German Radiological Society and the Professional Association of German Radiologists Position Paper on Coronary computed tomography: Clinical Evidence and Quality of Patient Care in Chronic Coronary Syndrome

Positionspapier von DRG und BDR zur Computertomografie des Herzens: Klinische Evidenz und Versorgungsqualität beim chronischen Koronarsyndrom

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ABSTRACT

This position paper is a joint statement of the German Radiological Society (DRG) and the Professional Association of German Radiologists (BDR), which reflects the current state of knowledge about coronary computed tomography. It is based on preclinical and clinical studies that have investigated the clinical relevance as well as the technical requirements and fundamentals of cardiac computed tomography.

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ZUSAMMENFASSUNG

Dieses Positionspapier ist eine gemeinsame Stellungnahme der Deutschen Röntgengesellschaft (DRG) und des Berufsverbandes der Deutschen Radiologen (BDR), die den aktuellen Wissenstand über die Computertomografie des Herzens wiedergibt. Es beruht auf präklinischen und klinischen Studien, welche die klinische Relevanz sowie die technischen Voraussetzungen und Grundlagen der Computertomografie des Herzens untersucht haben.

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1. Preamble

This position paper is a joint statement of the German Radiological Society (DRG) and the Professional Association of German Radiologists (BDR), which reflects the current state of knowledge about coronary computed tomography. It is based on preclinical and clinical studies that have investigated the clinical relevance as well as the technical requirements and fundamentals of cardiac computed tomography.

2. Introduction

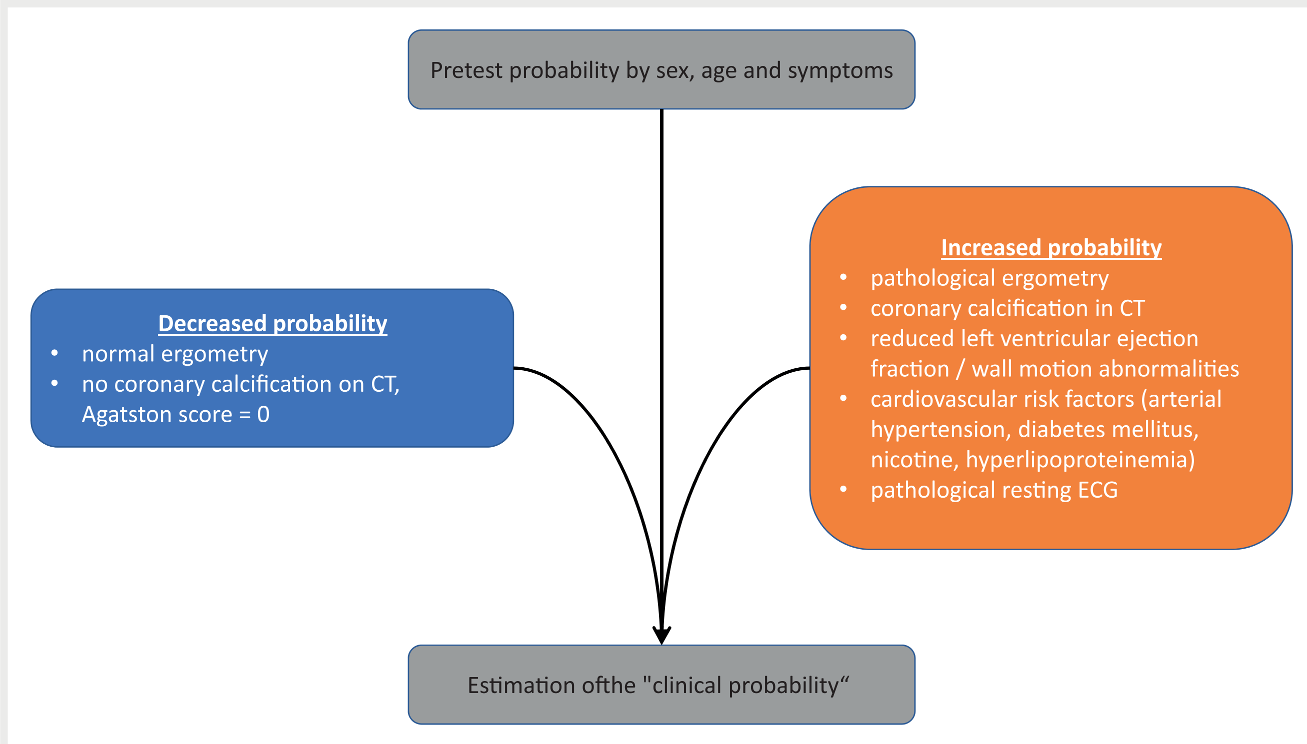
Coronary computed tomography (CT) was first used in the 1980 s to evaluate the perfusion of saphenous aortocoronary-bypass grafts [1]. However, by the end of the millennium, in spite of the worse spatial resolution, the focus was primarily on electron beam CT (EBT) because of the higher temporal resolution of up to 50 ms [2, 3]. As a result of the further technical development of CT, particularly the introduction of spiral CT, coronary CT-angiography (cCTA) has been able to be performed since the 2000 s in selected patients. However, since the introduction of the 64-slice CT scanner, cCTA can now be performed in the majority of patients to be examined in clinical practice with sufficiently high diagnostic image quality. The constant technical innovations in CT in recent years have further improved the image quality, thereby allowing implementation in previously unsuitable constellations, e. g. tachycardia and arrhythmia in atrial fibrillation [4].

In the same time period, a significant increase in the number of invasive diagnostic coronary angiography examinations was observed in Germany. In 2019 in Germany, approx. 726 300 invasive coronary angiography examinations (1999: 561 623) were performed. However, a percutaneous coronary intervention (PCI) was also performed in only approx. 41 % of cases (absolute: 295 799) compared to approx. 30 % of cases (absolute: 166 132) in 1999 [5, 6]. Even though the mortality rate of ischemic cardiomyopathy in Germany decreased between 1999 and 2014 from 356 to 189 per 100 000 inhabitants, Germany was still only in 15th place in the European comparison in 2014 despite the high number of coronary angiography examinations [7, 8].

Even the National Disease Management Guidelines on Chronic Coronary Artery Disease (2016), which were modified for the first time with respect to noninvasive methods and particularly cCTA and which indicate the importance of cCTA particularly in patients with a pretest probability between 15 % and 50 % due to the method's high negative predictive value, have had little effect on the number of invasive examinations in Germany [9].

The results of prospective clinical studies in recent years with large patient populations that underwent cCTA examination, for example the SCOT-HEART trial [10], the PROMISE trial [11], and the ISCHEMIA trial [12], and the pretest probabilities for coronary artery disease, which were adjusted based on the results of these studies [13], caused a paradigm shift in the current European ESC guidelines “Chronic Coronary Syndrome” (CCS) [14]. In these ESC guidelines published in 2019, noninvasive coronary assessment, generally in the form of functional tests like stress Magnetic Resonance Imaging (MRI), stress echocardiography, and single-photon emission computerized tomography (SPECT), and the morphological method cCTA are assigned a more important role in the workup of chronic coronary syndrome. cCTA continues to be primarily recommended in the group with low-intermediate pretest probability. The DISCHARGE study published in 2022 also supports and confirms this paradigm shift. This large prospective multicenter study examined the value of coronary CT and the use of an invasive cardiac catheter for the detection of relevant chronic heart disease in patients with stable chest pain and intermediate risk [15].

The determination of the amount of coronary calcium with “calcium scoring” (CASC) is also increasingly taken into consideration in the guidelines with respect to risk stratification. The CASC is used in the current ESC guidelines [11–13] primarily for estimating the “clinical probability” for coronary artery disease [13] (► **Fig. 1**).



▶ **Fig. 1** Pretest-probability and clinical likelihood [16].

For these reasons, an increase in cCTA examinations and a decrease in exclusively diagnostic coronary angiography examinations can be expected in the coming years.

This position paper discusses the current state of knowledge about coronary CT with respect to clinical evidence, quality of care, patient safety, legal aspects, and reimbursement and provides an overview of future developments.

3. Clinical evidence for coronary computed tomography

3. 1 Guidelines

The ESC guidelines regarding the diagnosis and management of chronic coronary syndrome and the National Disease Management Guidelines on Chronic Coronary Artery Disease were updated in 2019. To include the pathophysiology of coronary artery disease as a dynamic process of a chronic progressive but also regressive disease in the nomenclature, the original term "stable coronary artery disease" was retained in the ESC guidelines. The categorization of the disease based on clinical manifestation as acute coronary syndrome (ACS) and CCS is new [14].

In patients with suspicion of CCS, after the first impression, a detailed patient history including symptoms, comorbidities, and other possible causes for symptoms is first taken. A physical examination is then performed to evaluate the probability of coronary artery disease. If there is a probability of coronary artery disease, an ECG is performed, and the probability of ACS is evaluated. One possible approach is described in the guidelines "Chest Pain" (being updated) of the German College of General Practitioners and Family Physicians (DEGAM) [16]. Transthoracic echocardiography and lab tests can additionally be performed if necessary. In the case of persistent suspicion of CCS, the pretest probability of coronary artery disease can be assessed based on the patient's age, sex, and symptoms. The pretest probability of coronary artery disease was recalculated based on the CT data of the PROMISE and SCOT-Heart trials among other things. In general, this resulted in a reduction in pretest probabilities of up to 66 % compared to the values in the ESC guidelines from 2013 [17]. The pretest probabilities provide the basis for the selection of further diagnostic procedures, for example, an invasive cardiac catheter examination is indicated in the case of a pretest probability > 85 %. This threshold is no longer reached or exceeded when using the updated values (▶ **Fig. 2**) so that, based on the new updated pretest probabilities, there is, as a rule, initially no primary indication for an invasive cardiac catheter examination in patients with suspicion of CCS. The pretest probability can be modified by determining the newly introduced "clinical probability" which includes the known triad of age, sex, and symptoms as well as cardiac risk factors or prior examinations (echocardiography, stress ECG, or calcium scoring) (▶ **Fig. 1**). However, since consideration of the classic risk factors does not result in a better prediction of the presence of coronary stenoses [18], "it is difficult to assess the performance of the 'clinical probability' concept" [19]. According to the CCS guidelines, invasive cardiac catheter examination is only recommended as an "alternative test to diagnose coronary artery disease in patients with high clinical probability and severe treatment-refractory symptoms or in the case of typical angina

	Typical (%)		Atypical (%)		Non-anginal (%)		Dyspnea (%)	
Age (years)	Men	Women	Men	Women	Men	Women	Men	Women
30-39	3	5	4	3	1	1	0	3
40-49	22	10	10	6	3	2	12	3
50-59	32	13	17	6	11	3	20	9
60-69	44	16	26	11	22	6	27	14
≥70	52	27	34	19	24	10	32	12

▶ **Fig. 2** Pretest probability of obstructive coronary artery disease in symptomatic patients according to age, sex, and type of symptoms [13]. Dark blue: Groups in which noninvasive tests are most advantageous (pretest probability > 15 %). Light blue: Groups with a pretest probability for coronary artery disease between 5 % and 15 % in which a test for diagnosis on the basis of the clinical evaluation can be considered.

even at a low stress level and clinical evaluation indicating a high risk of a cardiovascular event" [20, 21].

Thus, primary noninvasive imaging is currently recommended in patients with suspicion of CCS. This applies to all patients with an intermediate risk (pretest probability 15–85 %). Depending on local availability and expertise, either noninvasive functional, i. e., ischemia detection, methods like stress echocardiography, stress MRI, stress PET, and stress SPECT, or the morphological method cCTA can be used for this purpose [20, 21]. According to the current National Disease Management Guidelines on Chronic Coronary Artery Disease, coronary CT is preferred particularly in the case of a low-intermediate pretest probability of 15–50 % [22].

3.2 Calcium scoring

A non-contrast low-dose CT examination for determining the calcium score can be a standard component of a cCTA examination for the workup of coronary artery disease. The most widely used and best studied calcium scoring method is the quantitative Agatston method (see the "Examination technique" section).

3.2.1 Calcium scoring in asymptomatic patients

Numerous studies and meta-analyses were able to show that asymptomatic patients without a measurable amount of coronary calcium (Agatston score 0) have only a low risk for cardiovascular events and no elevated overall mortality in the medium and long term [23, 24]. For example, the Heinz-Nixdorf-Recall study was able to show that the relative risk for a cardiovascular event in the case of a calcium score of 1–99, 100–399, 400–999 and ≥ 1000 is increased by a factor of 1.7, 4.0, 5.4, and 16.1, respectively [25, 26]. In a meta-analysis of 13 studies including 71 595 asymptomatic patients, one cardiovascular event occurred in only 0.47 % of 25 903 patients with a calcium score of 0 in the medium-term follow-up period of 50 months. In contrast, there was one cardiovascular event in 4.14 % of asymptomatic patients with a calcium score > 0 corresponding to a relative risk of 0.15 (95 % CI: 0.11–0.21; p < 0.001) [27].

A higher percentage of atherosclerotic changes in the case of a CAC score of 0 was seen in the prospective multicenter SCAPI (Swedish Cardiopulmonary Bioimage) study. A cCTA examination and a CAC scan were evaluated in 25 182 randomly selected individuals between the ages of 50 and 64 who were asymptomatic and without any known coronary artery disease. Athersclerotic changes were seen in 5.5 % of those in the group with a negative CAC score of 0. These changes were significant in 0.4 %. The percentage of cases of atherosclerosis in participants with a negative calcium score and a moderate 10-year risk due to cardiovascular risk factors was higher. Atherosclerosis was seen in 9.2 % of cases [28].

However, there is currently no study data allowing a final conclusion about calcium scoring with respect to possible screening examinations. Since early detection examinations for detecting non-communicable diseases, like calcium scoring examinations in asymptomatic individuals, e. g. as part of regular checkups, may only be performed as part of controlled screening programs approved by the German Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety in accordance with current regulations (§ 84 Radiation Protection Act), there is currently no legal basis for performing calcium scoring in this patient group.

3.2.2 Calcium scoring in symptomatic patients

The value of calcium scoring in symptomatic patients is unclear. A meta-analysis of data from 10 355 patients who underwent coronary angiography due to suspicion of coronary artery disease or acute coronary syndrome showed coronary stenosis > 50 % in 56 % of these patients. Calcium scoring with a value > 0 had a sensitivity of 98 %, a specificity of 40 %, a negative predictive value (NPV) of 93 %, and a positive predictive value of 68 % [27].

Among other things, the high NPV in this study was often used as an argument for not performing any additional examinations in the case of a CAC score of 0 (gatekeeper function) [29] In contrast, a subgroup analysis of the CORE64 study showed an NPV of only 68 % for coronary artery disease [30], and in the CONFIRM Register 3.5 % of patients with a CAC score of 0 had coronary stenosis ≥ 50 % and 1.4 % ≥ 70 % [31].

Studies using CT scanners of the latest generation in patients with a significant amount of coronary calcium, e. g. patients prior to planned TAVI [32, 33], show that it is possible to rule out relevant coronary artery disease with cCTA also in this patient population with a high percentage. Therefore, a function test with an ischemia detection method is recommended as the next step in the recommendations of the guidelines regarding CCS in the case of a high CASC in preliminary diagnostics and thus a high clinical pretest probability [14].

3.2.3 Calcium scoring for risk reclassification and for treatment management

A retrospective cohort study including 13 644 patients showed the relationship between the presence and extent of CAC and the use of statin therapy for risk reduction in atherosclerotic cardiovascular diseases [34]. The data from the MESA study has shown that the coronary calcium score not only provides superior discrimination and risk classification compared to other subclinical imaging markers or biomarkers [35, 36] but it is also strongly associated with the 10-year risk for atherosclerotic cardiovascular diseases. This association is independent and incremental with respect to traditional risk factors and can be seen in a graduated manner regardless of age, sex, and ethnic group [37].

An analysis of the Heinz-Nixdorf-Recall study was able to show that the additional determination of the calcium score (score = 0 vs. score ≥ 100) improves the stratification of patients with a high and low risk for coronary events [38]. Presumably, calcium scoring can thus help to perform an intensive risk factor modification adapted to the atherosclerotic plaque burden and the actual risk.

In patients with a borderline (5–7.4 %) or intermediate (7.5–19.9 %) risk for coronary artery disease according to the AtheroSclerotic CardioVascular Disease (ASCVD) Risk Score, calcium scoring can be used for individual risk evaluation for primary prevention, e. g., with statin therapy [39, 40]. In these groups, the determination of coronary artery calcification can result in a reclassification in a significant percentage of patients. For example, patients with an Agatston Score ≥ 100 or ≥ 75th age/sex/race percentiles can be reclassified in a higher risk group and those with a score of 0 in a lower risk group [40, 41].

The latest information regarding the use of calcium scoring for prevention in clinical practice indicates that calcium scoring improves current risk stratification and treatment decisions in people with hypertriglyceridemia without clinically relevant ASCVD risk [42].

Therefore, the cumulative 5-year ASCVD incidence was 15.9 % for a calcium score over 100 and 7.2 % for a calcium score of 0 in patients who qualify for treatment with icosapent ethyl (approved for lowering triglycerides since the end of 2021) and 13.9 % and 1.5 %, respectively, in those who do not qualify for this medication. This results in a number needed to treat of 29 for a calcium score greater than 100 and 64 for a calcium score of 0 for those qualifying for treatment with icosapent ethyl and a number needed to treat of 33 and 304, respectively, for patients who do not qualify for treatment with icosapent ethyl. Therefore, the calcium score could be used, for example, in the case of uncertainty regarding the use of statin therapy or for making decisions about additional treatments. However, there is a risk of undertreatment of patients with a calcium score of zero and overtreatment of patients with an elevated calcium score [43]. Therefore, for example, the ASCVD incidence for patients with a calcium score of 0 meeting the treatment requirements for icosapent ethyl increased to 10.8 % over a 10-year observation period. The results of the study by Cainzos-Achririca et al. can therefore provide a basis for the planning of randomized controlled studies for clarifying these questions [40].

In summary, in every CCS workup, a non-contrast CT scan for calcium scoring can be recommended prior to coronary CT angiography to determine an additional risk parameter, to identify patients with an extremely large amount of coronary calcium, and to perform a function test, e. g. a stress MRI, instead of coronary CT angiography, if applicable. Calcium scoring examinations in asymptomatic individuals, e. g., as part of regular checkups, are not allowed in accordance with current regulations.

3.3 Coronary CT angiography

With the adjusted pretest probabilities of coronary artery disease [13] that have been included in the current European Guidelines on Chronic Coronary Syndrome [14], noninvasive coronary CT imaging has been given a significantly more important role in the workup of chronic coronary syndrome.

The COURAGE trial [44], the SCOT-HEART trial [19], the PROMISE trial [45], and the ISCHEMIA trial [12], among others served as starting points for this development. With the publication of the COURAGE trial in 2007, which examined coronary artery disease patients with positive detection of ischemia and at least 70 % proximal coronary stenosis, the prognostic advantage of coronary revascularization was examined for the first time. The results showed that coronary intervention in addition to optimal medical treatment does not reduce the risk of death, heart attack, or other severe cardiovascular events in this patient population.

The SCOT-HEART trial showed that patients with stable chest pain who underwent coronary CT in addition to standard diagnostics in the workup of suspicion of coronary artery disease had a significantly lower rate of myocardial infarction (2.3 % vs. 3.9 %, p = 0.004) after an average of 4.8 years due to more intensive preventive treatment based on the CT results.

The results of the randomized ISCHEMIA trial were published in 2020 [10, 12]. A total of 5179 patients with noninvasively detected myocardial ischemia received either optimized medication-based treatment alone or in addition to invasive coronary angiography and possibly revascularization [12]. In 73 % of patients, coronary CT served as a gatekeeper to rule out patients with relevant left main artery stenosis (> 50 %) and to detect at least one single-vessel coronary artery disease with stenosis ≥ 50 % in one of the 3 coronary arteries. The agreement between cardiac catheter and CT was 97.1 % for the presence of a relevant left main stenosis ≥ 50 % and 92.2 % for the presence of significant coronary heart disease with stenosis ≥ 50 % in at least one coronary artery [46]. In the invasive group, 78 % of patients underwent revascularization. However, there was no significant difference in the cumulative 5-year event rate (death due to cardiovascular causes, myocardial infarction, hospitalization due to unstable angina pectoris, acute cardiac insufficiency, or survived cardiac death) (16.4 % in the invasive group and 18.2 % in the conservative group). There was also no significant group difference with respect to overall mortality (1.7 % vs. 1.0 % after one year and 9.0 % vs. 8.3 % after 5 years) also with respect to the secondary end points cardiovascular death and myocardial infarction. One advantage of the invasive approach was seen with respect to disease symptoms. In patients suffering from angina pectoris at the start of the study, complete freedom from symptoms could be achieved in 30 % more patients than with medication-based treatment alone [12]. On the whole, the ISCHEMIA trial showed that patients with suspicion of coronary artery disease benefit only symptomatically but not prognostically from an initial invasive diagnosis and treatment strategy after exclusion of left main stenosis via coronary CT compared to best medical treatment. As a limitation, it must be stated that during the approximately 5-year course of the study, 23 % of patients initially treated conservatively ultimately underwent coronary revascularization [12].

As mentioned above, there is currently no indication for calcium scoring alone as a screening method. At present, the same is also true for coronary CT angiography. However, for the future, cCTA is the only noninvasive method capable of detecting or ruling out unstable, non-calcified plaques. This raises the question as to whether coronary CT angiography could be useful in the future as a screening examination. As a first step, an answer to this question can only be provided by scientific examination of the topic in a narrowly defined group. This is also made possible by the changes in the Radiation Protection Act regarding screening, which allow implementation after scientific review within a narrow legal framework (§§ 84, 14 (3) Radiation Protection Act) [47].

In summary, based on the indicated studies, it can be stated that cardiac CT is equivalent to other invasive and noninvasive diagnostic methods with respect to its diagnostic significance in the primary diagnosis of CCS. Cardiac CT reduces the number of invasive catheter angiography examinations, the number of revascularization procedures, and the number of myocardial infarctions [10, 48]. Based on the current ESC guidelines, there is hardly a direct indication for invasive diagnostic procedures in patients with suspicion of chronic coronary syndrome.

3.4 Additional parameters

In addition to classic and established parameters in the analysis of coronary CT examinations like calcified, mixed, and non-calcified plaque, degree of stenosis, length and diameter of stenosis, additional plaque parameters have become increasingly established for evaluating cardiac risk. These parameters far exceed the simple degree of stenosis, as seen in invasive coronary angiography, and allow a more differentiated characterization of coronary lesions.

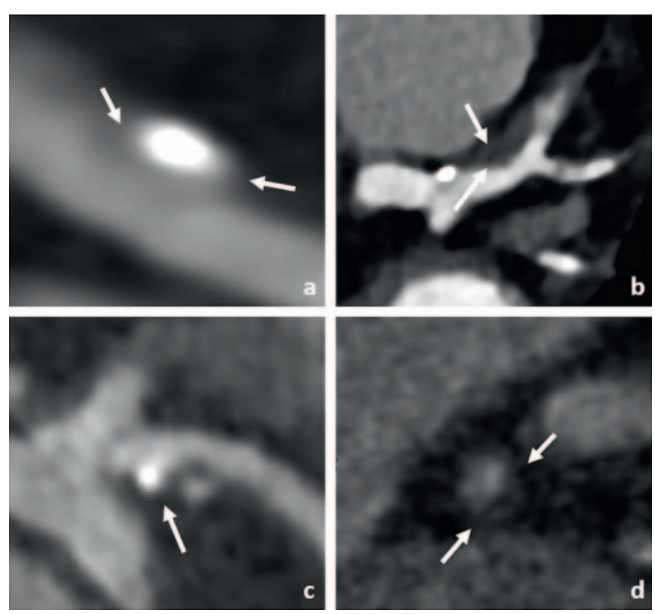
The ROMICAT II trial and the PROMISE trial were able to define various plaque parameters as independent and incremental risk factors for the occurrence of a cardiac event. These qualitative parameters are (▶ **Fig. 3**):

- Positive remodeling: Expansive, outward plaque growth without relevant stenosis of the vessel.
- Low attenuation plaque: Non-calcified atherosclerotic lesions with areas with low density (< 30 HU). These correspond to a fatty core.
- Spotty calcifications: Small calcifications (< 3 mm) with a high density (> 130 HU) within the atherosclerotic lesion.
- Napkin ring sign: Ring-shaped areas with increased density around a hypodense core of a non-calcified atherosclerotic lesion.

These changes are associated with an elevated risk for a relevant cardiac event both in patients with ACS and in those with CCS, and they are therefore also referred to as vulnerable or high-risk plaque features. Treatment should be reviewed and adjusted as needed [49].

The presence and extent of these high-risk plaque parameters should be an essential part of a coronary CT report. This was already taken into consideration in the current guidelines of the American Society of Cardiovascular Computed Tomography (SCCT) from 2021 [50]. The effect of these parameters on treatment regime is the current object of intensive research.

In addition to morphological parameters, other quantitative functional parameters will certainly become more important in the future for creating cardiac CT reports. The determination of the CT-based fractional flow reserve or CT-FFR has the greatest potential here. The FFR is determined via invasive pressure wire measurement during a cardiac catheter examination. The FFR provides the ratio of the mean intraarterial pressure of a coronary artery directly downstream from the stenosis (Pd) compared to the maximum pressure without stenoses or upstream from the stenosis (Pa) under maximum hyperemia. This is performed via the intravenous administration of adenosine during a cardiac catheter examination. For years it has been the invasive gold



▶ **Fig. 3** High-risk plaque features based on the finidings of the ROMI-CAT II- and PROMISE-trial: positive remodeling **a**; low attenuation **b**; spotty calcifications **c**; napkin ring sing **d**, marked with arrows.

standard for determining the hemodynamic relevance of a coronary stenosis [51].

With the help of mathematical models known as computational fluid dynamics (CFD), the principle was applied to CT data thus allowing noninvasive evaluation of hemodynamic conditions with respect to the relevance of a stenosis [52]. This plays a role particularly in intermediate stenoses [53, 54]. The PLATFORM study was able to show in patients with suspicion of coronary artery disease that the rate of cardiac catheterization without detection of obstructive coronary artery disease can be significantly reduced by using the CT-FFR (CT-FFR: 12 % vs. ICA: 73 %) [55]. This is limited by a lack of broad availability since to date only one clinically approved application is commercially available. This application can only be used off-site in the form of a cloud-based solution. Not yet commercially available software solutions based on machine learning from various manufacturers [56, 57] that can be used on-site also show very promising results and may soon be commercially available. Nevertheless the use of this comparably expensive method can already be helpful in individual cases from the standpoint of patient wellbeing and with respect to economic aspects.

4. Examination technique

Quality standards regarding the examination technique used in non-contrast cardiac CT for calcium scoring and coronary CTA provide the basis for good diagnostic significance. The image quality of the examination should be assessed by a specialist immediately after completion of the reconstructions on the CT scanner. Various anatomical landmarks which are listed in detail in the two sections "CT calcium scoring" and "coronary CT angiography" are used for visual quality assessment.

The two examination techniques have the following in common: To avoid motion artifacts, CT scans must be acquired with at least 64 detector rows and a rotation time of < 0.35 seconds. Prospective ECG triggering or retrospective ECG gating should be used depending on heart rate and the presence of arrhythmia. The patient is in a supine position with arms over the head. The heart should be in the isocenter of the scanner. Both the topogram and the scan should be acquired in inspiration. The $CTDI_{vol}$ is based on the current reference values, adapted to the particular medical question. The standard matrix for visualization of the heart should be a small Field-of-View (FOV) 512 × 512 pixels adapted to the size of the heart. Moreover, an additional scan with a "large" FOV completely covering the thorax and the surrounding soft tissues must be acquired to visualize secondary findings. The heart is reconstructed with a smooth (soft) kernel. The thorax is additionally reconstructed with a hard kernel. Cardio or stent-specific kernels are also available depending on the manufacturer.

4.1 CT calcium scoring

The patient is positioned and prepared as described above. The artifact-free visualization of calcifications of the coronary arteries and the heart valves and the identification of the coronary ostia are the basis for the visual quality assessment of the image.

The boundaries of the scan region are the carina and the cardiac apex. The recommended scan parameters are 100–120 kV, a rotation time of < 0.35 seconds, and a collimation of < 1 mm in spiral mode. In the case of scanners with a corresponding detector width, individual rotations with complete acquisition are also possible. For calcium scoring, an individual series in end-diastole is needed. For the reconstruction of images of the heart and the thorax, the slice thickness and the increment should be 3 mm to ensure comparability with the published calcium scores, mainly the Agatston score [58]. For example, windowing can be performed with a width (w) of 400 HU and a center (c) of 100 HU, but these can vary as needed.

4.2 Coronary CT angiography

Optimal image quality is reliably achieved when the patient has a low heart rate of ≤ 65 beats/minute and a regular heart rhythm during the examination. If this requirement is not met, a beta blocker should be administered (see the section "Medication-based heart rate control"). In addition, nitrates should be administered to improve vessel lumen evaluation (see the section "Medication-based vessel dilation"). Heart rhythm, rate, blood pressure, and all administered medications must be documented.

The basis for the visual quality assessment of the image is the ability to identify coronary plaques and the leaflets and cusps of the heart valves. To ensure adequate enhancement of the coronary arteries (blood pool > 250 HU), the contrast agent should be adapted to the patient's weight (0.2–0.4 g iodine/kg body weight). An iodine delivery rate of 1.2–2.0 g iodine/second is recommended [59]. Using a contrast agent with 300 mg iodine/ml results in a volume of 60–80 ml contrast agent and an injection rate of 4–6 ml/s for the average patient. The standard for the triggering of a scan is bolus tracking (cutoff value 120–180 HU), with the positioning of the region of interest (ROI) depending on the scanner type. Alternatively, a test bolus strategy can be used. [60]

The scan region should extend at least from the aortic bulb to the cardiac apex in patients after bypass operations when an arterial in-situ bypass is to be visualized. Prior to TAVI, the region can be expanded to include the subclavian artery. Typical scan parameters are 70–120 kV, rotation time of < 0.35 seconds (360°), and a collimation of < 0.7 mm. In the case of a regular, low heart rate (< 65 beats/minute), dose-sparing, prospective ECG triggering can be used. If these requirements are not met, the more robust, retrospective ECG gating with or (in exceptional cases with pronounced arrhythmia) without ECG-adjusted dose modulation should be used. However, this is associated with higher radiation exposure. The reconstructed slice thickness for evaluating CTA should be ≤ 0.7 mm. In the case of prospective ECG triggering, multiple cardiac phases should be reconstructed to identify the phases with minimal motion artifacts or various phases for every coronary artery. The minimum requirements for retrospective ECG gating are two spatially overlapping reconstructions (increment < slice thickness) of the heart. Moreover, curved or straightened MPRs of the LAD, CX, and RCA should be created. For example, the window width can be 600 HU and the window center 200 HU. This can be adjusted as needed. Supporting reconstruction algorithms, e. g. for artifact reduction or quality improvement, with iterative reconstruction are optional.

4.3 Special considerations for pediatric patients

For the pediatric patient population, suitable, age-adapted protocols with a reduced dose should be used (e. g., the lowest possible tube voltage). In the case of optimal examination conditions, high-pitch/single-shot protocols are also available depending on the scanner. The amount of contrast and flow rate should be reduced based on age and size. Non-contrast examinations for calcium scoring are usually not indicated in young patients.

5. Patient safety

When the safety measures recommended when using ionizing radiation are taken into consideration and when properly indicated, computed tomography is a safe examination technique. Possible risks can result from the use of ionizing radiation, the administration of iodinated contrast agents and nitroglycerin, and the use of medication-based heart rate control.

5.1 Ionizing radiation

Like every examination using ionizing radiation, CT is subject to the Radiation Protection Act and the Radiation Protection Ordinance [61]. When used properly, CT does not result in any acute deterministic radiation effects due to the low doses used by modern CT scanners. Chronic and delayed radiation effects require a differentiated assessment.

McCollough et al. estimate that a CT scan with a dose between 1 and 10 mSv is associated with a risk of fatal cancer of 1:2000 [62]. The natural incidence of fatal cancer of approx. 400:2000 (20 %) increases in this dose range by 0.2 % to 20.02 % (401:2000) [63]. For certain tumor entities, there may be other additive risks depending on the total dose. However, there was no increased cancer risk also in this case for doses less than 30 mSv [64]. In the case of an average dose of approx. 4.4 mSv for a diagnostic coronary angiography examination [65] and an average dose of 0.63–4.7 mSv for a coronary CT examination [66], the risk of fatal cancer for coronary CT is lower than or approximately equal to an invasive diagnostic coronary angiography.

However, there is an additional complication risk for invasive diagnostic coronary angiography due to the invasiveness of the examination. The risk of non-fatal complications (e. g., asymptomatic occlusion of the radial artery, hematoma at the puncture site) in coronary angiography is 1–30 % and the risk of fatal complications is 0.08–0.1 % [67–69]. Therefore, regardless of possible therapeutic consequences, coronary CT has a significantly better safety profile for the patient when comparing complication frequency and severity.

Of course, only physicians with the corresponding CT expertise can correctly determine the indication for CT and perform coronary CT examinations. In addition to the regulations in the Radiation Protection Act, Section 299a of the German Criminal Code prohibits the taking of bribes in the health care sector. Therefore, the referring physician, usually a general practitioner, internist, or cardiologist, may not receive any direct or indirect personal advantage as a result of a CT examination. Critical review of the indication helps to ensure patient safety and use of the 4-eyes principle ensures economic efficiency. In statutory health insurance, in accordance with the Quality Assurance Agreements per § 135 Paragraph 2 of the German Social Code Book V (in connection with the Regulations on Continuing Medical Education of the State Chambers of Physicians), radiological methods like MRI, CT, and angiography can only be performed by specially qualified radiologists [70, 71].

5.2 Contrast agent

In general, the non-ionizing, low-osmolar, iodinated contrast agents typically used today are very safe. The incidence of acute side effects is approx. 0.2–0.7 % [72–74] and the incidence of severe acute side effects is approx. 0.04 %. Fatal contrast agent reactions are very rare with an incidence of 1:170 000 [75].

5.3 Allergic reaction

The incidence of allergic reactions is estimated to be 0.05–0.1 % after intravenous administration of iodinated contrast agents and is even lower (0.03–3 %) for non-ionizing contrast agents as normally used today [76–79]. The risk factors for hypersensitivity to iodinated contrast agent are not fully understood [78].

5.4 Contrast-induced nephropathy

Compared to invasive coronary angiography, cardiac CT has an advantageous safety profile with respect to the risk for contrast-induced nephropathy. At present, contrast-induced nephropathy is believed to be extremely rare, particularly in CT. However, the actual incidence of contrast-induced nephropathy is still not sufficiently known in spite of numerous studies. However, the available data indicate that the intravenous administration of an iodinated contrast agent in patients with an eGFR ≥ 45 ml/min/1.73 m^2 is not an independent risk factor for post-contrast acute kidney failure and that post-contrast acute kidney failure in patients with an eGFR between 30 and 45 ml/min/1.73 m^2 is very rare [80–83]. Two studies showed an elevated risk for contrast-induced nephropathy in patients with an eGFR < 30 ml/min/1.73 m^2 [80, 81].

In comparison to other examinations using contrast agent, invasive coronary angiography seems to have an elevated risk for contrast-induced nephropathy. The intraarterial and suprarenal contrast injection resulting in a short and insignificantly diluted contrast bolus in the kidneys may be responsible for this. In addition, the risk of arterio-arterial thromboembolisms due to catheter manipulation should be mentioned [82, 84–86].

5.5 Effects on thyroid function

Iodinated contrast agents can disrupt thyroid function, e. g., hyperthyroidism, or, in the presence of latent hyperthyroidism, can trigger manifest hyperthyroidism. Moreover, the use of scintigraphy to diagnose thyroid diseases, e. g., an autonomous adenoma, is blocked for at least 3 months by the administration of iodine.

Although clinically relevant, the prevalence of thyroid dysfunction caused by iodinated contrast agents has not been sufficiently studied. The published data shown a prevalence between 0.05 % and 5 % but this rate is higher in patients with preexisting thyroid disease [87–90]. Although it is rare, the disease can have severe or even life-threatening consequences if it goes untreated. Therefore, as a rule, thyroid dysfunction is ruled out prior to the administration of an iodinated contrast agent. This is usually done by performing a lab test to determine the patient's basal TSH level. However, there are currently no generally accepted recommendations in this regard [89, 91].

5.6 Medication-based vessel dilation

Provided that there are no contraindications, nitrates should be administered prior to CTA to cause vasodilation thereby allowing optimal vessel lumen evaluation [92]. 400–800 mg sublingual nitroglycerin that can be administered either as a tablet or spray (typically 1–2 tablets or 1–2 sprays) are commonly used [93]. The 800 mg dose and the spray form are typically preferred due to the ease of application [94]. To ensure optimum effectiveness, the spray should be administered sublingually approximately 5 minutes prior to the examination. After administration, the duration of action is approximately 20–30 minutes [95]. It is recommended to administer the spray after measuring the patient's blood pressure on the CT table to avoid syncopal episodes caused by a sudden drop in blood pressure [96]. An overview of contraindications and common side effects is provided in ▶ **Table 1**.

▶ **Table 1** Contraindications and common side effects of the administration of nitroglycerin premedication. HOCM, hypertrophic obstructive cardiomyopathy.

Contraindications	Phosphodiesterase inhibitors
	Severe hypotension (systolic blood pressure under 90 mm Hg)
	Severe aortic valve stenosis, HOCM
	Allergy to nitrates or other ingredients
Side effects	Drop in blood pressure, syncope
	Headache, dizziness, lightheadedness
	Tachycardia
	Allergic reaction
	Asthenia at the administration site

5.7 Medication-based heart rate control

For optimal image quality, a heart rate ≤ 65 beats per minute with the lowest possible variability should be targeted even in the case of modern CT scanners [97] (see the section "Examination technique"). Heart rate is typically controlled by the administration of cardioselective beta blockers (e. g., metoprolol) prior to the start of the examination [98]. Under the consideration of comorbidities and contraindications (▶ **Table 2**), no clinically relevant complications were seen in multiple large studies. Raju et al. retrospectively evaluated the data of 662 patients, who received an average of 19 mg metoprolol (maximum 67 mg) until the target heart rate of less than 60 beats per minute was reached [99]. No unwanted side effects were seen. Kassamali et al. reported similar results in 679 patients who underwent coronary CT angiography. The average metoprolol dose was 20 mg (maximum: 70 mg). Complications were seen in 10 (1.47 %) patients, with the complications requiring intervention in only 3 (0.44 %) patients [99]. The complications included a second-degree atrioventricular block in two patients.

▶ **Table 2** Contraindications and side effects with respect to the administration of ß-blockers for heart rate control.

Contraindications	(Allergic) bronchial asthma or severe chronic obstructive pulmonary disease
	Mobitz type II or III atrioventricular block
	Bradycardia (under 50 beats/minute)
	Severe hypotension (systolic blood pressure under 100 mm Hg)
	Acute congestive heart failure
	Allergy to beta blockers or their ingredients
Side effects	Bronchospasm
	Bradycardia
	Atrioventricular block
	Hypotension
	Raynaud's phenomenon
	Allergic reaction

Titrated intravenous administration of metoprolol has become established. One possible dosing scheme is initial i. v. administration of 5 mg followed by 2.5 mg i. v. every 3–5 minutes until the target heart rate is achieved. The recommended highest dose is 15 mg i. v. To reduce the preparation time in the scanner, oral administration of 100 mg one hour prior to the examination is also possible if local conditions allow [98]. The cardioselective beta blocker esmolol i. v. can be used as an alternative in patients with bronchial asthma requiring treatment. It has a rapid onset of action but a short half-life of only 9 minutes. Administration is adapted to body weight. 50–100 µg/kg body weight is recommended here. The slightly less favorable risk profile compared to metoprolol must be taken into consideration. Therefore, it should only be used in the indicated patient population. A further possibility for lowering heart rate is to administer benzodiazepines, e. g., 1 mg lorazepam sublingual, or ivabradine (I_f-channel inhibitor) per os.

In summary, cCTA has a very favorable risk-benefit profile compared to invasive coronary angiography when properly indicated according to the CCS guidelines. This is true with regard to both the possible consequences of ionizing radiation and unwanted contrast agent side effects. The application of contrast agent during CT imaging is established globally and has a very low complication rate. Predisposing factors must be investigated during the informed consent discussion and taken into consideration accordingly. Contrast agents should be applied in accordance with the approved uses, and the contrast administration protocol should be adjusted to the particular medical question and CT scanner.

Sufficient heart rate control during cardiac CT imaging is important for ensuring good diagnostic image quality. Various medications and application forms can be used here. These should be selected based on individual experience, the patient, and applicability. All of these drugs have a favorable risk profile and are established in the clinical routine. Major complications caused by the administration of medication were not observed [99]. In contrast, the frequency of relevant complications during diagnostic coronary angiography (death, myocardial infarction, stroke, pericardial effusion or tamponade, percutaneous coronary intervention due to iatrogenic coronary dissection, or unplanned bypass operation within 72 hours after diagnostic left hearth catheter examination) is 0.082–0.44 % [100, 101].

6. Reporting

6.1 Qualification recommendations

Cardiac CT is an integral part of the advanced training curriculum published by the German Radiological Society and the German Young Radiology Forum, and the module "M5 heart and vessels" describes in detail the cardiac imaging training content [102] (https://www.forum-junge-radiologie.de/de-DE/4927/curriculum/). The ensure the quality standards of cardiac cross-sectional imaging, the Cardiac and Vascular Diagnostics working group of the German Radiological Society created a level-based certification program for cardiac imaging, which, starting with the second qualification level, far exceeds the knowledge needed to become a board-certified radiologist. The qualification levels can be achieved separately for CT and MRI and include the following levels:

- Qualification level Q1 corresponds to fundamental knowledge of the heart anatomy, the (patho)physiology, the indications, technical implementation, and reporting in adults.
- Qualification level Q2 indicates an ability to independently perform and interpret cardiac cross-sectional imaging. The Q2 qualification level builds on level Q1 and requires a thorough understanding of the subjects listed above.
- Qualification level Q3 requires comprehensive knowledge of cross-sectional cardiac imaging. Achieving this level also means that the physician is qualified to review applications submitted to the certification program of the Cardiac and Vascular Diagnostics working group.

The prerequisites for achieving each qualification level are a certain number of CME points from a Q-course certified by the Cardiac and Vascular Diagnostics working group, a fixed number of interpreted and documented examinations, and, starting at Q2, successful completion of an exam. Details can be found on the website of the Cardiac and Vascular Diagnostics working group (https://www.ag-herz.drg.de/de-DE/1201/ueberblick/). The examination numbers can be documented online using the case collections on the CONRAD platform or optionally using the European Cardiac MR/CT Registry (https://www.mrct-registry.org/) of the European Society of Cardiovascular Radiology. Registry in the ESCR MR/CT Registry is mandatory.

In addition to the certification of medical personnel, centers and courses can also be certified. As part of the consolidation of medical technical professions in the German Radiological Society, certification for radiographers is also offered. Detailed information and documentation regarding the individual certification processes can be found online on the homepage of the Cardiac and Vascular Diagnostics working group (https://www.ag-herz.drg.de/de-DE/129/zertifizierung/).

6.2 Reporting

The examination report should contain at least the following: Clinical data for determining the proper indication and estimating the pretest probability of coronary artery disease, like symptoms, onset of symptoms, cardiovascular risk factors, and known prior examinations. Data regarding the examination technique including acquisition technique and administered medication, image postprocessing, examination quality, and findings: Calcium score, presence of coronary anomalies, type of coronary circulation, plaques (calcified, mixed, not calcified, high-risk), coronary stenoses, heart valves, pericardium, extracardiac findings. Information regarding radiation exposure. In addition, decision aids that are important for the referring physician should be included in the report in the form of a classification or percentiles so that important clinical consequences are standardized and easy to identify.

6.3 Structured reporting

In addition to traditional reports written in free form, structured reporting has become increasingly established in the clinical routine. Various studies have shown that structured reporting results in a lower rate of diagnostic errors, a higher level of completeness and understandability of the radiology report, and a higher level of satisfaction on the part of the referring physician and other colleagues [103, 104]. Ghoshhajra et al. were able to show in a study on cCTA that the agreement between radiologists and referring physicians with respect to the number of coronary arteries with severe stenosis increased significantly (53 % (free form) vs. 68 % (structured report); $p = 0.04$; $\kappa = 0.31$ vs. 0.52) [105]. Especially in the context of medically and technically demanding examinations with intensive interdisciplinary communication like cardiac CT, these characteristics are significantly more important.

In addition to numerous general radiological societies [106, 107], multiple cardiovascular imaging societies have expressed their support for structured reporting in a joint consensus paper [108]. The European Society of Cardiovascular Radiology issued a concrete recommendation for structured reporting in the case of pre-transcatheter aortic valve replacement (TAVR) cross-sectional imaging [109].

To make structured reporting templates broadly available, the Cardiac and Vascular Diagnostics working group created a number of templates during a consensus conference [110]. They are based on the corresponding recommendations of the professional societies depending on the pathology with the goal of promoting a high-quality standard for reporting. All templates created to date are available online via an open-source license (www.befundung.drg.org) and can be used directly for reporting. English-language reporting templates of the Radiological Society of North America (RSNA) and the European Society of Radiology (ESR) can be found on the platform www.radreport.org.

6.4 CAC-DRS, MESA percentile, and CAD-RADS

For calcium scoring and cCTA, structured decision support tools have also become established in the clinical routine in the form of the Coronary Artery Calcium Data and Reporting System (CAC-DRS) and Coronary Artery Disease Reporting and Data System (CAD-RADS) classification systems [111]. The CAD-RADS classification in particular is important for reporting. With respect to the amount of coronary calcium, the MESA percentiles are given preference over the CAC-DRS classification for the reasons mentioned above.

6.4.1 CAC-DRS

The CAC-DRS allows classification of the Agatston values for structured reporting, however without adjustment for age and sex [58] (▶ **Table 3**). Classification is performed preferably based on the Agatston score (A0: score 0, A1: score 1–99, A2: score 100–299, A3 ≥ 300) or alternatively visually (V0: no coronary calcifications to V3: significant amount of coronary calcium) primarily in the case of non-ECG-gated examinations [112, 113]. The modifier N describes the number of affected coronary vessels (example: Agatston score 287 in 2 vessels = CAC-DRS 2/3). In addition, pharmacopreventive measures can be derived from the CAC-DRS classification.

The standardization of the classification makes it possible to ensure a standardized and targeted evaluation of the amount of coronary calcium and to provide information in a compact and clear manner to the disciplines providing further treatment.

Alternatively, in clinical practice and in studies like the analysis of the SCOT-Heart Study [114], the calcium score is divided into six categories: 0: none; 1–10: minimal; 11–100: low; 101–400: moderate; > 400: pronounced; > 1000: severe coronary sclerosis.

▶ **Table 3** Classification according to CAC-DRS and treatment recommendations (according to [105]). ASA, acetylsalicylic acid.

CAC-DRS	Agatston Score	Risk	Treatment recommendation
0	0	Very low	No statin therapy (exception: familial hypercholesterolemia)
1	1–99	Slightly elevated	Moderate statin therapy
2	100–299	Elevated	Moderate to intensive statin therapy plus ASA 100 mg
3	> 300	Elevated to extremely elevated	Intensive statin therapy plus ASA 100 mg

▶ **Table 4** The degree of stenosis is determined based on the percentage lumen diameter stenosis (according to [110]).

Lumen diameter stenosis [%]	Nomenclature
0	No stenosis
1–24	Minimal stenosis
25–49	Minor stenosis
50–69	Moderate stenosis
70–99	Severe stenosis
100	Occlusion

6.4.2 MESA percentiles

Moreover, structured categorization on the basis of percentile curves based on the results of the Multi-Ethnic Study of Atherosclerosis (MESA) study is recommended [113]. These thus allow classification of the Agatston Score in the appropriate reference group weighted according to age, sex, and ethnicity. While an Agatston Score of 100 would be classified as low for an 84-year-old patient within the framework of the atherosclerotic aging process, the same Agatston Score would be high for a 45-year-old patient. Doubling of the Agatston Score is associated with a 15–35 % higher probability of a relevant cardiac event (stroke, myocardial infarction, cardiovascular death) [27, 113].

An online tool for calculating MESA percentiles is available free of charge (at https://www.mesa-nhlbi.org/Calcium/input.aspx). The report should include the calculated percentiles.

6.4.3 CAD-RADS

The CAD-RADS classification depends on the degree of stenosis and the number of affected vessels. The degree of stenosis is classified based on the percentage lumen diameter stenosis (▶ **Table 4**). All vessels with a diameter of more than 1.5 mm should be used for the evaluation. The CAD-RADS classification does not apply to vessels with a diameter of less than 1.5 mm. Evaluation is not recommended. Allocation to one of the CAD-RADS classes is performed largely based on the maximum detected degree of stenosis (▶ **Table 5**) [115]. The category "CAD-RADS 4" is divided into the subcategories 4A (70–99 % stenosis) and 4B (stenoses in 3 coronary arteries > 70 % or > 50 % stenosis of the left main coronary artery) [115]. The CAD-RADS categories are accompanied by recommendations regarding the further diagnostic approach and patient management (▶ **Table 5**) [115].

The CAD-RADS classification system also uses modifiers. The category "CAD-RADS N" is used for examinations with non-diagnostic quality. The modifier can be used alone or in combination with one of the numeric categories (example: CAD-RADS 4/N = left main stenosis > 50 %, the remaining coronary segments cannot be evaluated). Other modifiers that can be added in an analogous manner are "S" (stent), "G" (graft = bypass), and "V" (vulnerable). The V modifier is used when a plaque has two or more of the high-risk plaque features mentioned above (low-density plaque, positive remodeling, microcalcifications, napkin ring sign) and is therefore a vulnerable plaque (▶ **Fig. 3**).

▶ **Table 5** CAD-RADS categories in chronic coronary syndrome (according to [109]). CAD, coronary artery disease.

	Maximum degree of stenosis [%]	Interpretation	Further diagnostic workup	Patient management
CAD-RADS 0	0 (no stenosis or plaque)	CAD ruled out	None	▪ Consider non-atherosclerotic causes
CAD-RADS 1	1–24	Minimal non-obstructive CAD	None	▪ Preventive therapy ▪ Risk modification
CAD-RADS 2	25–49	Mild non-obstructive CAD	None	▪ Preventive therapy ▪ Risk modification *Particularly in the case of plaques and multiple affected segments*
CAD-RADS 3	50–69	CAD with moderate coronary stenosis	Consider function testing	▪ Symptom-oriented, anti-ischemic, and preventative pharmacotherapy ▪ Risk factor modification
CAD-RADS 4	A: 70–99	CAD with severe coronary stenosis	A: Consider function testing or invasive coronary angiography	▪ Symptom-based, anti-ischemic, and preventative pharmacotherapy ▪ Risk factor modification ▪ Consider further treatments, incl. revascularization, according to guidelines
	B: Left main > 50 % or 3 coronary arteries > 70 %		B: Invasive coronary angiography	
CAD-RADS 5	100 (occlusion)	CAD with complete occlusion of a coronary artery	Consider invasive coronary angiography or vitality diagnostics	
CAD-RADS N	Non-diagnostic examination quality	Not possible to rule out CAD	Consider alternative/additional diagnostic workup	–

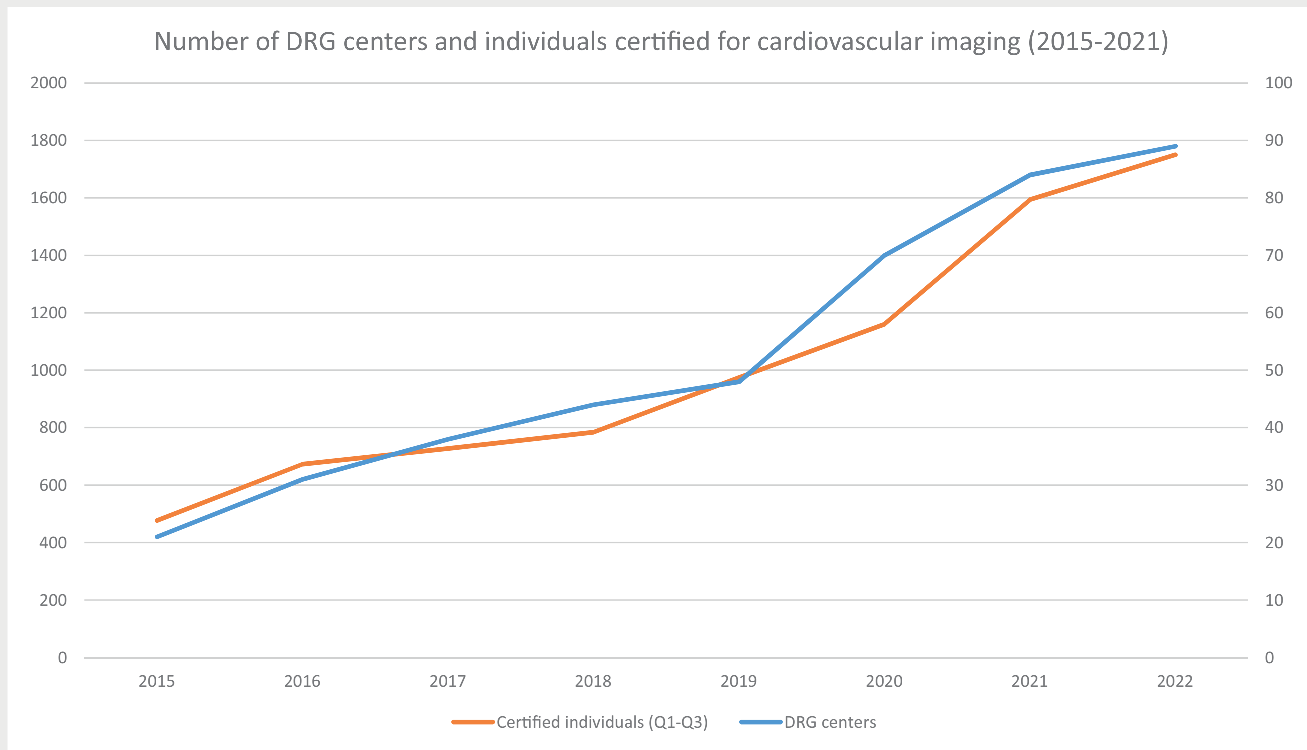
6.5 Extracardiac findings

In addition to the heart, other anatomical structures are always also imaged during cardiac cross-sectional imaging examinations resulting in incidental and secondary findings in a significant number of examinations [116]. According to the literature, the rate of incidental findings is 6–58.5 % [117, 118]. The type of imaging that is performed affects the prevalence of incidental findings. They are seen most rarely in the case of non-contrast CT for calcium scoring and more frequently in examinations to evaluate bypass vessels or pulmonary veins [119]. According to a systematic review of 13 studies, the frequency of incidental findings in cardiac CT angiography is 41 % with 16 % being clinically relevant [120]. Suspicious pulmonary masses (26.6 %), hiatal hernias (20.8 %), aortic anomalies (10.8 %) were most common with a cumulative frequency of 58.2 % among the 2160 clinically significant extracardiac incidental findings. In one study on emergency care by Onuma et al., an alternative extracardiac disease was able to be identified as the cause of acute angina pectoris symptoms in 16 % of patients based on cardiac cross-sectional imaging so that further imaging was not necessary [121]. Dewey et al. were able to confirm this with 12.9 % detected extracardiac causes for atypical angina pectoris [122]. In a further study by Lehmann et al., extracardiac findings changed management in 1.3 % of patients and provided an alternative explanation for angina pectoris symptoms in 4.1 % of patients [123]. Moreover, the detection rate of incidental findings is higher if a large field of view representing the entire acquired anatomy was reconstructed [124].

While life-threatening diseases like lung cancer can be detected early, follow-up examinations can result in additional radiation exposure and costs without proven benefit [119, 125]. Due to their comprehensive specialist training and broad medical knowledge, radiologists are uniquely qualified to evaluate corresponding incidental findings and to minimize the above-described disadvantages. The reconstruction of a large field of view for complete coverage of the entire scan volume and all relevant findings is therefore mandatory.

6.6 Opinion regarding radiology reporting

In summary, to ensure high-quality patient care, cardiac computed tomography requires the competence of a radiology specialist in order to meet the method- and content-related demands regarding cardiac CT and structured reporting, to comply with radiation protection regulations, to interpret extracardiac findings, and to possess the necessary overview of non-organ-related pathophysiological relationships between the thorax and upper abdomen. Care provided by those outside the discipline cannot fully meet these demands. In addition to professional competence in radiology, the 4-eyes principle should be employed when determining the indication for cardiac CT in order to ensure examination quality. The ability to correctly determine indication and to estimate radiation exposure and consequences with respect to not only the heart but also the other organs included in the scan is an essential skill of radiology specialists. Regular continuing and advanced training in this very dynamic area of medicine is also important. To interpret cardiac CT examinations, a radiologist must have reached at least Q2 status according to the Cardiac and Vascular Diagnostics working group of the German Radiological Society.



▶ **Fig. 4** Number of DRG centers and individuals certified for cardiovascular imaging (2015–2021).

For quality assurance, not only regular discussion of the findings with the referring non-radiology colleague(s) but also incorporation of the corresponding selective expertise of the other cardiovascular disciplines from cardiac surgery, pediatric cardiology, and cardiology is useful. This exchange makes a significant contribution to mutual quality assurance in patient care and helps to ensure targeted diagnostic workup of every patient that is as comprehensive as possible.

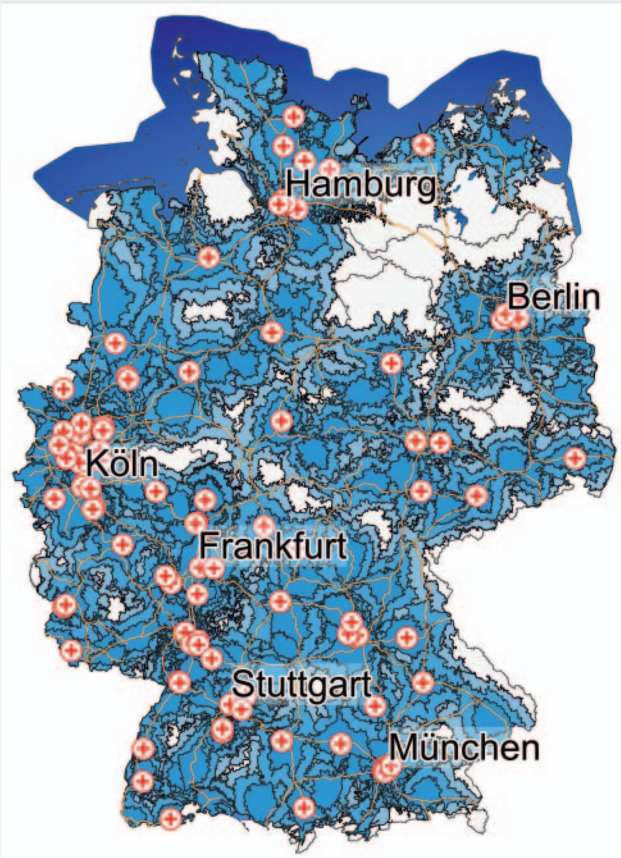
Coronary CT has numerous diagnostic possibilities, but the limitations must also be taken into consideration. In classic coronary CT as in invasive coronary angiography, diagnostic evaluation of the myocardium is not possible. Inflammatory changes of the myocardium, e. g., in the case of myocarditis, fibrosis, and myocardial scars, cannot be diagnosed. Adjustments to the CT protocol for specific medical questions are possible in principle, e. g. when acquiring a late contrast phase to evaluate myocardial contrast enhancement in the case of inflammation, when performing dynamic contrast-enhanced imaging to detect a hypoperfused region when diagnosing ischemia, or when using functional imaging to detect movement abnormalities in the case of myocardial scars [126–128]. However, this is the exception in the clinical routine. It is important to have sufficient knowledge of the advantages and disadvantages of the additionally available diagnostic methods like MRI and SPECT and to use them accordingly. Only in this way can patients be directed to the best possible diagnostic method for their clinical symptoms and particular medical issue which is decisive for correctly determining the indication.

7. Quality of care

The quality of care in Germany with respect to coronary CT is ensured on various levels and by various structures, for example, the German Radiological Society under the guidance of the Cardiac and Vascular Diagnostics working group, and the Professional Association of German Radiologists. In these societies, radiologists are categorized as clinical or academic-scientific, and participate in regular training and continuing education programs. This is implemented in all organizational forms of outpatient and inpatient radiology in Germany.

This broad and high-quality clinical care is provided by the 86 cardiovascular centers and 1750 people in Germany currently certified by the Cardiac and Vascular Diagnostics working group of the German Radiological Society (status 11/20). 11.7 % attain cardiovascular training status Q3, 16.6 % reach level Q2, and 71.7 % receive the initial certificate Q1. Since 2015, the number of certified centers has increased by 300 % (2015: 21) and the number of certified specialists by 235 % (2015: 475). The data from the previous year with the corresponding growth is shown in ▶ **Fig. 4** [129]. 56 of the 99 (56.6 %) postal code regions in Germany have direct access to a certified center with 2 centers being located in 9 regions and 3 centers in 4 regions. ▶ **Fig. 5** shows the coverage in Germany based on a 30-minute, 45-minute, and 60-minute driving time [129]. These numbers show that for coronary CT the transition from limited local availability to widely available expertise has already been successfully accomplished.

In the future, quality-assuring measures for coronary CT examinations should be created, established, and continuously further



▶ **Fig. 5** Overview of the cardiovascular imaging certified centers (red crosses) in Germany in November 2022 and their corresponding catchment areas in 30/45/60 minutes driving time (dark blue/light blue/turquoise). Triangles represent CT Q2- and Q3-certified radiologists, circles for MRI Q2- and Q3-certified radiologists.

developed as in the case of other already established quality-assuring measures (e. g. the methods used for stroke treatment or chest pain units which have recognized certification methods) ([130, 131]). Possible benchmarking parameters could be, for example, good or very good image quality in > 90 % or > 95 % in patients receiving sublingual administration of nitroglycerin and/or ß-blockers.

As a result of the creation of the Cardiac and Vascular Diagnostics working group in 2001 and the establishment of continuous certified training, continuing education, and advanced training programs in 2010, quality-assured cardiac and vascular imaging is now widely available in Germany. The steady increase in certified centers and people (▶ **Fig. 4**) is a strong indicator of an established effective specialization process and the success of the dedicated training, continuing education, and advanced training programs. This development was also supported by a structured continuing education program of the German Radiological Society as the foundation for the certification of centers. Cardiovascular continuing education programs are offered throughout Germany, locally and nationally, as separate continuing education courses and workshops and in the form of conventions (e. g. annual convention of the ESCR, German Cardiodiagnostic Days (https://www.kardiodiagnostik.de)) and the German X-ray Congress). This is supported by a comprehensive online program both in Germany and internationally, e. g., the courses of the ESR. In addition, the fully digital learning platform CONRAD with selected and diverse DICOM data-based real cardiovascular case presentations allows flexible training, continuing education, and advanced training as well as certification not just during the global COVID-19 pandemic restrictions.

In summary, radiology in private practice and in the hospital ensures broad availability of high-quality, specialized patient care. Key elements for ensuring this quality of care have been established since 2010 by the Cardiac and Vascular Diagnostics working group of the German Radiological Society and have been continuously further developed. The certification of both individuals and centers is a further important component of quality assurance. The multilevel course system with the necessary requirements ensures a nationwide high level of quality in radiology and cardiac imaging. Further quality assurance measures are regular scientific conventions, continuing education events, and a digital learning platform of the Cardiac and Vascular Diagnostics working group of the German Radiological Society.

8. Reimbursement

Cardiac CT examinations are not yet sufficiently represented in the GOÄ (medical fee schedule) and the EBM (uniform value scale). As part of ongoing work to update the two physician's fee scales, concrete service legends and assessment proposals were provided by the Professional Association of German Radiologists. The report from the Institute for Quality and Efficiency in Health Care from 2020 recommended a benefit assessment for cardiac CT [133]. It was then classified in 2021 as a new examination method by the Federal Joint Committee in accordance with § 135 Paragraph 1 Sentence 1 of the Fifth Book of the Social Code. In 2022, the Federal Joint Committee examined whether cCTA improves the current diagnostic process in the case of suspicion of chronic coronary artery disease and will be available in the future as a service covered by statutory health insurance [134]. However, it is still unclear when corresponding updates would actually be implemented. Therefore, in the outpatient sector, billing for this service is only currently possible based on the GOÄ (medical fee schedule).

For this purpose, together with the German Radiological Society, the Cardiac and Vascular Diagnostics working group, and the FuNRAD (Forum of Radiologists in Private Practice), the Professional Association of German Radiologists published a joint recommendation for the billing of cardiac CT and MRI examinations [135]. The recommendation is limited to the representation of regularly billable fee schedule items and services that are additionally necessary or billable in the individual case. Coronary CT angiography is thus currently billed as chest CT with supplementary images, multiple contrast-enhanced high-pressure injections, ECG, computer-aided analysis, as well as a detailed report, possibly supplemented by pulse oximetry. The fee amount is to be determined in the individual case by determining the suitable increase factor (§ 5 GOÄ).

9. Summary

- In national and international guidelines on the diagnosis of chronic coronary syndrome and chronic coronary artery disease, coronary CT has become the diagnostic method of first choice in all patients with an intermediate risk and has replaced diagnostic coronary angiography particularly in patients with a low-intermediate risk (15–50 %).
- This development was based on the PROMISE study, the SCOT-HEART study, and the ISCHEMIA study and on the risk tables derived from these studies.
- In the case of correct determination of indication and correct technical implementation, coronary CT has a low risk for complications, particularly compared to diagnostic invasive coronary angiography.
- The minimal technical requirement for implementation is a CT scanner with at least 64 rows and a rotation time of less than 0.35 s.
- As part of the CCS workup, a non-contrast CT scan should be performed prior to coronary CTA for calcium scoring.
- Coronary CT requires the skills of a competent, specialized, and Q2- or Q3-certified radiologist to meet the method-related demands regarding cardiac CT, structured reporting, radiation protection, and extracardiac findings in order to ensure high-quality patient care.
- Reimbursement must currently be considered insufficient.
- The quality of care in Germany is already very good thanks to good spatial coverage with specially qualified radiologists.
- Nationwide care by qualified radiologists is ensured even in the case of increasing demand. Since no additional CT units need to be installed and services can only be rendered upon GP and specialist referral in order to prevent non-indicated volume increases, this process is also economically viable.

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