Efficacy and safety of coronary computed tomography angiography in patients with a high clinical likelihood of obstructive coronary artery disease

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ABSTRACT

Background: The CAT-CAD trial showed that coronary computed tomography angiography (CTA) in patients with a high prevalence of coronary artery disease (CAD) and indications for invasive coronary angiography (ICA) reduces the number of patients undergoing ICA by two-thirds and nearly eradicates non-actionable ICAs. However, the long-term benefits of this non-invasive strategy remain unknown.

Aims: To evaluate the long-term efficacy and safety of a non-invasive strategy employing coronary CTA vs. ICA as the first-line imaging test in stable patients with a high clinical likelihood of obstructive CAD.

Methods: The long-term outcomes were evaluated for 36 months following randomization and included the efficacy outcome (analyzed as the composite of major adverse cardiovascular events (MACE): all-cause death, acute coronary syndrome, unplanned coronary revascularization, urgent hospitalization for a cardiovascular reason, a stroke) and the safety outcome (analyzed as a cumulative incidence of serious adverse events).

Results: One hundred and twenty participants at a mean age of 60.6 (7.9) years (female, 35.0%) were randomized with an allocation ratio of 1:1 to coronary CTA and direct ICA as the first-line anatomical test for suspected obstructive CAD. There were no significant differences between both diagnostic strategies neither in terms of the long-term efficacy (MACE occurrence: 15.5% in coronary CTA group vs. 16.7% in ICA group; log-rank P = 0.89) nor the long-term safety (cumulative number of serious adverse events: 36 vs. 38; P = 0.79, respectively).

Conclusions: Long-term follow-up of the randomized CAT-CAD trial confirms that the strategy employing coronary CTA is an effective and safe, non-invasive, outpatient-based alternative to ICA for patients with a high clinical likelihood of obstructive CAD.

Key words: chronic coronary syndrome, coronary artery disease, coronary computed tomography angiography, invasive coronary angiography, percutaneous coronary intervention

INTRODUCTION

The CAT-CAD trial is the first published randomized study evaluating a non-invasive strategy employing coronary computed tomography angiography (CTA) vs. invasive coronary angiography (ICA) as the first-line imaging test in stable patients with a high clinical likelihood of obstructive coronary artery disease (CAD) and indications for invasive testing [1]. The design and conduct of the trial were based on data indicating a significantly lower prevalence of obstructive CAD than

WHAT'S NEW

We aimed to evaluate the long-term outcomes of a non-invasive, outpatient-based strategy employing coronary computed tomography angiography (CTA) as the first-line imaging test in stable patients with a high clinical likelihood of obstructive coronary artery disease (the CAT-CAD trial). This is the first randomized trial that confirmed the high diagnostic performance of coronary CTA as an effective and safe alternative to the conventional invasive approach in high-risk patients.

predicted by the formerly recommended calculators (the Diamond-Forrester model) [2] and by low rates of coronary revascularizations following invasive diagnostic examinations. Thus CTA renders most invasive tests potentially avoidable [3–5]. Importantly, the study showed that outpatient-based coronary CTA features high diagnostic performance. Therefore, it may act as an effective 'gatekeeper' reducing the number of patients undergoing invasive cardiac catheterization by two-thirds and nearly eradicating non-actionable ICAs in the diagnostic process.

Our findings preempted the most recent guidelines regarding chronic coronary syndromes, which thoroughly revised symptom-based pre-test probability (PTP) scores, resulting in a 2–4 fold reduction of obstructive CAD probability as compared to the previous estimations [6–8]. Notably, the indications for initial coronary CTA as an alternative to a direct invasive coronary angiography (ICA) strategy were extended to patients with non-conclusive or equivocal functional test results. Also, the guidelines outlined the importance of more accurate CAD risk stratification factors (PTP modifiers), allowing for a more precise estimation of the pre-test likelihood of obstructive CAD. Finally, the choice of the initial test considered a given patient's characteristics and preference, availability, as well as local expertise.

However, it remains unknown whether the short-term benefits related to the non-invasive diagnostic approach reported in the CAT-CAD trial were not offset by adverse clinical events observable during longer follow-up. Herein, we provide the long-term analysis of a 36-month follow-up from randomization.

METHODS

The CAT-CAD trial was a prospective, randomized, open-label, single-center study, comparing the efficacy and safety of diagnostic strategies employing non-invasive coronary CTA vs. direct ICA in patients with a high clinical likelihood of obstructive CAD. The design, study protocol, and the short-term outcomes of the CAT-CAD trial were previously reported (Clinical Trials no. NCT02591992) [1, 9]. The research protocol complied with the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the local Ethics Committee. Before randomization, all subjects provided written informed consent.

Study population

Between 2015 and 2016, 252 patients were referred for direct ICA (indications: 1. left ventricular ejection fraction <50% with typical angina symptoms; 2. PTP 50%–85% with positive/intermediate/non-conclusive/equivocal functional test; 3. PTP >85%). One hundred and twenty consecutive participants with a mean age of 60.6 (7.9) years (female, 35.0%) and a high clinical likelihood of obstructive CAD (either with or without previous CAD diagnosis) were randomized with an allocation ratio of 1:1. Based on a block randomization scheme, patients who met the inclusion criteria were randomly assigned to two equal, parallel cohorts: the non-invasive group employing coronary CTA as the first-line anatomical diagnostic test or the invasive group where patients went directly to ICA (Figure 1).

The subsequent diagnostic and therapeutic course

Regardless of the assigned strategy, all diagnostic procedures were performed, analyzed, and interpreted by the institutional Heart Team including interventional cardiologists (MK/CK/JP) experienced in coronary CTA evaluation (>5000 examinations each). Equivocal cases required a consensus of at least two of them. Decisions regarding further patient management were based on imaging findings and clinical data, including symptoms and results of functional testing. The subsequent course of treatment was determined following a routine clinical practice.

Outcome assessment

The previously reported short-term outcomes were evaluated within three months from the participants' entering the study, or before the last diagnostic/therapeutic procedure. Thereby, the following short-term outcomes were analyzed: the number of patients undergoing ICA, the number of patients with non-actionable ICA, the median volume of contrast material, and cumulative radiation dose [1]. The long-term efficacy and safety outcomes were evaluated for each participant during 36 months from the study entry.

The efficacy outcome was a combination of major adverse cardiovascular events (MACE): all-cause death, acute coronary syndrome, unplanned coronary revascularization (including restenosis), urgent hospitalization for a cardiovascular reason, a stroke. The safety analysis included the cumulative number of serious adverse events: major adverse cardiovascular events (MACE), as mentioned above, unplanned percutaneous coronary intervention (PCI) as a treatment of ICA complications, urgent coronary artery bypass grafting (CABG) as a result of PCI or coronary

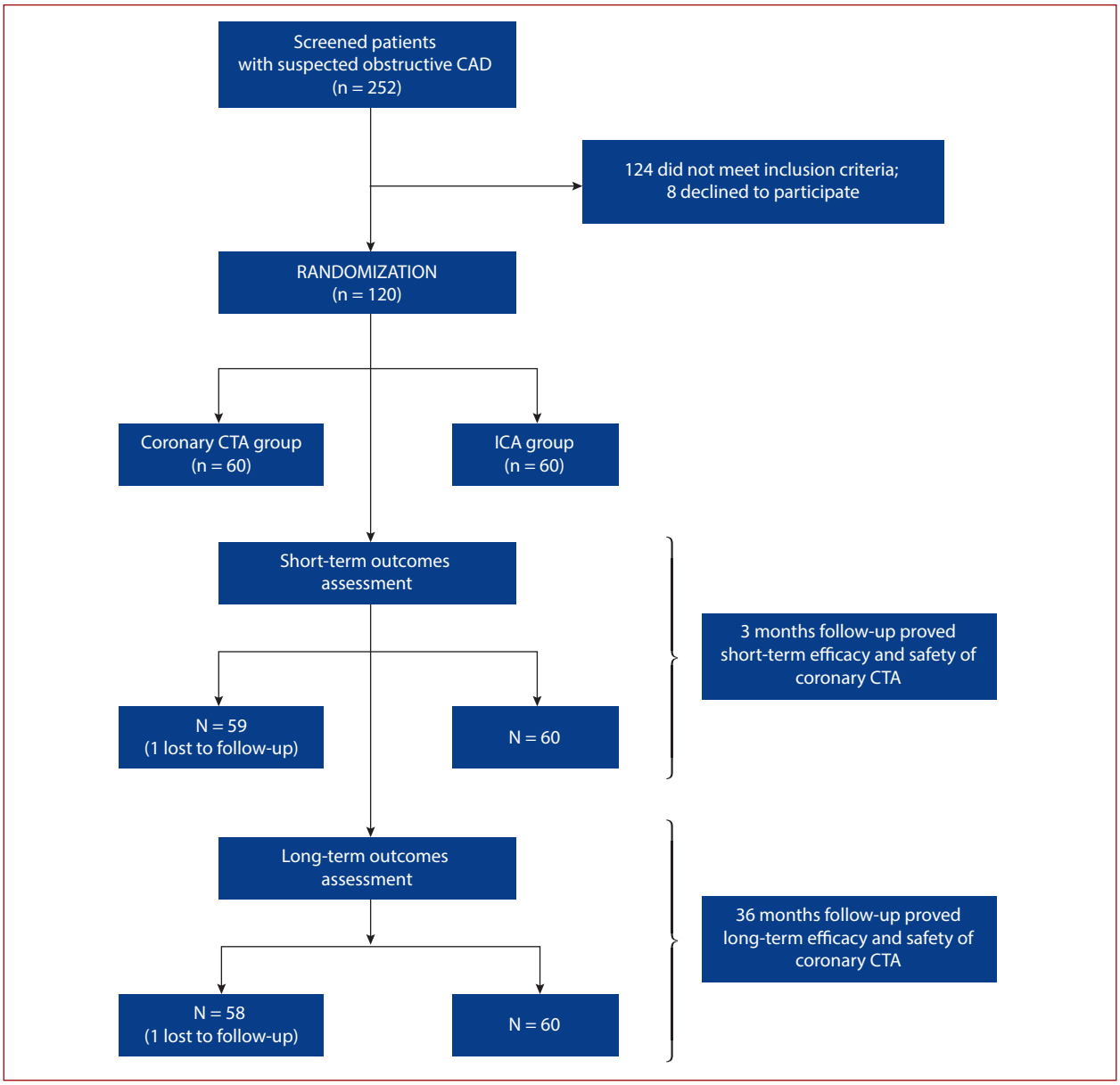

Figure 1. Patient flow chart presenting enrolment, randomization, and the two-staged 36-months follow-up

Abbreviations: CAD, coronary artery disease; CTA, computed tomography angiography; ICA, invasive coronary angiography randomized in a 1:1 ratio

angiography complications, surgical treatment of local vascular complications or with blood products, hospitalization or prolongation of hospitalization for local vascular complications, the occurrence of a pseudoaneurysm, fistula, or occlusion in the vascular access site, a decrease in renal function (a fall of at least one stage of chronic kidney disease), 2–5 type bleeding defined by the "Bleeding Academic Research Consortium", a life threat, a need for hospitalization or its prolongation and permanent or substantial health damage.

Follow-up questionnaires for all outcomes were completed via email, telephone interviews, outpatient clinic appointments, or from the last available medical record for all but two study patients who were lost to follow-up.

Statistical analysis

The primary analysis was conducted according to the "intention-to-treat" principle. The distribution of the data was evaluated using the D'Agostino-Pearson test. Continuous variables with normal distribution were compared using Student's t-test and presented as mean (SD). Continuous variables with non-normal distribution were compared using the Mann-Whitney test and presented as medians with lower and upper quartiles. Categorical variables were compared using the chi-square or the Fisher exact test and presented as percentages (relative and absolute frequencies). Efficacy outcomes assessment included a univariate cox-regression analysis and the time-to-first-event analysis presented with Kaplan-Maier curves. Both

Table 1. Baseline characteristics of the study participants in the coronary computed tomography angiography and invasive coronary angiography groups

Variable	Coronary CTA group (n = 60)	ICA group (n = 60)	*P*-value
Age, years, mean (SD)	66.0 (7.2)	67.2 (8.6)	0.40
Female sex, n (%)	22 (38.6)	20 (33.3)	0.70
Body mass index, kg/m^2, mean (SD)	27.6 (3.4)	28.4 (4.3)	0.27
Risk factors, n (%)			
Diabetes, n (%)	12 (20.0)	17 (28.3)	0.29
Hypertension, n (%)	47 (78.3)	52 (86.7)	0.23
Systolic blood pressure, mm Hg, mean (SD)	132.3 (18.1)	132.3 (19.7)	0.99
Diastolic blood pressure, mm Hg, mean (SD)	78.2 (9.7)	76.5 (9.4)	0.35
Hyperlipidemia, n (%)	54 (90.0)	52 (86.7)	0.57
Current or past tobacco use, n (%)	42 (70.0)	36 (60.0)	0.25
Family history of CAD, n (%)	21 (35.0)	20 (33.3)	0.84
CAD characteristics, n (%)			
History of coronary revascularization	17 (28.3)	24 (40.0)	0.18
Previous acute coronary syndrome	8 (13.3)	8 (13.3)	1.00
Previous PCI	12 (20.0)	21 (35.0)	0.15
Previous CABG	6 (10.0)	3 (5.0)	0.49
Current typical angina symptoms	26 (43.3)	19 (31.7)	0.19
Current atypical angina symptoms	34 (56.7)	41 (68.3)	0.19
Mid-high PTP	54 (90.0)	52 (86.7)	0.78
High PTP	6 (10.0)	8 (13.3)	0.78
Clinical history, n (%)			
Heart failure	13 (21.7)	9 (15.0)	0.35
Atrial fibrillation	7 (11.7)	9 (15.0)	0.59
Valvular heart disease (≥moderate)	3 (5.0)	4 (6.7)	0.50
Chronic obstructive pulmonary disease	3 (5.0)	1 (1.7)	0.31

Abbreviations: CAD, coronary artery disease; CTA, computed tomography angiography; ICA, invasive coronary angiography; PCI, percutaneous coronary intervention; PTP, pre-test probability

treatment strategies were compared with the use of log-rank tests. Safety outcomes were assessed with a logistic regression model that evaluated the potential association between the occurrence of at least a single serious adverse event during the follow-up and the allocation to either of the treatment cohorts.

The study group size was calculated based on the following statistical power assumptions: $\alpha = 5\%$; $\beta = 80\%$; the mean number of invasive procedures in the direct ICA group was estimated to be 1.2 (0.5) with an expected reduction by 22% in the coronary CTA group. The resulting number of patients needed to participate was $2 \times 58 + 4$ patients (to account for exclusions or crossovers). This number was also estimated to be sufficient to achieve the statistical power described above for the other outcomes.

All analyses were conducted using either MedCalc® Statistical Software version 15.11.4 (MedCalc Software Bvba, Ostend, Belgium) or SPSS, version 24.0 (IBM Corp, Armonk, NY, USA). A *P*-value <0.05 was considered significant.

RESULTS

There were no significant differences between the study participants with regard to the baseline characteristics (Table 1). The overall prevalence of obstructive CAD was 53.3%, without significant differences between the two groups ($P = 0.46$). Similarly, both strategies showed no significant differences in terms of the number of patients undergoing elective coronary revascularization as the outcome of the diagnostic/therapeutic procedure (26.7% in the coronary CTA group vs. 35.0% in the ICA group, $P = 0.43$) (Figure 2).

Short-term outcomes

The initial coronary CTA strategy significantly reduced the number of patients undergoing invasive examination by 64.4% ($P < 0.0001$) and those with non-actionable ICAs by 88.1% ($P < 0.0001$). Interestingly, such a strategy demonstrated a potential to reduce the number of hospitalizations by 65.8% ($P < 0.0001$) and the resulting diagnostic costs by 63% ($P < 0.0001$). Over the diagnostic and therapeutic course, there were no significant differences in the median volume of contrast material (the coronary CTA group, 80.3 [65.0–165.0] ml vs. the ICA group, 90.0 [55.0–100.0] ml; $P = 0.10$). Yet a non-significant trend towards higher radiation dose in the coronary CTA cohort was observed (9.9 [7.0–22.1] mSv vs. 9.4 [5.2–14.0] mSv; $P = 0.05$, respectively). Notably, there were no serious adverse events during the short-term follow-up.

Long-term outcomes

Of 120 randomized patients, 118 were available for evaluation (2 patients were lost to follow-up). A detailed patient flow chart (Figure 1) and the specific components of the long-term efficacy and safety outcomes (Table 2) are provided.

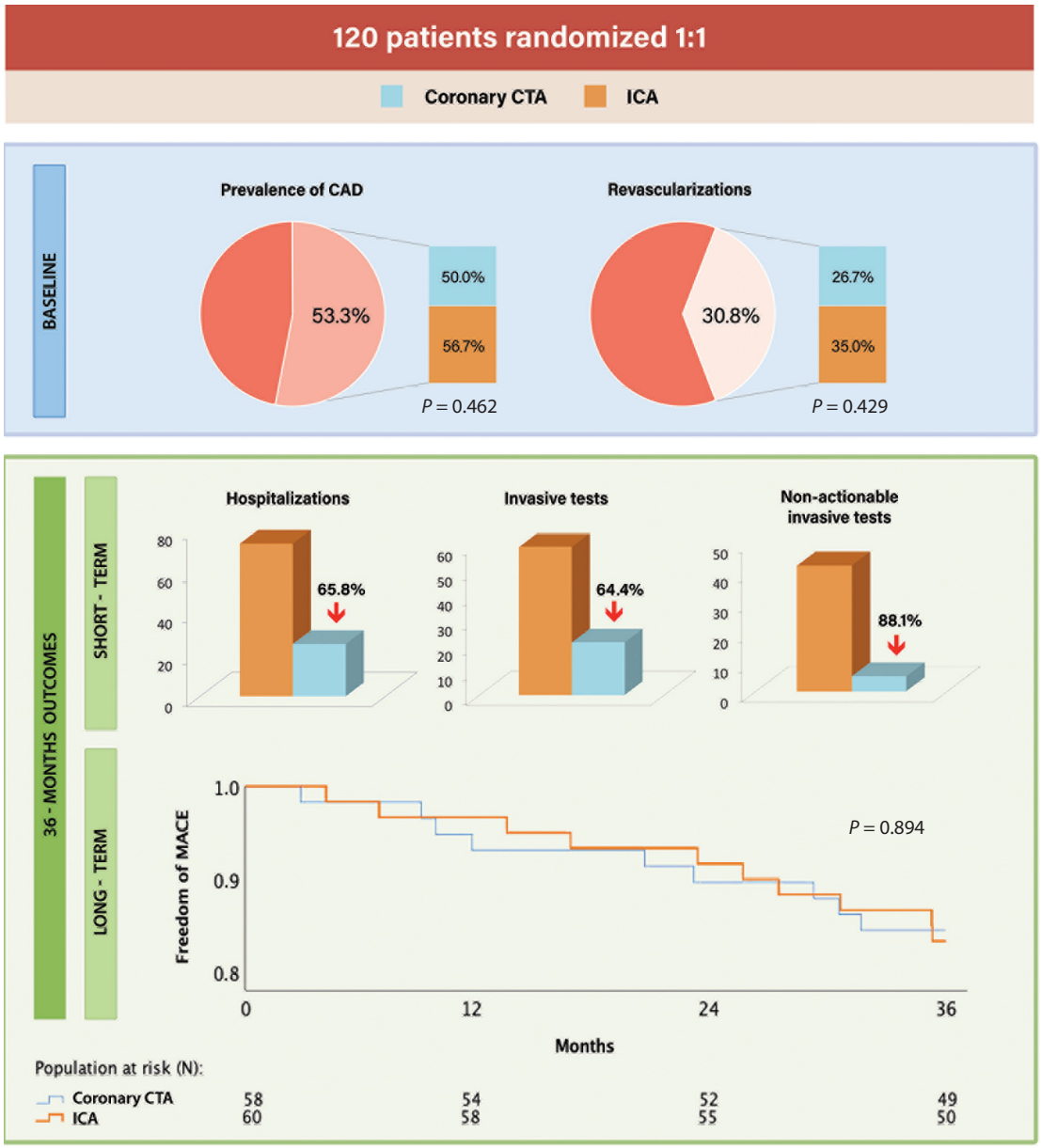

Figure 2. 36-months outcomes of the randomized CAT-CAD trial. The baseline panel includes percentage values of the prevalence of CAD and performed revascularizations (per-patient) in the entire study population, and separately in the two study cohorts. The red arrows indicate the relative decrease in the number of short-term outcomes (per-patient) in both diagnostic strategies. The long-term efficacy outcome (time to a MACE occurrence) is presented with Kaplan-Meier curves

Abbreviations: see Figure 1

Long-term efficacy outcome

During the 36-month follow-up, the composite of all-cause death, acute coronary syndrome, unplanned coronary revascularization (including restenosis), urgent hospitalization for cardiovascular reasons and stroke, occurred in 9 (15.5%) patients in the coronary CTA group compared to 10 (16.7%) in the ICA group (log-rank $P = 0.89$). The hazard ratio (HR) for the rate of MACE did not reach statistical significance between the two diagnostic strategies (HR, 1.06; 95% confidence interval [CI], 0.43–2.62). There were 4 vs. 1 all-cause death; however, only 1 vs. 0 cardiac death in the coronary CTA arm. Non-cardiac deaths were due to cancer, procedural complications of aortic aneurysm pre-planned surgery, with the two remaining with an unconfirmed cause of death.

Long-term safety outcome

The cumulative number of serious adverse events did not differ significantly between both investigated cohorts (36 in the coronary CTA group vs. 38 in the ICA group; $P = 0.79$). The logistic regression model demonstrated no association of any adverse event with regard to the allocated group (odds ratio [OR], 1.1; 95% CI, 0.2–7.4). Similarly, there was no difference in the number of patients diagnosed with at least one serious adverse event (22 vs. 23; $P = 0.89$, respectively).

Table 2. Cumulative number of serious adverse events during the long-term follow-up of patients randomized to the coronary computed tomography angiography and invasive coronary angiography groups

Serious adverse event	Coronary CTA	ICA	*P*-value
Death (all-cause), n (%)	4 (11.1)	1 (2.6)	0.17
Non-cardiac death	3 (8.3)	1 (2.6)	0.29
Cardiac death	1 (2.8)	0 (0.0)	0.49
Acute coronary syndrome, n (%)	2 (5.6)	2 (5.3)	0.68
Unplanned coronary revascularization (including restenosis), n (%)	3 (8.3)	6 (15.8)	0.32
Urgent cardiovascular hospitalization, n (%)	5 (13.9)	6 (15.8)	0.80
Stroke, n (%)	0 (0.0)	0 (0.0)	—
Unplanned PCI as a treatment of ICA complications, n (%)	0 (0.0)	0 (0.0)	—
Urgent CABG as a result of PCI or ICA complications, n (%)	0 (0.0)	0 (0.0)	—
Surgical treatment of local vascular complications or with blood products, n (%)	0 (0.0)	0 (0.0)	—
Hospitalization or prolongation of hospitalization due to local vascular complications, n (%)	0 (0.0)	0 (0.0)	—
Pseudoaneurysm, fistula, or occlusion in the vascular access site, n (%)	0 (0.0)	0 (0.0)	—
Renal function decrease, n (%)	3 (8.3)	2 (5.3)	0.48
Bleeding (2–5 type) , n (%)	1 (2.8)	0 (0.0)	0.49
Life threat, n (%)	6 (16.7)	5 (13.2)	0.80
Need for hospitalization or its prolongation, n (%)	9 (25.0)	10 (26.3)	0.87
Durable or substantial health damage, n (%)	3 (8.3)	6 (15.8)	0.32
Total	36	38	0.79

Renal function decrease was defined as a fall of at least one stage of chronic kidney disease; bleeding was defined by the "Bleeding Academic Research Consortium"
Abbreviations: see Table 1

DISCUSSION

Comparing the patients from both non-invasive (coronary CTA) and invasive (ICA) cohorts, there were no significant differences in terms of their baseline characteristics, their previous medical history, PTP, as well as the extent and prevalence of CAD. The short-term follow-up together with the long-term outcomes proved the efficacy and safety of the innovative, non-invasive, outpatient, coronary CTA-based strategy for triage of chest pain patients with a high clinical likelihood of CAD.

The CAT-CAD trial was the first published randomized study investigating the efficacy and safety of the non-invasive diagnostic strategy employing coronary CTA as the first-line anatomical test for patients with a high actual prevalence of obstructive CAD. Moreover, it was the first study enrolling patients regardless of the previous history of CAD and/or prior interventional treatment. Importantly, in our cohort, the prevalence of significant CAD (53%) was higher than in the only other similar CONSERVE study (39%) [10, 11]. Our current 36-month follow-up is also substantially longer than 12 months in the CONSERVE trial.

There were several major studies (SCOT-HEART, PROMISE, PLATFORM), which showed that coronary CTA is feasible as compared to other non-invasive tests in the diagnosis of patients with suspected CAD [12–14]. However, those studies examined coronary CTA vs. ICA among patients with an intermediate to high-intermediate clinical likelihood of CAD, with a 4 times lower prevalence of obstructive CAD compared to the CAT-CAD trial. So far, the impact of coronary CTA in the population of patients already scheduled for ICA has not been sufficiently explored.

Our previous analyses showed that in the short-term the non-invasive, outpatient-based strategy employing coronary CTA reduced the number of invasive examinations and the need for hospitalizations. This translated into reduced diagnostic costs and decreased potential risks related to invasive procedures. Our currently reported long-term outcomes provide the missing evidence that the reported initial gains are not offset by later increases in invasive testing, urgent hospitalizations, symptoms-driven revascularizations, or other adverse events.

The CAT-CAD trial results potentially extend the use of coronary CTA to include a new group of patients, previously diagnosed with invasive tests [15–17]. There is robust evidence that coronary CTA has the potential to nearly obviate non-actionable ICAs. Due to its low risk and outpatient-based design, coronary CTA is suitable for clinical assessment and may be considered advantageous by obviating the need for invasive examination of patients with non-obstructive arteries and/or by allowing preparation of more controlled revascularization (patient counseling, antiplatelet pre-treatment, choice of operator, interventional planning). Our results support, while simultaneously extending, the updated role of coronary CTA in the diagnosis of patients with suspected obstructive CAD. This is particularly relevant in the light of recently published guidelines regarding chronic coronary syndromes.

Study limitations

We acknowledge several limitations of the current study. First, it was an open-label study and individual decisions for treatment options may have been influenced by the initial diagnostic modality employed. Second, it was a single-center trial testing a relatively small group of patients, which did not allow for a robust evaluation of clinical complications associated with either strategy. Third,

patients with decreased renal function were excluded; yet, the favorable risk profile of intravenous vs. intraarterial injection of iodinated contrast media could benefit strategies involving coronary CTA for initial triage [18, 19]. Fourth, the study was performed in an experienced center with a high-volume coronary CTA program, which may not reflect the common clinical situation at many institutions. Finally, the exclusion criteria (such as chronic kidney disease, high likelihood of in-stent restenosis, contraindications to ICA, significant arrhythmias, or body mass index [BMI] >35 kg/m^2), as well as the inclusion of stable patients only, preclude extrapolation of this data to a broader patient population.

CONCLUSIONS

The long-term results of the CAT-CAD randomized trial show the feasibility of a non-invasive diagnostic strategy employing coronary CTA as the first-line anatomical imaging test in stable patients with a high clinical likelihood of obstructive CAD. Given that the non-invasive approach is potentially effective and safe, it can constitute an alternative to the invasive, hospitalization-dependent, expensive, higher risk, direct ICA strategy. Our findings correspond to the recently published guidelines regarding chronic coronary syndromes and support the need for extended use of coronary CTA [20].

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