p.m., AF). The mean HR during the scan was 73 b.p.m. (range 48–112 b.p.m.). In 46 patients DSCT-angiography was performed at HR >65 b.p.m. (n = 43) and/or in the presence of AF (n = 7).

Influence of heart rate and rhythm on reconstruction window

In patients with HR <65 b.p.m. and sinus rhythm, the optimal reconstruction window for all coronary vessels (left anterior descending, left circumflex, and right coronary artery) was found at 70% of the R-R cycle in 90% (38/42) of patients (Figure 1). In the remaining four patients, 80 and 60% (n = 3), respectively, were considered as the optimal reconstruction phase for all vessels. In one of the 42 patients, separate reconstructions for the left coronary system (70%) and the right coronary artery had to be done (30%). In patients with HR >65 b.p.m. and sinus rhythm (n = 39), separate reconstructions for the LCA (30%, n = 5; 60%, n = 4; 70%, n = 7) and the RCA (30%, n = 5; 40%, n = 9; 60%, n = 2) had to be done in 16 of 39 patients. In the remaining 23 patients, the optimal reconstruction window was found at 30% in six patients, 40% in eight patients, two patients at 60%, and at 70% in seven patients. In patients with AF (n = 7) we found that optimal image quality was obtained using absolute time intervals related to the R-wave. In two patients 550 ms, in three patients 400 ms, and in two patients 350 ms before the R-wave were considered to be optimal.

Diagnostic accuracy to detect coronary stenosis

Coronary angiography revealed 18 stenoses >75%. By DSCT, 17 were correctly identified and one was underestimated. Of 24 stenoses ranging from 50 to 75%, 17 were correctly classified, five were overestimated, and three were underestimated by DSCT. In 1165 of 1174 segments, significant (>50% stenosis) atherosclerotic disease was correctly ruled out (Tables 3 and 4). In nine segments, the findings assessed in DSCT were false-positive due to an overestimation. In eight of the 13 segments where DSCT revealed false-positive or -negative results severe calcifications were present. In two of seven false-positive results, the coronary vessel tapered to a very small diameter <1.0 mm and thus a vessel occlusion was incorrectly assumed by DSCT. All patients (n = 9) with at least one stenosis >75% (sensitivity 100%) and 11 of 12 (sensitivity 88%) patients with at least one stenosis ranging from 50 to 75% were correctly identified by DSCT. The NPV to exclude stenoses >75% and >50% on a patient basis was 100 and 98%, respectively. Stenoses >75% were correctly excluded in 76 of 79 patients (specificity 96%) and stenoses >50% in 63 of 67 patients (specificity 91%). In seven patients without any lesion >50%, at least one lesion >50% (n = 4) or >75% (n = 3) was incorrectly diagnosed by DSCT. The corresponding PPV for the detection of patients with at least one lesion >50% and >75% were 73 and 75%, respectively (Tables 2–4).

Figure 1 Significant 85% stenosis of the LAD. (A) Volume rendered reconstruction at diastole (70% of the R-R cycle). (B) Conventional invasive angiography. (C) Curved multiplanar reformatted image. Lesion is indicated by arrows. See online supplementary material for a colour version of this figure.

| Table 2 Consensus table of dual-source CT and quantitative coronary angiography regarding stenosis severity on a segment basis |
|--------------|-----------|-----------|-----------|
| QCA          | DSCT      | Stenosis degree | <50%     | >50%     | >75%     |
|              |           |              |          |          |          |
| <50%         | 1165      |              | 3        | 0        |
| >50%         | 5         | 16           | 1        |
| >75%         | 4         | 5            | 17       |

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Accuracy values for the detection of stenoses were not significantly different among patients with HR > 65 b.p.m. (n = 46, mean HR 79 b.p.m.) and < 65 b.p.m. (n = 42, mean HR 58 b.p.m.) as indicated by overlapping confidence intervals. The data expressing diagnostic accuracy are given in Tables 3 and 4.

Stenosis quantification
Quantitative analysis of the stenosis degree revealed good concordance between DSCT and QCA (Spearman’s correlation coefficient \( r = 0.76, P < 0.0001, 95\% \) CI 0.58–0.84). Bland-Altman analysis also implies good intermodality agreement with limits of agreement at −19.1 and 27.3% and suggests a trend to overestimate stenosis severity with DSCT by 4.1%. The concordance of stenosis grading between QCA and DSCT is given in Table 2. Interobserver variability of stenosis quantification by DSCT was 5.2% indicating good reproducibility.

Radiation exposure
Radiation exposure was calculated based on the dose length product as reported in a recent publication of Hausleiter et al. The mean calculated dose was 9.6 mSv (range 7.1–12.3 mSv).

Discussion
This is one of the first studies demonstrating that DSCT allows to reliably evaluate the coronary status of patients with an intermediate pretest likelihood for CAD. In contrast to earlier studies using MSCT systems with lower temporal resolution,\(^{11,12}\) dual-source technology has demonstrated sufficient clinical robustness even in the presence of arrhythmias and without the usage of negative chronotropic pretreatment in higher HR.

Clinical suitability of dual-source CT
One important finding of the present study was the fact that DSCT allows to assess the coronary status in patients with HR exceeding 65 b.p.m. with the same diagnostic accuracy as in lower HR. This fact is a major progress concerning the clinical utility of coronary CTA because with the current single source CT systems, pharmaceutical HR control or multisegment reconstruction algorithms have to be applied to avoid motion artefacts. Both of these options are affected by several problems.\(^2,3,12\) Beta-blocker therapy is not effective or is contraindicated in up to 20% of patients.\(^7,13\) Multisegment reconstruction algorithms that use data of up to four consecutive heart beats offer optimal temporal

<table>
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<th>Table 3</th>
<th>Segment-based diagnostic accuracy of DSCT to detect coronary stenoses</th>
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<tr>
<td>Degree of stenoses</td>
<td>Sensitivity</td>
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<tr>
<td>All patients</td>
<td>50–75%</td>
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<td>&gt;75%</td>
<td>17/18 (94%)</td>
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<tr>
<td>All &gt;50%</td>
<td>38/42 (90%)</td>
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<tr>
<td>HR &gt; 65 b.p.m. and/or atrial fibrillation (n = 46)</td>
<td>All &gt;50%</td>
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<td>&lt;65 b.p.m.</td>
<td>All &gt;50%</td>
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<th>Table 4</th>
<th>Patient-based diagnostic accuracy of DSCT to detect coronary stenoses</th>
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<tr>
<td>Degree of stenoses</td>
<td>Sensitivity</td>
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<tr>
<td>All patients</td>
<td>50–75%</td>
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<tr>
<td>95% CI</td>
<td>62–99%</td>
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<tr>
<td>&gt;75%</td>
<td>9/9 (100%)</td>
</tr>
<tr>
<td>95% CI</td>
<td>66–99%</td>
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<tr>
<td>All &gt;50%</td>
<td>20/21 (95%)</td>
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<tr>
<td>95% CI</td>
<td>76–99%</td>
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NPV, negative predictive value; PPV, positive predictive value; CI, confidence interval; HR, heart rate; QCA, quantitative coronary angiography.
resolution only in a small HR range. Therefore, even small variations of the HR lead to non-uniform temporal resolution during the scan. Consequently, this approach is prone to artefacts.\(^3\) In the present study, we demonstrated that with constant temporal resolution of 82.5 ms, DSCT can generate artefact-free images independently of the HR. However, post-processing of data acquired at higher HR or AF is more demanding because different reconstructions for different coronary vessels have to be done. It is remarkable that the best reconstruction window for the RCA frequently was found in systole, especially in higher HR. In lower HR the optimal window was constantly found at 70–80% of the R-R interval. This observation thus may be used to reduce radiation exposure by optimizing tube modulation.

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**Figure 2** Left circumflex artery with extensive calcification; method to determine stenosis severity: using a lower threshold representing 50% of the peak density Hounsfield value within the coronary lumen, the lumen contour is automatically detected. Diameters in the proximal and the distal reference segment are set into relation to the tightest diameter within the stenosis. In this case a diameter stenosis of 75% was calculated for dual-source CT. (A) Curved multiplanar reformation, arrows indicate the proximal reference, the lesion-, and the distal reference site. (B) Proximal reference, axial view perpendicular to the centreline. (C) Axial view at the lesion site. (D) Axial view at the distal reference. (E) Invasive angiogram showing no high grade lesion. (F) Quantitative coronary analysis reveals a 30% stenosis. See online supplementary material for a colour version of this figure.
and restricting full X-ray energy to only a very short ECG-phase. We further observed that we were also able to achieve diagnostic image quality in a small subset of five patients with AF indicating a satisfactory robustness. However, the performance of dual-source MSCT in patients with AF especially in those with fast ventricular response has to be proven in larger patient cohorts.

Diagnostic performance of dual-source CT

In earlier studies it has been demonstrated that MSCT-derived stenosis quantification is difficult, especially in the presence of calcifications that sometimes lead to an overestimation of the stenosis severity.1 Because of this source of error, there are concerns that the number of false-positive lesions would be unacceptably high in patients with a low prevalence of coronary stenoses. However, in a recent scientific statement of the American Heart Association, MSCT angiography gained a class IIa recommendation as a first line diagnostic test for patients with an intermediate likelihood for significant coronary stenoses although most of MSCT-validation studies were performed in high prevalence patient cohorts. In the present study we therefore aimed to test the performance of DSCT in clinically relevant patients, who had an intermediate pretest likelihood for coronary disease. Our results reveal that DSCT remains relatively specific to detect high grade coronary lesions also in a low prevalence patient cohort with slightly lower specificity (90 vs. 92–97%) and PPV (74 vs. 83–95%) when compared with the average values reported from 64-slice studies in high prevalence cohorts.2,6,7 We found high PPVs (80%) for detection of high-grade coronary stenosis (>75% stenosis diameter) and moderate values for detection of intermediate lesions (70%) owing to a trend to overestimate lesion severity. This trend to overestimate stenosis severity should be taken into account when interpreting CTA exams. Remarkably, sensitivity and NPVs were both in a comparable high range as reported in studies with strict preselection and exclusion criteria like high calcium scores, fast HR, and AF.2,7 Similar to earlier generation, MSCT scanners severe vessel calcification still affect assessment of coronary vessels and contributed to 64% of false-negative and -positive findings (Figure 2). Another reason for false-positive findings by DSCT is sudden vessel tapering from large to small vessel diameters mimicking total vessel occlusions.

Clinical implications and limitations

The results of our study underscore the potential of DSCT as a first line diagnostic tool to manage patients with an intermediate likelihood for coronary artery stenoses. That imaging modality allows to assign patients quickly to different clinical pathways. Patients with significant disease (at least one stenosis >75%) may be directed to catheter-based intervention, as these high-grade lesions reveal haemodynamic relevance in over 85% of cases. If DSCT identifies one or multiple intermediate lesions (50–75%), a stress test to assess the functional relevance (nuclear tests, stress echocardiography, MRI) of these specified lesions should be recommended prior to an invasive procedure and a revascularization procedure will then only follow if there is evidence for ischaemia. The major strength of the technique is its very high NPV allowing to accurately exclude coronary stenoses. By translating such an algorithm to our study, DSCT allowed to either exclude significant CAD (<50% stenosis) or to determine severe CAD (>75% stenosis) with a highly probable need for revascularization in 72 out of 88 patients without additional testing. Only three patients would have unnecessarily been sent to invasive angiography, in 12 patients additional functional testing would have been recommended, and only one patient with an intermediate likelihood would have been missed by DSCT-angiography. These results thus demonstrate that 81% of patients with an intermediate likelihood for CAD can be correctly triaged by DSCT-angiography alone.

DSCT is an X-ray-based technology and thus associated with ionizing radiation. The radiation exposure of DSCT-coronary angiography in our study was calculated as 9.8 mSv per patient. By optimizing tube modulation with restricting full X-ray energy only to a short interval within the ECG-cycle (e.g. 60–70% instead of 30–80% like in the present study) and further downregulation or shut down of the X-ray energy in the remaining time, more effective reduction of the radiation exposure can be expected in future. For this purpose, however, HR modulation would be mandatory again.

Supplementary material

Supplementary material is available at European Heart Journal online.

Conflict of interest: none declared.

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Clinical vignette
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Left ventricular pseudoaneurysm as a late complication of mitral annuloplasty

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A 59-year-old hypertensive male, 1 year after uncomplicated mitral annuloplasty for regurgitation with MAZE procedure, with a history of chronic obstructive pulmonary disease and repeated pulmonary embolism, returned to our intensive care unit for a transient episode of dyspnoea and chest pain, which quickly subsided on treatment.

Echocardiography revealed a bizarre pulsating sac in the usual transverse sinus localization between the left atrium, the ascending aorta, and the pulmonary artery (Panels A and B). We diagnosed a left ventricular (LV) pseudoaneurysm 50 mm in length, with a narrow orifice in the subaortic region of the LV outflow tract, adjacent to the mitral annuloplastic ring (Panel C). The dual-source computer tomography added information on the size and spatial orientation of the pseudoaneurysm (Panel D). The coronary angiogram was normal. The patient was referred to surgery, and a 3 mm entry of the pseudoaneurysm was successfully closed by a stitch.

This accidentally discovered LV pseudoaneurysm originating from the aorto-mitral junction was a rare late complication of mitral annuloplasty with an asymptomatic progressive course.

Panel A. Transoesophageal long axis, arrow at the pseudoaneurysm entry in the LV outflow tract.

Panel B. Short-axis view, pseudoaneurysm (PSA) adjacent to the left (l) and non-coronary (n) aortic valve cusps.

Panel C. Flow into the pseudoaneurysm at systole.

Panel D. Two-dimensional multiplanar reconstruction clearly depicts pseudoaneurysm (PSA) between the left atrium (LA), the ascending aorta (AA), and the pulmonary artery (PA).

See online supplementary material for movie clips of depicted echocardiographic images at European Heart Journal online.

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