ORIGINAL ARTICLE

Benefits of the selective invasive strategy guided by CTA and CTA-derived fractional flow reserve in patients with coronary artery disease

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ABSTRACT

Background: Coronary computed tomography angiography (CTA) has high diagnostic accuracy in ruling out significant stenosis of coronary arteries. The additional use of CTA- derived fractional flow reserve (FFR) further enhances diagnostic utility of coronary CTA. Some patients interrogated non-invasively have diseased coronary arteries and undergo further diagnostic testing, including invasive coronary angiography (ICA). Patients with one-vessel disease may benefit from invasive interrogation limited to the diseased vessel only.

Aims: We analyzed the impact of a "diseased-vessel-only" selective invasive diagnostic approach in 100 patients undergoing ICA following coronary CTA (and CT-FFR) as compared to the traditional "full ICA" approach. We aimed to compare contrast volume and radiation dose used during ICA in both scenarios, seeking potential benefits for the patient in reducing those values by the "diseased-vessel-only" approach.

Results: Sensitivity, specificity, positive predictive value, and negative predictive value of CTA in prediction of subsequent revascularization were 96%, 75%, 51%, and 99%, respectively, and for CT-FFR 90%, 90%, 69%, and 97%, respectively. Using CTA as a method to guide ICA would reduce contrast volume and estimated radiation dose (ED) by 35% and 42.0%, respectively (P <0.0001 for both). Taking into consideration CT-FFR results, contrast volume would be reduced by 57% and ED by 69% (P <0.0001 for both).

Conclusion: These real-world data support the concept that vessels with <50% diameter stenosis on quantitative computed tomography and with hemodynamically insignificant CTA-derived FFR result may be omitted during ICA. Such an approach would result in substantial reductions in contrast media volume used, as well as patients' exposure to radiation during ICA, while not leading to misdiagnoses.

Key words: coronary computed tomography angiography, coronary angiography, coronary artery disease, CT-FFR, fractional flow reserve

INTRODUCTION

Coronary computed tomography angiography (CTA) gained acceptance as a first-line non-invasive diagnostic modality in the triage of patients with chest pain [1]. The method has high diagnostic accuracy in ruling out significant stenosis of coronary arteries in patients with an intermediate probability of coronary artery disease (CAD) [2–4]. The additional use of CTA-derived fractional flow reserve (FFR) further enhances diagnostic utility of coronary CTA, mainly by increasing its specificity [5–8]. By default, some patients interrogated non-invasively have diseased coronary arteries and undergo further diagnostic testing, including invasive coronary angiography (ICA).

WHAT'S NEW?

Coronary computed tomography angiography (CTA) and CTA-derived fractional flow reserve (CT-FFR) may limit invasive coronary angiography to just one (diseased) vessel or completely abolish the indication to this invasive procedure. Using CTA and CT-FFR as a guiding tool in referral to invasive coronary angiography may result in a substantial reduction in iodine contrast media volume and radiation exposure used during the coronary artery disease diagnostic process. The aforementioned benefits are greater for CT-FFR than CTA. Moreover, such an approach reduces the number of catheters used, consequently reducing costs and the number of potential mechanical complications that may occur during catheterization.

Conceivably, patients scheduled for ICA with one-vessel disease may benefit from invasive interrogation limited to the diseased vessel only, presumably resulting in lower contrast media usage, lower radiation dose, and fewer complications related to catheterization. The additional use of CT-FFR may further reduce the need for both arteries and patients' invasive interrogations. However, there are no guidelines addressing performing ICA after coronary CTA, and potential benefits of the sequential diagnostic strategies require evaluation.

Therefore, we prospectively sought to analyze the impact of a "diseased-vessel-only" selective invasive diagnostic approach in patients undergoing ICA following coronary CTA (and CT-FFR) as compared to the traditional "full ICA" approach. The potential benefits of such an approach were defined as a reduction of contrast media volume and radiation dose used during ICA, regardless of whether the particular vessel was subject to ICA or not. The costs of such a novel approach were defined as missing significant coronary stenosis defined as either coronary stenosis ≥50% or coronary stenosis undergoing subsequent revascularization.

METHODS

Study group

From September 2015 to August 2016, we included 116 consecutive patients who underwent ICA following CTA performed at a single center (Institute of Cardiology, Warsaw, Poland). ICAs were performed if CTA findings suggested significant or borderline coronary artery stenosis (>50% diameter stenosis [DS]) in an artery amenable for intervention (at least 2.0 mm reference diameter) in the presence of clinical symptoms suggestive of CAD or additional tests indicating cardiac ischemia. We excluded patients who underwent ICA more than 6 months following CTA (n = 10) and those in whom CTA image quality prevented evaluation of the coronary artery lumen due to motion artifacts or severe calcifications (n = 6). Clinical and demographic information, medical history, and cardiovascular risk factors (hypertension, hyperlipidemia, diabetes, body mass index, smoking, being male) were prospectively collected during the hospital stay of the patients, based on their medical records, laboratory blood test analysis, and physical examination. The study was approved by the institutional ethical committee.

CTA examination and analysis

Coronary CTA was performed on a dual source 2 × 192-slice Somatom Force (Siemens, Forcheim, Germany) scanner. Sublingual nitrates were administered before scanning in all patients. If necessary, beta-blockers were administered intravenously targeting a heart rate of <70 beats per minute. The protocol for CTA image acquisition complied with the Society of Cardiovascular Computed Tomography (SCCT) guidelines [9]. Assessment of luminal diameter stenosis was performed using an 18-segment coronary model. Quantitative diameter stenosis analysis (QCT) was performed with Syngo.via (Siemens Medical Systems) software by an experienced investigator blinded for the results of ICA. The intraobserver correlation coefficient performed in 60 randomly chosen vessels was 0.98 (95% confidence interval [CI], 0.97–0.99; *P* <0.0001 for correlation). Per-vessel maximum stenosis was categorized as 0%, 1%–24%, 25%–49%, 50%–69%, 70%–99%, and 100% according to the SCCT guidelines [10].

CTA-derived FFR computation

CT-FFR analysis was performed by a single observer using dedicated software (cFFR v.2.1, Siemens) based on machine-learning algorithms [8]. A dedicated workstation was used to analyze mid-diastolic CTA data. Defining coronary lumen was a semi-automatic, two-step process- segmentation of coronary artery centerlines followed by coronary mesh delineation, both with manual correction if necessary. Tree-dimensional, color-coded models of coronary trees were assessed by an observer blinded for quantitative computed tomography (QCA) and FFR results. Any questionable results were consulted with the second observer and solved by consensus. In all major coronary arteries with stenosis above 40%, a point 40 mm distal to the minimal lumen area (MLA) was used as a location to define CT-FFR result, as described by Solecki et al. [11].

ICA examination and angiographic analysis

ICAs were performed on standard cardiology fluoroscopy equipment (Axiom, Siemens Healthcare, Forchheim, Germany), in pulsed fluoroscopy mode with the default frame rate of 10 frames per second. Access site and utilization of additional tools (i.e. fractional flow reserve [FFR] assessment or intravascular ultrasound [IVUS]) were left to the operator's discretion. Therapy decision was made based on angiographic results in the context of the patient's symptoms and other test results, such as stress ECG or echocardiography. Given data from the literature, visual vessel assessment during ICA is highly subjective [12, 13]. Quantitative Coronary Angiography (QCA) was chosen to define diameter stenosis (%DS) in a repetitive manner. ICA images were submitted to Qangio XA (Medis, Leiden, the Netherlands) software for QCA analysis. Maximum diameter stenosis was automatically defined with subsequent manual aligning of the course of the vessel, if necessary. Per-vessel maximum stenosis was categorized as 0%, 1%–24%, 25%–49%, 50%–69%, 70%–99%, and 100%. During the diagnostic part of ICA, contrast media volume (with accuracy of up to 1 ml) used for opacification of each of the main vessels (left and right coronary arteries) was recorded. Similarly, the radiation doses used during each vessel imaging were recorded; air kinetic energy released per unit mass (air kerma [AK]; mGy) and the dose area product (DAP; μG·m^2), both measured using built-in software in the fluoroscopy system (Axiom, Siemens Healthcare, Forchheim, Germany). Estimation of effective dose (ED) was based on a conversion coefficient of 0.185 mSv Gy^{-1}, as calculated by Boagert et al. [14]. On QCA, DS of at least 50% was defined as CAD, and the quantitative computed tomography (QCT) results were compared with the QCA results.

Statistical analysis

The categorical variables were presented as numbers and percentages. The continuous variables are expressed as mean (SD) or median (interquartile range [IQR]) as appropriate. Descriptive statistics were used to analyze per-patient accuracy of CTA. The diagnostic performance of CTA in the detection of significant CAD was then determined by using the receiver operating characteristic (ROC) curves, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) parameters and their corresponding 95% confidence intervals (CIs); it was compared to QCA >50% DS as the reference standard. The Wilcoxon test (for not normally distributed data) was used to assess the equality of values in continuous variables. A probability value of 0.05 or less was considered significant. All 3 groups (“routine”, “no ICA if >50 DS on QCT”, and “no ICA if <0.8 on CTA-derived-FFR) were independently analyzed in pairs. All statistical analyses were conducted using MedCalc version 13.0 (MedCalc Software, Mariakerke, Belgium).

RESULTS

Baseline characteristics

In this study, 116 consecutive patients who underwent CTA and subsequently ICA were identified. After applying exclusion criteria, the final population consisted of 100 patients in whom 200 vessels (right coronary artery [RCA] and left coronary artery [LCA] for each patient) were assessed. The baseline characteristics of the population (mean age 67.1 [8.8] years, female 33%) are summarized in Table 1. The majority of patients (54%) presented with typical angina.

Table 1. Baseline patient characteristics and clinical assessment

	n = 100
Age, years, mean (SD)	67.1 (8.8)
Male sex, %	67
Height, m, mean (SD)	1,70 (0.09)
Body weight, kg, mean (SD)	82.1 (13.2)
Body mass index, kg/m^2, mean (SD)	28.5 (4.15)
Hypertension, %	91
Diabetes mellitus, %	32
Hyperlipidemia, %	89
Smoking history, %	68
Pack-years, years, median (IQR)	20 (14–35)
Current smoker, %	15
Ejection fraction, %, median (IQR)[a]	60 (60–65)
Atypical angina, %	46
Typical angina, %	54
CCS 1, n (%)	7/54 (13.0)
CCS 2, n (%)	28/54 (51.9)
CCS 3, n (%)	16/54 (29.6)
CCS 4, n (%)	3/54 (5.6)
Chronic kidney disease, %	35
PCI history, %	17
CABG history, %	6
AMI history, %	13
Family history of CAD, %	28
Stress electrocardiograph:	
Performed, %	39
Clinically positive, n (%)	6/39 (15.4)
ECG-positive, n (%)	24/39 (61.5)
Negative, n (%)	6/39 (15.4)
Inconclusive, n (%)	3/39 (7.7)
Serum total cholesterol, mmol/l, mean (SD)	4.3 (1.1)
Low-density lipoprotein cholesterol, mmol/l, mean (SD)	2.5 (0.9)
High-density lipoprotein cholesterol, mmol/l, mean (SD)	1.4 (0.4)
Statin, %	90
ACE-inhibitor or ARB, %	86
Calcium channel blocker, %	44
β-blockers, %	85
Acetylsalicylic acid use, %	100

Abbreviations: ACE, angiotensin-converting enzyme; AMI, acute myocardial infarction; ARB, angiotensin II receptor blocker; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; ECG, electrocardiography; IQR, interquartile range; PCI, percutaneous coronary intervention

[a]Data available for 81 patients

In this group, Canadian Cardiovascular Society grade 2 was most commonly observed. Thirty-nine patients had undergone stress tests before coronary imaging: 24 tests had been positive electrocardiographically, 6 clinically, 3 had been inconclusive, and 6 negative. Among 17 patients with percutaneous coronary intervention (PCI) history, all stents were imaged by CTA, without significant blooming artifacts precluding stent patency evaluation. During ICA, either FFR or IVUS was used in 16 cases. Median time interval between CTA and ICA was 47 (IQR, 22–82) days. Overall, at least one >50% DS stenosis as assessed by QCA (including chronic total occlusions) was found in 78 patients. Subsequently, 64 patients were revascularized, including 52 PCIs and 12 coronary artery bypass grafting (CABG) procedures.

Table 2. Diagnostic accuracy of CTA in detection of lesions >50%DS on QCA

Per artery (n = 200)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
>50% on QCT	99	97	94	100
Per patient (n = 100)				
> 50% on QCT	100	77	94	100

Abbreviations: CTA, coronary computed tomography angiography; NPV, negative predictive value; PPV, positive predictive value; QCA, quantitative coronary angiography

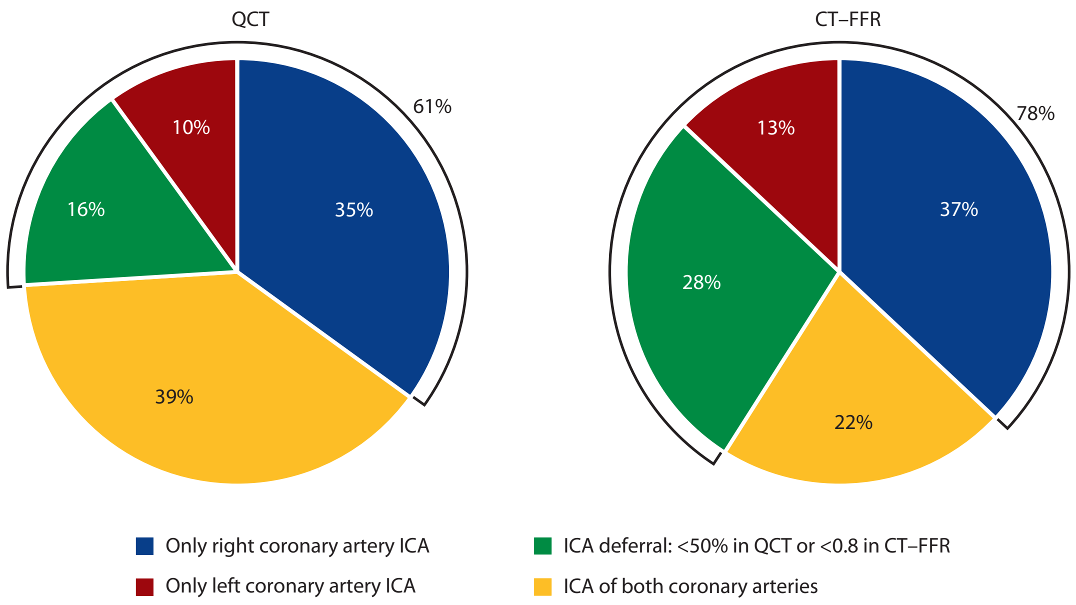

Figure 1. Changes in invasive diagnostics based on non-invasive testing

Abbreviations: CT-FFR, computed tomography fractional flow reserve; ICA, invasive coronary angiography; QCT, quantitative computed tomography

Selective "diseased-vessel-only" diagnostics strategy based on CTA

Based on the ROC curve (AUC, 0.977; 95% CI, 0.957–0.989; *P* <0.001), sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of CTA in detecting 50% DS on QCA were 99%, 97%, 94%, and 100%, respectively (Table 2).

Based on the ROC curve (AUC, 0.849; 95% CI, 0.810–0.882; *P* <0.001), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of CTA in prediction of subsequent revascularization were 96%, 75%, 51%, and 99%, respectively.

If CTA angiographic results had been considered before ICA, 43 (43%) patients would have undergone single ("diseased") vessel diagnostic strategy, and 19 (19%) patients would not have undergone ICA at all.

Comparisons of radiation doses and volume of contrast media used during the traditional diagnostic strategy vs. "diseased-vessel-only" ICA are presented in Figure 1 (radiation dose) and Figure 2 (contrast media volume). During the invasive procedure, a median of 57.5 (IQR, 44–70) ml of contrast agent and a median radiation dose of 6.17 (IQR, 3.64–8.56) mSv were used (Figure 1). Using CTA as a method to guide ICA would translate into reducing median contrast volume and radiation dose by 35% (from 57.5 ml to 37.5 ml) and 42.0% (from 6.17 mSv to 3.60 mSv), respectively (*P* <0.0001 for both) (Figures 2 and 3). None of the arteries assessed by QCT as stenosed <50% was subsequently described as stenosed >50% by QCA, and none was subsequently treated invasively.

Selective "diseased-vessel-only" diagnostics strategy based on CT-FFR

Diagnostic performance of CTA-FFR in prediction of subsequent revascularization (AUC, 0.899; 95% CI, 0.864–0.927; *P* <0.001) expressed as sensitivity, specificity, PPV, and NPV was 90%, 90%, 69%, and 97%, respectively.

Additional use of CTA-derived FFR as a method to guide ICA would result in deferral of ICA in 28 cases and excluding one of the coronary arteries from ICA in 50 cases (Figure 1). Investigated parameters' medians would be reduced: contrast volume by 57% (from 57.5 ml to 25 ml) and ED by 69% (from 6.17 mSv to 1.97 mSv; *P* <0.0001 for both) (Figures 2 and 3). Eight vessels, assessed with CTA-derived FFR as not significantly stenosed (>0.8), were eventually revascularized. On the other hand, 19 vessels with CTA-derived FFR

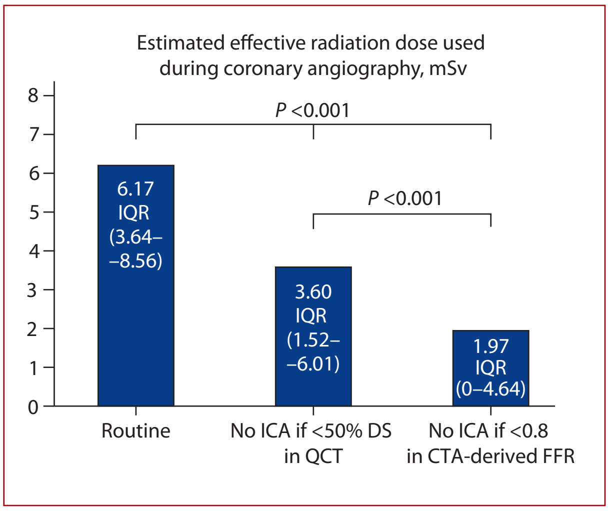

Figure 2. Estimated effective radiation dose used during coronary angiography routinely and in comparison with two strategies based on non-invasive testing

Abbreviations: see Figure 1

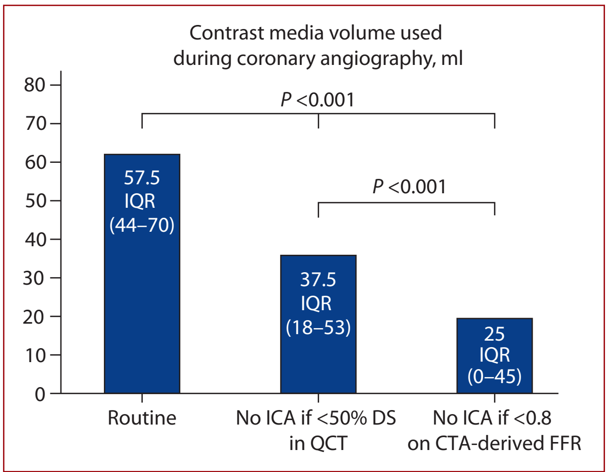

Figure 3. Contrast media volume used during coronary angiography routinely and in comparison with the two strategies based on non-invasive testing

Abbreviations: see Figure 1

result ≤0.8 were treated conservatively mainly due to small vessel caliber <2 mm (n = 15). Moreover, all those values ranged within the grey zone (0.75 and 0.8).

DISCUSSION

It is estimated that 126 million people live with coronary artery disease worldwide, including 18 million in the US, accounting for 366 000 deaths and estimated $218 billion in direct and indirect costs in the US only [15]. CTA used to diagnose CAD non-invasively is a rapidly expanding diagnostic modality, translating globally into substantial numbers of patients [1]. At least 10% of those patients (and due to changed pre-test-probability calculators in the latest European guidelines, likely more) may be diagnosed with >50% coronary stenosis and referred to ICA [16].

CAD diagnostic process with both CTA and ICA is associated with the use of radiation and contrast media. Considering their possible detrimental effect on the skin, bone marrow, and kidney function, different ways of minimizing their utilization are being developed, both on hardware and procedural level [17, 18]. There are no guidelines addressing performing ICA after CTA, and most interventionalists tend to catheterize all main epicardial coronary arteries in such situations (anecdotal information). Considering the vast number of patients suspected of CAD, any change in contemporary diagnostic practice may profoundly affect radiation doses and the amount of contrast media volume used in the process.

In this single-center investigation of patients suspected of CAD, we sought to determine how CTA findings may influence further invasive diagnostics in terms of contrast media volume and radiation exposure. In the present study, sensitivity, specificity, PPV, and NPV for coronary CTA were 99%, 97%, 94%, and 100%, respectively, for diagnosis of >50% coronary stenosis on ICA. These values are similar to those reported in previous studies and confirm that CTA has reliable accuracy for both exclusion and diagnosis of significant CAD [19–21]. Given the high NPV reported here and in previous studies, we hypothesized that vessels assessed by CTA as free of >50% stenosis may not be examined during ICA.

The findings from our study indicate that consideration of CTA results to guide ICA may benefit patients with CAD by a significant reduction of contrast media usage and radiation exposure. This benefit was most pronounced in the case of excluding LCA from ICA, as its visualization requires multiple contrast injections in different projections. Restricting ICA to the RCA only would result in contrast media volume reduction by 64% if guided by CTA and 73% if guided by CTA-derived FFR. In the case of LCA-ICA-only, radiation exposure in an analogous scenario would be decreased by 61% and 78% for CTA and CTA-derived FFR, respectively.

In the analyzed group, no artery described as stenosed <50% DS on QCT was subsequently assessed as stenosed >50% DS on QCA.

In the present study, the basic and more advanced non-invasive diagnostics provided incremental benefits in consequent qualification for ICA. Implementing CTA-derived FFR would lead to a greater number of deferred and "single-vessel-only" procedures. Consequently, the reduction in the investigated parameters was significantly higher for the CTA-derived FFR algorithm than the CTA-alone-based algorithm. The additive value of considering CTA-derived FFR results in the diagnostic process is depicted in Figure 4.

Importantly, refraining from unnecessary catheter manipulation/exchange and vessel ostium intubation may reduce rare but very serious complications, including iatrogenic vessel dissection or embolic events.

Given the increasing numbers of patients undergoing CTA, the "diseased vessel" invasive diagnostic strategy

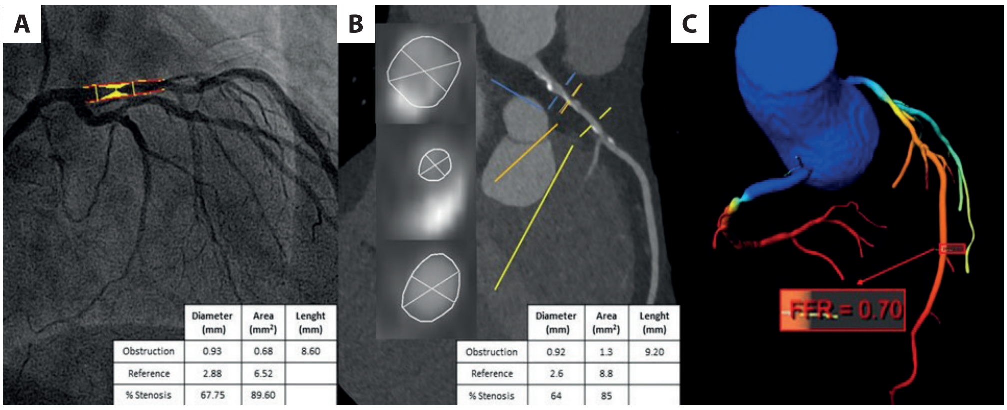

Figure 4. Incremental benefit of non-invasive diagnostic methods over routine, invasive coronary angiography. Quantitative coronary angiography (**A**) and quantitative coronary tomography (**B**) assessment of the left anterior descending artery stenosis — both methods perform similarly, demonstrating borderline lesion. Computed tomography angiography-derived fractional flow reserve (**C**) value <0.8 indicates the hemodynamic significance of the stenosis

may lead to a significant decrease in contrast media usage, radiation exposure as well as, possibly, subsequent complications and procedural adverse events, without any deleterious consequences. Appreciating recent evidence that CTA is a highly useful modality also in patients with a high risk of CAD, one may anticipate the discussed matter will prove to be even more important [22]. Further improvement in the selection of patients requiring ICA may be achieved with additive information obtained with CT-based volumetric quantification of myocardial perfusion, which is a complementary functionality of modern CT equipment [23].

Study limitations

We acknowledge several limitations of the current study. The sample size was limited and was derived from a single center. The study was conceived as an observational, non-randomized project, based on prospectively collected data. Non-randomization and the fact that several operators performed ICAs may have influenced procedural aspects such as projection selection, number of contrast injections, and additional tools (i.e. FFR, IVUS) utilization, which may have affected the radiation exposure and contrast media administration. This, however, reflects everyday practice. Moreover, an agreement between non-invasive and invasive FFR measurements was performed based on only 12 cases. Nonetheless, robust evidence in the literature indicates good accordance between the two methods.

Recognizing its inherent limitations, the study does have the advantage of representing daily practice in a diverse patient population, as no clinical exclusion criteria were applied.

We are aware that implementation of proposed changes in routine procedures may be deemed a deviation from the standard of care. Further, large-scale randomized investigations are needed to confirm the safety of the presented concept and provide well-established endpoints (i.e. differences in the incidence of contrast-induced nephropathy, mechanical complications of ICA, etc.).

These real-world data support the concept that vessels with <50% DS on QCT and not hemodynamically significant on CTA-derived FFR may be omitted during ICA. Such an approach would result in substantial reductions in contrast media volume usage, as well as patients' exposure to radiation during ICA, while not leading to misdiagnoses.

Article information

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