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ORIGINAL PAPER

In vivo comparison of key quantitative parameters measured with 3D peripheral angiography, 2D peripheral quantitative angiography and intravascular ultrasound

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Abstract

The aim of this study was to compare the measures of luminal stenosis between the two-dimensional (2D) and three-dimensional (3D) Quantitative Vessel Analysis (QVA) generated by CAAS QVA software and intravascular ultrasound (IVUS). Invasive contrast angiography is considered gold standard for diagnostic imaging and intervention in both coronary and peripheral arterial disease. However, it is based on 2D images depicting complicated 3D arterial anatomy. To overcome these limitations, 3D QVA has been developed to bridge the gap between 2D QVA and endovascular imaging. Thirty porcine femoral angiograms (common, profunda and superficial) with matching intravascular ultrasound (IVUS) pullbacks featuring variable degree of stenosis were analysed by 2D QVA, 3D QVA and quantitative IVUS. All 3 modalities provided similar data regarding the length of the investigated segment. Median lumen diameter was nearly identical in IVUS (4.69 mm) and in 3D QVA (4.76 mm) but quite a bit lower in 2D QVA (4.47 mm, Kruskal–Wallis test $p = 0.1648$). Lumen area measured in 2D QVA was lower than in IVUS and in 3D QVA. Lumen areas rendered by IVUS and 3D QVA were similar. Bland–Altman plots showed that the lowest differences were observed between IVUS and 3D QVA. IVUS and 3D QVA results were consistently higher than 2D QVA. 3D QVA is a useful surrogate of IVUS for precise luminal morphology measurements of peripheral arteries, rendering results that are much closer to IVUS than 2D QVA can provide.

Keywords QCA · IVUS · IAF—imaging, angiographic/fluoroscopic · Peripheral angiography

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Introduction

Invasive contrast angiography continues to be the gold standard for diagnostic imaging and intervention in both coronary artery disease (CAD) and peripheral arterial disease (PAD) [1, 2]. However, conventional angiography provides only two-dimensional (2D) images in an attempt to reflect a complicated three-dimensional (3D) arterial anatomy. The limitations of 2D angiography have been widely examined and described for coronary arteries [3] and, to a lesser extent, for peripheral arteries [4, 5]. Out-of-plane magnification, foreshortening and vessel overlap [6], may significantly impact and even bias the determination of lesion length, eccentricity and tortuosity. To overcome these limitations and provide more truthful reflection of the actual vascular anatomy, 3D vessel analysis has been developed and is currently being validated against phantoms with known-dimensions [7] and compared with intravascular ultrasound [8, 9], mostly regarding its application in coronary atherosclerosis.

Three-dimensional reconstruction of the vessel is performed by integrating two 2D angiographic projections and imaging geometry, which results in correction of foreshortening, geometric distortion and out-of-plane magnification [10]. It has been previously shown that 3D quantitative coronary angiography (QCA) is able to accurately assess the diameter, length and volume in coronary artery disease and to provide the comprehensive geometry analysis of the coronary vessels [11]. However, the characterization and validation of 3D peripheral quantitative angiography is lagging behind its coronary counterpart. Accordingly, we used a set of peripheral angiograms and corresponding intravascular ultrasound pullbacks from in vivo (animal) studies to compare the measures of luminal stenosis between the 2D and 3D Quantitative Vessel Analysis (QVA) generated by CAAS QVA FDA-approved software (Pie Medical Imaging, Maastricht, Netherlands), and intravascular ultrasound (IVUS).

Materials and methods

The study hypothesis was that the 3D QVA would be able to mitigate the well-known shortcomings of 2D QVA such as suboptimal length measurements and limited ability to render reliable data for severity and distribution of the atherosclerotic narrowing. As such, 3D QVA is expected to approach the accuracy and precision of IVUS, which is recognized as superior to 2D angiography, and gold standard for in-vivo quantification of lumen and vessel cross-sectional areas as well as plaque distribution, shape and burden.

Study material

Thirty porcine femoral angiograms (common, profunda and superficial) with matching IVUS pullbacks featuring variable degree of stenosis were analysed. All raw imaging data were recorded at the Skirball Center for Innovation of Cardiovascular Research Foundation, New York, USA and transferred to the core laboratory for analysis (KCRI, Krakow, Poland).

Analyses and software

2D QVA

Quantitative analyses were performed by a trained analyst experienced in the use of the CAAS analytical software. Off-line 2D QVA analyses were performed with QVA module of CAAS 5.10.2 software (Pie Medical Imaging B.V., The Netherlands 2013) rendering a total number of 30 QVA 2D measurements. Projection for 2D QVA analyses were chosen from all available, basing on the CoreLab procedures for 2D QVA. This procedure defines the projection for 2D analysis as one, which fulfils the following criteria: sharp contours of the vessel (good quality of the recording), no overlapping or minimal overlapping of the study segment with other vessels, carina of bifurcations which define region of interest (ROI) clearly visible, ROI viewed with minimal shortening.

Before performing measurements, each image was calibrated using catheter calibration method. The catheter size was 8 French in all the cases. For each femoral artery, measurements were performed depicting particular vessel (angiograms with clearly visible region of interest, ROI) and on IVUS pullback. Firstly, matching vessel segments on angiograms and IVUS pullback were identified on the basis of corresponding anatomical landmarks (bifurcations). Length of the segment was defined from carina of the first bifurcation to carina of the second bifurcation. Contours of the ROI were drawn resulting in the following set of measurements:

- Length between two clearly identified anatomical bifurcations (length of segment).
- Lumen diameter (min, max and mean) and lumen area (min, max and mean) in segment.

3D QVA

Based on the 2D QVA analyses, core lab identified additional projections of investigated arteries, for which the differences in angulation were at least 30°. Then, 2D QVA analyses of identified projections were performed. Using two angiographic projections with drawn contours of the ROI, 3D reconstruction of the ROI was performed with the use of 3D QVA module of CAAS 5.10.2 software (Pie Medical Imaging B.V., Maastricht, the Netherlands 2013). Due to missing second angiography projection, which fulfilled the entry criterion for 3D reconstruction (difference in angulation at least 30°), 6 arteries were not eligible for 3D reconstruction, leaving 24 vessels for this purpose. Automatic measurements were performed on the 3D model of each artery, resulting in:

- Length between two clearly identified anatomical bifurcations (length of segment).
- Lumen diameter (min, max and mean) and lumen area (min, max and mean) in segment.

IVUS

Off-line IVUS analyses were performed with CAAS Intra-Vascular 1.1 (Pie Medical Imaging B.V., Maastricht, the Netherlands 2014) giving a total number of 30 measurements. Lumen area was drawn inside the ROI in IVUS pullback with the 1 mm interval. Basing on drawn contours of the lumen, the software automatically performed

measurements of lumen diameter and lumen area (min, max and mean) at each frame.

More information regarding the software and methodology of performed analyses is presented as 'Supplementary Material'.

Comparison of angiography vs. IVUS

We took into consideration 3 parameters for further analyses/comparisons: the ROI length, lumen diameter and lumen area. These parameters were chosen because of their highest clinical significance. We compared the vessel parameters assessed in 2D QVA to the corresponding parameters assessed in 3D QVA and IVUS in all possible compilations.

Statistical analyses

For continuous variables (differences in length, diameter and lumen area measurements), data was presented as median with the first and the third quartile. This continuous data was compared using Kruskal–Wallis test for 3 groups. When the Kruskal–Wallis test showed a significant difference between analysed groups, nonparametric comparisons for each pair were performed using Wilcoxon method to identify where the statistically significant differences were present. No formal power calculation has been performed.

Agreement between 2D QVA, 3D QVA and IVUS was presented using Bland Altman method [12].

All statistical analyses were performed using the JMP®, Version 13.1.0. SAS Institute Inc., 2016 and Statistica 12.0, StatSoft® Poland. A p-value < 0.05 was considered as statistically significant.

Results

ROI length

We compared the region of interest (ROI) length, measured in three modalities. The distribution of these measurements was different than normal, so we used the non-parametrical tests for comparison of achieved results.

The highest measurements of ROI length was observed in 3D QVA (median 65.0 mm), lower in IVUS (median 61.3 mm) and the lowest in 2D QVA (median 58.3 mm). The distribution of ROI length is presented in Table 1.

We did not find any significant differences between all three methods of ROI length measurement (Kruskal–Wallis test $p = 0.7431$, Fig. 1a). All three modalities provided similar data regarding ROI length, small differences were not statistically significant.

Lumen diameter

Lumen diameter in all measured locations

When we took into consideration the median value of lumen diameter, we could observe that this value was nearly identical in IVUS (median 4.69 mm) and in 3D QVA (median 4.76 mm) but quite a bit lower in 2D QVA (median 4.47 mm). The comparison of lumen diameter distribution in all modalities is presented in Table 1.

Differences between the 3 modalities were not significant (Kruskal–Wallis test $p = 0.1648$). 3D QVA provided the highest value and 2D QVA the lowest value of lumen diameter. The highest difference was observed between 2D QVA and IVUS, but the observed differences were not statistically significant (Fig. 1b).

Maximal lumen diameter

In regard to the maximal lumen diameter, the highest median was reported for IVUS (6.05 mm), then for 3D QVA (5.85 mm) and the lowest for 2D QVA (5.38 mm). The distribution of lumen diameter is presented in Table 1. Differences between the 3 modalities were significant (Kruskal–Wallis test $p = 0.0287$). Post-hoc test showed, that the 2D QVA provides the significantly lower value of maximal lumen diameter than IVUS ($p = 0.0115$). Differences between other modalities were not statistically significant.

Minimal lumen diameter

The highest median for minimal lumen diameter was observed for 3D QVA assessment (4.13 mm), then for

Table 1 Results of vessel measurements in investigated modalities

Modality	ROI length (mm)	Lumen diameter all (mm)	Lumen diameter max (mm)	Lumen diameter min (mm)	Lumen area (mm^2)
QVA3D	65.0 [35.3; 76.1]	4.76 [4.06; 5.49]	5.85 [4.98; 6.27]	4.13 [3.23; 4.58]	18.1 [13.0; 23.8]
IVUS	61.3 [35.1; 75.5]	4.69 [3.60; 5.65]	6.05 [5.41; 6.67]	3.45 [2.72; 4.29]	17.8 [11.5; 23.6]
QVA2D	58.3 [34.1; 71.8]	4.47 [3.73; 5.19]	5.38 [4.70; 5.79]	3.35 [3.08; 4.15]	15.9 [10.9; 21.2]

QVA3D three-dimensional quantitative coronary angiography, *IVUS* intravascular ultrasound, *QVA2D* two-dimensional quantitative coronary angiography, *ROI* region of interest

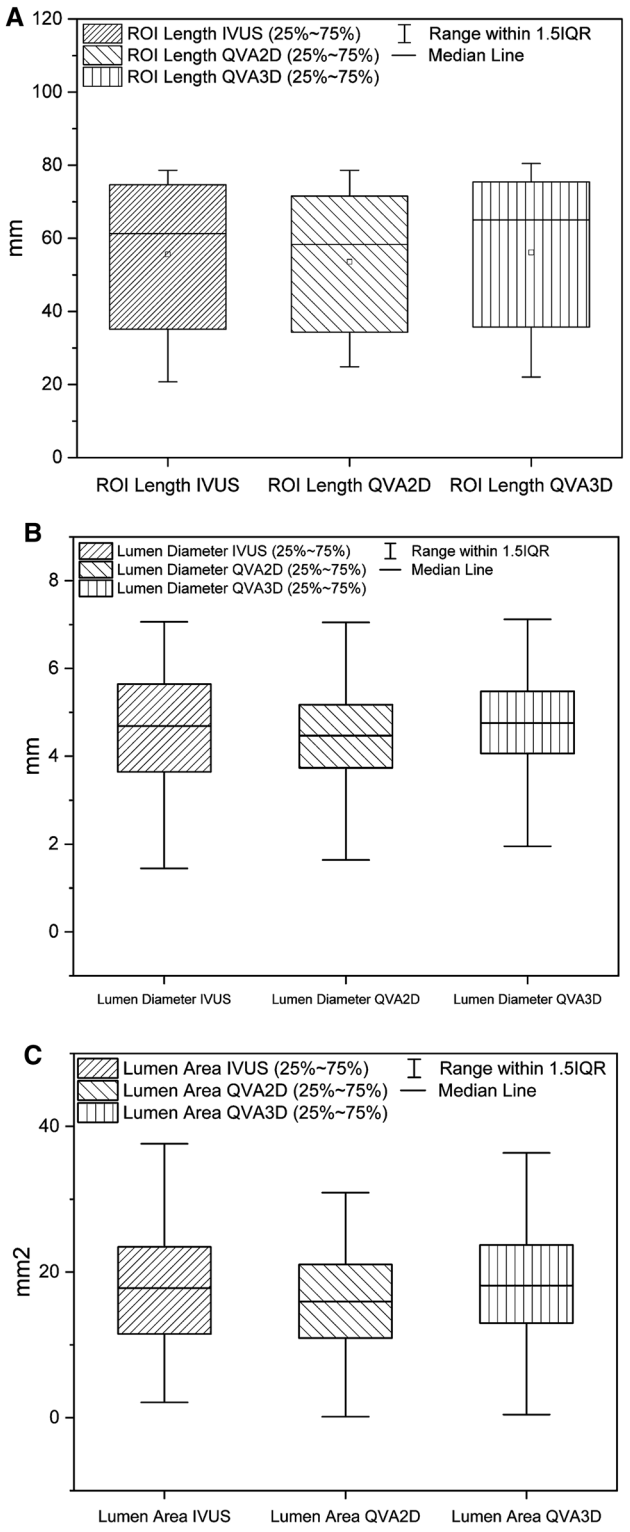

Fig. 1 Comparison of vessel parameters assessed in three modalities. **a** Comparison of ROI length; **b** comparison of lumen diameter; **c** comparison of lumen area; *QVA3D* three-dimensional quantitative coronary angiography, *IVUS* intravascular ultrasound;, *QVA2D* two-dimensional quantitative coronary angiography, *ROI* region of interest

IVUS (3.45 mm) and the lowest for 2D QVA (3.35 mm). The distribution of minimal lumen diameter is presented in Table 1. The observed differences between the 3 modalities in minimal lumen diameter assessment were not statistically significant (Kruskal–Wallis p = 0.1737).

Lumen area

The highest median of lumen area was observed in 3D QVA (18.1 mm^2), then in IVUS (17.8 mm^2) and the lowest in 2D QVA (15.9 mm^2). The distribution of lumen area measured in all modalities is presented in Table 1. Differences between the 3 modalities were statistically not significant (Kruskal–Wallis p = 0.1473). The lumen areas results achieved in IVUS and 3D QVA were similar (Fig. 1c).

Inter-modalities agreement

For the visualization of the measurements' agreement between the 3 modalities, the Bland–Altman plots were prepared for all pairs of them, and for all 3 ROI/lumen parameters (ROI length, lumen diameter and lumen area).

Plots presenting the agreement of ROI length measurements show a high agreement between the 3 modalities—almost all measurements were between ±2SD (dotted lines), single outliers occurred for longer ROI and were observed around 70 mm of length (Fig. 2).

Bland–Altman plots for lumen diameter measurements (min, max, mean) show that the lowest differences were observed between IVUS and 3D QVA—mean difference was very close to 0 (middle continuous line), IVUS results are higher than 2D QVA—mean difference above 0 and 2D QVA results are lower than 3D QVA—mean difference below 0 (Fig. 3).

The analysis of agreement between all 3 modalities in regard of lumen area measurement (min, max, mean) shows the similar findings to the previous plots. The smallest difference (near zero) is between IVUS and 3D QVA, IVUS provided higher lumen area values than 2D QVA and 2D QVA provided smaller areas than 3D QVA (Fig. 4). Outliers appeared in larger vessels, while for vessels with area under 10 mm^2 the agreement between modalities was very high.

Graphic presentation of inter-modality concordance showed that a greater agreement was achieved for smaller parameter values, while the agreement became lower when the bigger vessels were analysed. Comparison of the IVUS with 3D QVA measurements demonstrated a good agreement for all analysed parameters; mean differences were near zero. Vessel measurements performed by IVUS provided higher value of all parameters in comparison to 2D QVA—mean differences were always higher than 0. Finally, the difference between 2D QVA and 3D QVA is less than 0 for

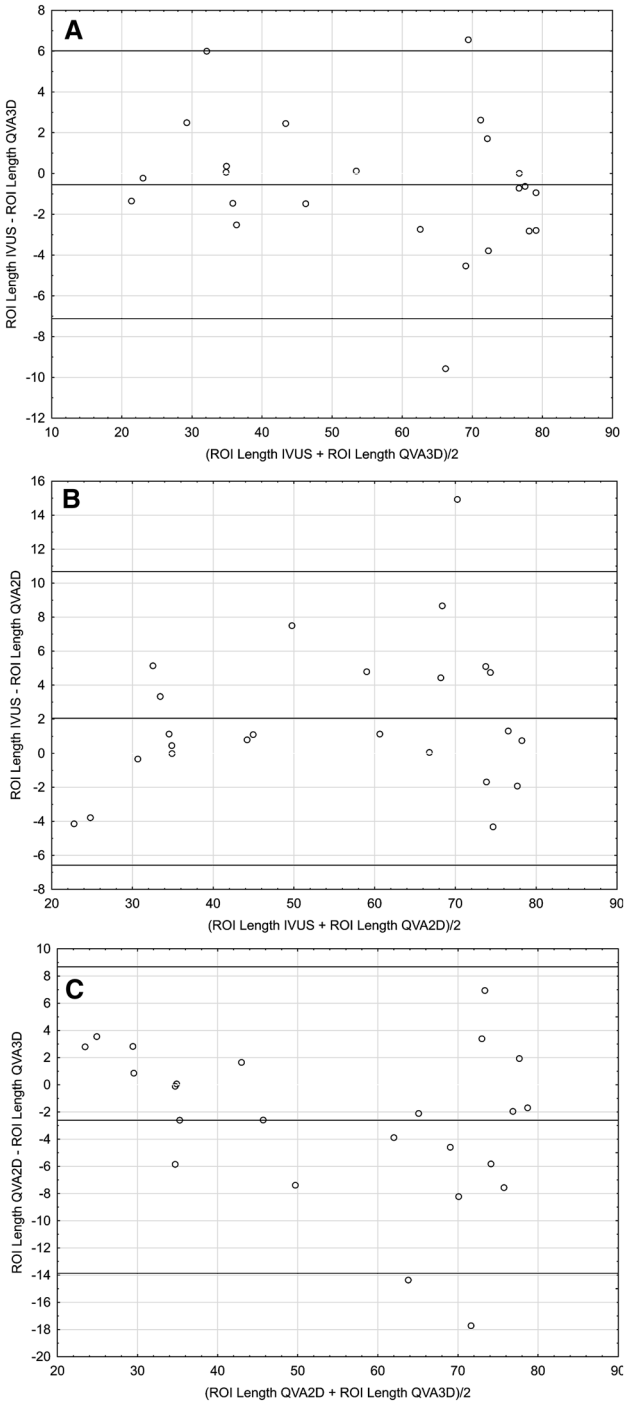

Fig. 2 Bland–Altman plots for ROI length. **a** Comparison between IVUS and QVA3D; **b** comparison between IVUS and QVA2D; **c** comparison between QVA3D and QVA2D; *QVA3D* three-dimensional quantitative coronary angiography, *IVUS* intravascular ultrasound, *QVA2D* two-dimensional quantitative coronary angiography, *ROI* region of interest

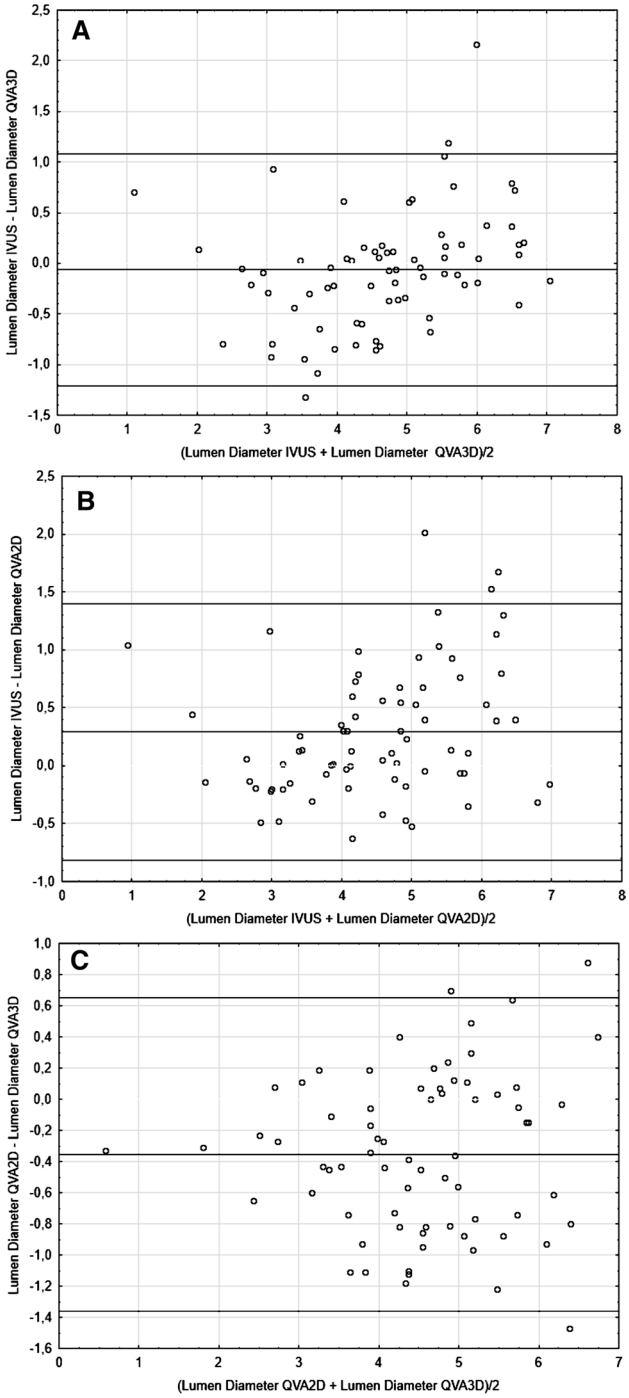

Fig. 3 Bland–Altman plots for lumen diameter. **a** Comparison between IVUS and QVA3D; **b** comparison between IVUS and QVA2D; **c** comparison between QVA3D and QVA2D. *QVA3D* three-dimensional quantitative coronary angiography, *IVUS* – intravascular ultrasound, *QVA2D* two-dimensional quantitative coronary angiography

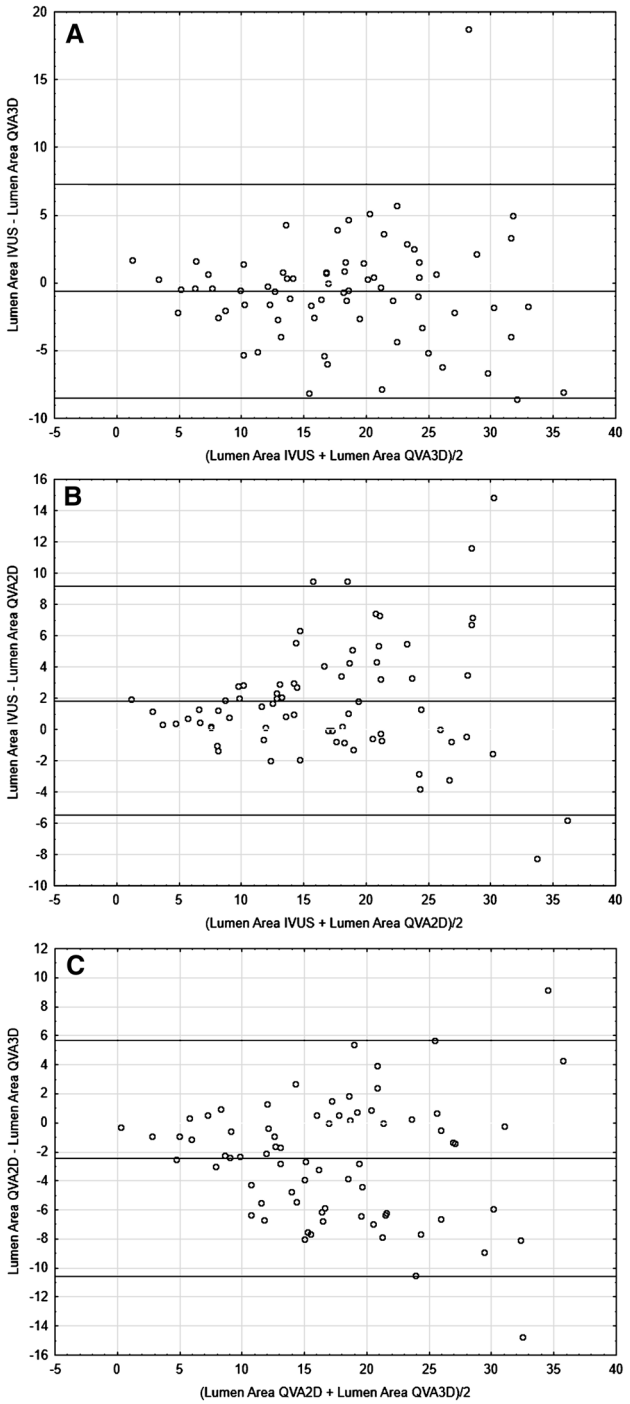

Fig. 4 Bland–Altman plots for lumen area. **a** Comparison between IVUS and QVA3D; **b** comparison between IVUS and QVA2D; **c** comparison between QVA3D and QVA2D; *QVA3D* three-dimensional quantitative coronary angiography, *IVUS* intravascular ultrasound, *QVA2D* two-dimensional quantitative coronary angiography

all comparisons, which means that the lowest values of vessel size parameters were achieved in the 2D QVA modality.

An representative example of 3D QVA reconstruction based on two 2D images is presented on Fig. 5.

Discussion

The present study shows that the 3D QVA renders similar measurements of the key clinical parameters of peripheral luminal morphology to the IVUS. As such, it improves the precision of characterizing the lesion from 2D QVA. This suggests that 3D QVA could provide valuable and reliable surrogate for endovascular imaging in assessment of lumen morphology, similar to its coronary counterpart. Despite obvious merits of endovascular imaging in improving acute and long-term outcomes of percutaneous intervention [13], its routine adoption is hindered by added cost and time. Whereas, contrast angiography is still an indispensable mainstay for percutaneous intervention. Thus, improving its precision and versatility to the point where it could at least partially substitute for endovascular imaging, continues to be a desirable objective.

The length of predefined ROI, which is one of the most critical parameters from clinical point of view because of its key role in choosing the length of the treatment device, was very similar in all modalities. However, this can be attributed to the investigation of straight segments in the present study, where the inferiority of 2D QVA, previously demonstrated for 2D QCA [14], could not be convincingly assured. An investigation in tortuous segments would be much more likely to reveal such differences.

The assessment of lumen diameter in IVUS, which is a reference method for this measurement, was more comparable to the 3D QVA than to 2D QVA. Vessel diameter measured in 2D QVA was clearly smaller than evaluated in other modalities. Similar correlations between 2D QVA and 3D QVA were reported previously, and our findings are concordant with the published data [14]. The most precise measurement of lumen diameter is afforded by the IVUS visualization of defined ROI. Our analyses support the position that 3D QVA provides lumen measurement very similar to those derived from IVUS, whereas 2D QVA metrics is less accurate and the values are consistently lower than those obtained from IVUS or 3D QVA. As such, relying on 2D QVA may lead to underestimation of vessel diameter and eventual selection of treatment device with lower diameter than truly required for the target lesion. In contrast, 3D QVA appears to provide more accurate data regarding lumen diameter and should provide better procedural guidance without the need to use endovascular imaging.

Relations and differences observed for lumen diameter assessment extend to measurements of lumen area. While high agreement could be seen between IVUS and 3D QVA, values from 2D QVA were the lowest. Previously reported comparisons showed that the 3D reconstruction could slightly underestimate the lumen area parameters

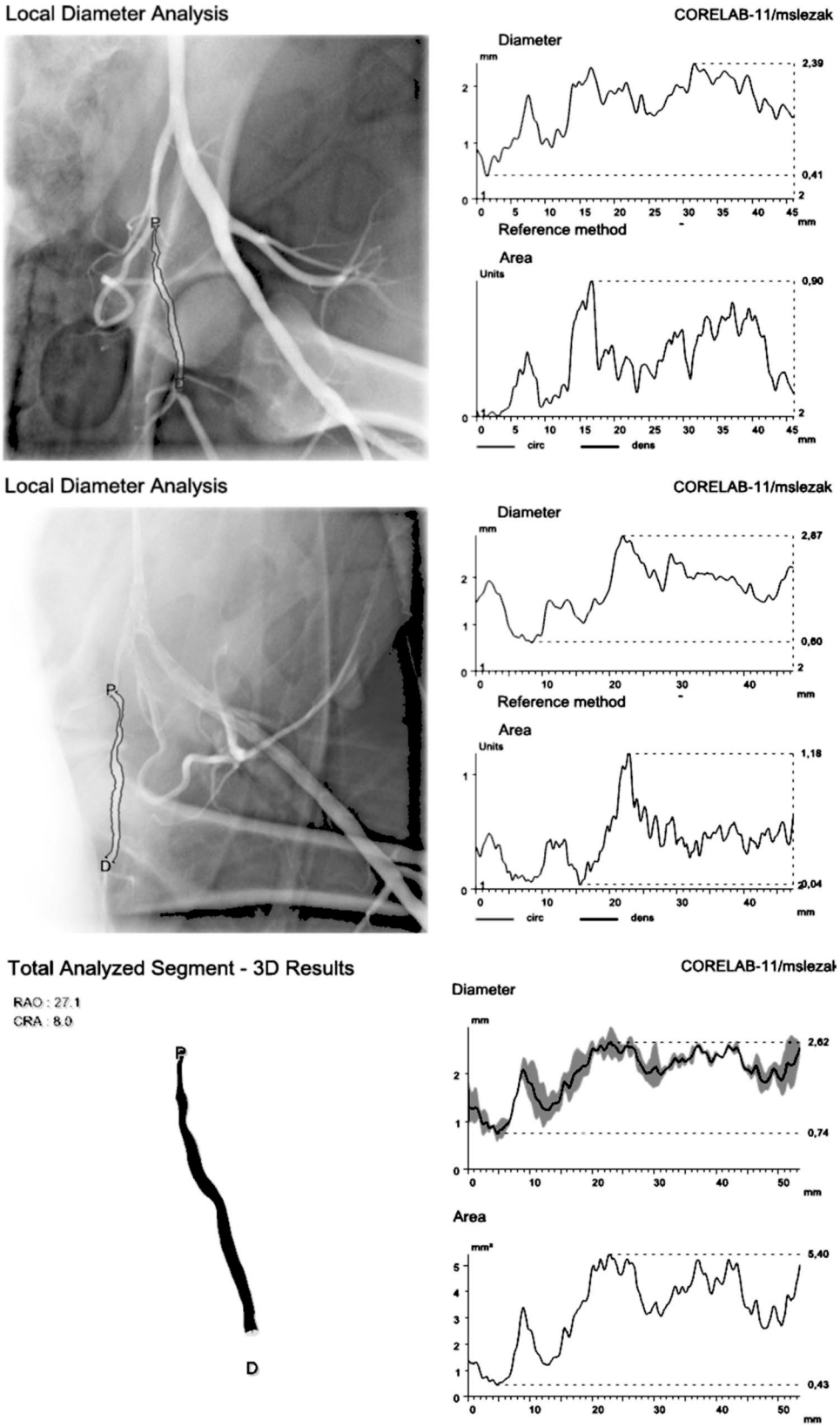

Fig. 5 An representative example of 3D QVA reconstruction based on two 2D images

in comparison to IVUS assessment [15]. Lumen area measurement is particularly clinically significant for the progression of disease assessment and patient qualification for the invasive treatment. Taking into consideration the clinical importance of lumen area assessment and the downsides of IVUS visualization (e. g. the necessity of additional device employment, potential problems with IVUS probe delivery into the tortuous, narrowed or calcified lesions, procedure prolongation, added costs), 3D QVA visualization could become a valuable and reliable surrogate for endovascular imaging in assessment of lumen morphology and subsequent procedural guidance. Stent or balloon undersizing (axial geographic miss) and mispositioning (longitudinal geographic miss) during PCI continue to be underappreciated and found in more than 60% of coronary cases [16]. Previous studies have shown that longitudinal and axial geographic miss results in endothelial flow disturbances, increased intramural wall stress and increased wall shear stress, causing unfavourable healing with more pronounced intimal hyperplasia formation [17]. These effects are further complicated by local drug delivery. With successful adoption of drug-eluting devices in peripheral arterial intervention, similar negative consequences of device-lesion mismatch, such as the edge effect restenosis, can be expected to increase [18]. Similarly, precise assessment of vessel and stenosis size is of paramount importance for the emerging field of venous intervention, where it is established already that IVUS guidance is mandatory due to insufficient accuracy of 2D angiography [19]. As such, there is theoretical appeal to 3D QVA for guidance in venous intervention if it could obviate the need to employ IVUS routinely. However, it has to be stated clearly that validation of 3D QVA applied to venograms still needs to be undertaken.

The high agreement of the 3D QVA results with IVUS assessment, significantly better than the 2D QVA, can be found in several recently published studies. Observed agreement allows using the 3D QVA methodology not only for better vessel visualization than 2D QVA, but also for functional assessment of target lesion [14]. Precise vessel measurement provides by 3D QVA has also proved significance for intervention strategy definition [20] and results with better choice of the treatment device than 2D QVA.

For the trial purposes, the 2D QVA, 3D QVA and IVUS analyses were performed off-line at CoreLab, but all of them could be performed in the CathLab during catheterization. 2D QVA is already available on angiography X-ray systems and can be access real time during the angiography procedure. From clinical perspective, it is usual practice to acquire at least two angiograms for better evaluation of investigated vessel, particularly in case of tortuosity, non-circular stenosis or vessel overlapping. 3D QVA, which needs two 2D angiograms as input, can be accessed real-time during catheterization. What is more, QVA allows a non-biased way of deciding on vessel size. It is known that visually estimation leads to more variation [21]. QVA allows with just two clicks to get the length, diameter and percent of stenosis in an accurate and reproducible way. IVUS imaging is precise and provide very comprehensive visualization of vessel shape, but it is costly and requires introducing additional device into the vessel, so is performed usually in selected cases, while angiography is a standard part of each intravascular procedure.

In conclusion, thanks to its high quantitative concordance with IVUS, 3D QVA may have important clinical application as the tool for selection of specific devices based on the anatomic pathway to the lesion. It may aid proper sizing and positioning of the treatment devices used to adequately cover and precisely treat the lesion, which is of increasing importance due to rapid expansion of local drug delivery therapies in peripheral intervention. Moreover, several studies comparing 3D QCA and FFR had shown that when FFR is not available 3D QCA may assist in the assessment of functional severity of intermediate lesions [22, 23].

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

Ethical approval The study analyzed angiographic and IVUS images generated in a course of an animal study undertaken with a different purpose.

Human and animal rights The original animal study that rendered the imaging data was approved by Institutional Animal Care and Use Committee of CRF Skirball Center for Innovation and was conducted in conformance to the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals. All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.

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