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Research paper

Computed tomography angiography versus angiography for guiding percutaneous coronary interventions in bifurcation lesions – A prospective randomized pilot study

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ABSTRACT

Background: There is no data on the impact of coronary computed tomography angiography (coronary CTA), as an addition to angiography, on the outcomes of percutaneous coronary interventions (PCI) in bifurcation lesions.

Methods: Patients with stable coronary artery disease scheduled for elective bifurcation PCI were randomized 1:1 to planning the procedure based on coronary CTA and angiography (CTA group) or angiography alone (CA group). The primary efficacy endpoint was the immediate angiographic result. Secondary efficacy endpoints were: a) procedural characteristics and b) postprocedural fractional flow reserve (FFR) in the side branch (SB) in a subgroup of patients. Safety outcomes were: a) periprocedural myocardial infarction, b) contrast use and c) radiation dose.

Results: PCI of 45 lesions in the CTA group and 47 lesions in the CA group was performed. Postprocedural lumen diameters in the main branch (MB) and SB, frequency of SB compromise or occlusion and mean SB FFR values were not different between study groups. Two or more stents were implanted less frequently in the CTA group than in the CA group (18% vs. 43%, $p = 0.01$). This difference was driven by less frequent MB 2-stent overlap in the CTA group (7 vs. 21%, $p = 0.046$) and numerically less SB stenting (11% vs. 21%, $p = 0.07$). Proximal optimization technique was used more frequently in the CTA group (44% vs. 21%, $p = 0.018$).

Conclusions: CTA-assisted bifurcation PCI leads to similar immediate results compared with angiography alone, however is associated with higher use of single-stent procedures with proximal optimization, less frequent 2-stent overlap and less SB stenting.

1. Introduction

Percutaneous coronary interventions (PCI) in bifurcation lesions are challenging procedures due to their technical complexity and higher risk of potential adverse effects, including in-stent restenosis, thrombosis and periprocedural myocardial infarction (MI). A side branch (SB) is involved in about 20% of all PCI procedures, which means that the issue of its optimization remains fundamental.[1] Available data suggest that a one-stent crossover technique with drug-eluting stent and provisional SB stenting has more favorable outcomes in comparison with a planned two-stent strategy.[2] Planning of bifurcation PCI is routinely based on visual estimation of coronary angiography. This approach has its limitations including assessment of vessel lumen only, suboptimal visualization of calcifications, vessel foreshortening and overlapping. Coronary computed tomography angiography (coronary CTA) is currently gaining recognition in coronary imaging, due to its high

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Abbreviations

CA	coronary angiography
CAD	coronary artery disease
CTA	computed tomography angiography
FFR	fractional flow reserve
MB	main branch;
MI	myocardial infarction
PCI	percutaneous coronary intervention
POT	proximal optimization technique
SB	side branch
TIMI score	'thrombolysis in myocardial infarction' score
TLR	target lesion revascularization
QCA	quantitative coronary angiography

sensitivity and specificity in the assessment of lesion severity, as well as extended potential of visualizing lesion morphology including plaque and vessel wall.[3] Since coronary CTA imaging is increasingly performed in different clinical scenarios and it recently proved to be useful in percutaneous management of such complex lesions like chronic total occlusions, it seems reasonable to incorporate the CTA images into the process of planning of PCI in bifurcation lesions.[4] To the best of our knowledge there is no data on the role of coronary CTA in planning of bifurcation PCI. Hence the aim of our study was to investigate the impact of coronary CTA, in addition to angiography, on the outcomes of PCI in bifurcation lesions.

2. Materials and methods

2.1. Study design

This was a prospective, randomized, single-blinded, single-center pilot study designed to verify the potential role of adding coronary CTA to the routine preprocedural assessment of patients with stable coronary artery disease scheduled for elective PCI of bifurcation lesions. Detailed study protocol was published earlier.[5]

2.2. Study population

Between May 2012 and December 2015 patients diagnosed with stable coronary artery disease and scheduled for elective PCI of coronary bifurcation with reference SB diameter >2 mm were screened for inclusion. Diagnosis of stable coronary artery disease was established according to the European Society of Cardiology guidelines.[6] Revascularization was decided individually based on clinical presentation, angiographic appearance of the lesion and results of non-invasive and invasive ischemia testing. Exclusion criteria were: a) persistent atrial fibrillation or other arrhythmia with irregular ventricular rhythm; b) allergy to contrast medium; c) glomerular filtration rate <50 ml/min; d) two or more diagnostic procedures with high radiation exposure (>4 mSv) regardless of body region within last 3 months; e) PCI of in-stent restenosis; f) PCI of chronically occluded vessel. The study was approved by the Institutional Review Board and was performed in accordance with the II Helsinki Declaration. Since there were no previous reports in this field, it was impossible to estimate the effect of adding CTA analysis on the bifurcation PCI procedure. Therefore, the study group was not calculated, but arbitrarily sized as at least 90 patients.

2.3. Randomization and study groups

All included patients, after signing informed consent, underwent a coronary CTA examination. Next, the primary investigator (R.W.) performed randomization 1:1 in blocks of 10 patients by drawing a blank envelope with group assignment written inside. The envelopes were prepared by a person not involved directly in performing the study. In the first group PCI was planned with the use of angiography only (CA group), in the second group with the use of angiography and coronary CTA (CTA group). Patients were blinded to their allocation throughout the study period.

2.4. Coronary CTA

The minimal time interval between angiography and CTA, as well as between CTA and PCI, was 48 h. Prior to each CTA examination and PCI procedure, the serum creatinine level was checked to exclude of contrast-induced nephropathy (CIN). CTA examinations were performed on 2 × 128 SOMATOM Definition Flash or 2 × 192 SOMATOM Force scanner (Siemens, Forchheim, Germany). Prior to the scan, every patient received 0.8 mg of nitroglycerin sublingually. Patients with heart rate >65/min without contraindications to beta-blockers received consecutive boluses of 2.5 mg metoprolol i.v (maximum dose 10 mg). For each examination 60–80 ml of non-ionic contrast medium (Iomeron 400, Bracco, Italy) was administered via antecubital vein. A retrospectively ECG-gated acquisition protocol with beam collimation 128 × 0.6 mm or 192 × 0.6 mm and 80–120 kV tube voltage adjusted to body mass was applied. Imag data sets were reconstructed in mid-to end systole (35–45% of RR interval) and diastole (65–75% of RR interval) with 0.6-mm slice thickness and 0.4-mm increment. Images were analyzed off-line using dedicated software (Syngo® Circulation, Siemens, Forchheim, Germany) by one observer (R.W.) with 5-

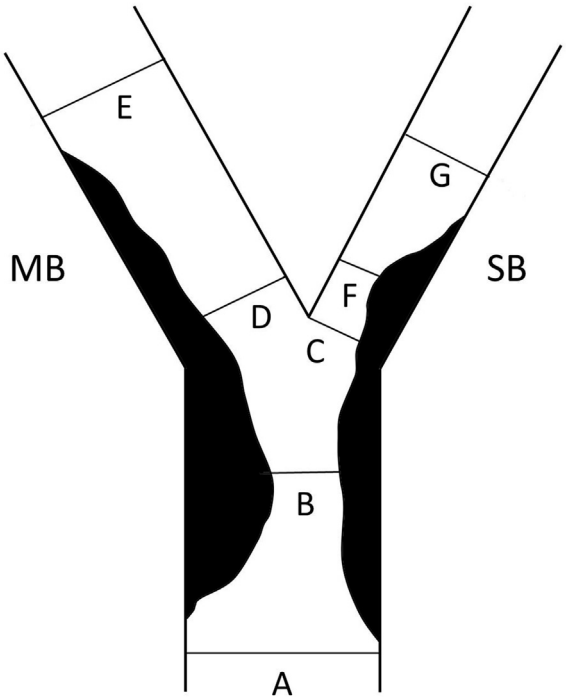

Fig. 1. Schematic presentation of measurements made in each examined bifurcation by CTA and QCA. A – proximal reference segment in MB; B – minimal lumen diameter at proximal MB; C – lumen diameter at SB ostium; D – minimal lumen diameter at distal MB; E – distal reference segment in MB; F – minimal lumen diameter at SB; G – reference segment in SB.

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