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Clinical validation of a novel software for quantitative analysis of coronary intravascular ultrasound☆,☆☆

Freek Nijhoff [a], Karel G. Van Den Hengel [b], Tristan L.B. Slots [b], Pieter R. Stella [a], Pierfrancesco Agostoni [a,]*

[a] Department of Cardiology, University Medical Center Utrecht, Utrecht, The Netherlands
[b] Pie Medical Imaging, Maastricht, The Netherlands

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ABSTRACT

Purpose: CAAS IntraVascular (CAAS-IV) is a recently released software that provides options for sophisticated quantitative coronary ultrasound (QCU) analysis. The aim of this study was to validate CAAS-IV for QCU in diseased human coronaries.
Methods: Ten preprocedural and 5 postprocedural IVUS studies were derived from daily practice. Intraobserver, interobserver, intersoftware (CAAS-IV vs. Curad) and interplatform (CAAS-IV vs. Volcano console) variability were assessed for cross-sectional area (CSA) measurements. Interobserver and intersoftware comparisons were made for volume measurements.
Results: Measurements of lumen, EEM, plaque and stent CSA demonstrated small differences in the intraobserver (0.0 ± 3.7%, −0.7 ± 2.8%, −0.5 ± 7.0% and −0.9 ± 3.4%), interobserver (0.1 ± 4.4%, 0.1 ± 3.4%, −0.5 ± 8.2% and −0.8 ± 4.3%), intersoftware (−0.3 ± 4.5%, 0.2 ± 2.4%, 0.4 ± 6.8% and −0.5 ± 3.2%) and interplatform (0.7 ± 7.9%, 0.9 ± 4.0%, −1.1 ± 12%, −1.8 ± 3.6%) comparisons. For lumen, EEM, plaque and stent volume, the interobserver (−2.1 ± 9.3%, 0.9 ± 5.6%, 3.4 ± 7.2% and −0.2 ± 3.6%) and intersoftware (−2.2 ± 6.2%, −2.6 ± 6.1%, −2.7 ± 12% and −4.1 ± 3.2%) differences were substantially larger. Excluding large side-branches and calcifications, post-hoc measurements of lumen, EEM, plaque and stent volume showed small differences in the interobserver (−0.3 ± 3.2%, 0.9 ± 2.4%, 2.9 ± 4.4% and −1.3 ± 1.8%) and intersoftware (0.5 ± 2.5%, −1.2 ± 1.7%, −3.4 ± 5.1% and −1.5 ± 2.2%) comparisons. Analysis time for entire pullbacks was reduced by 19.2 [14.9–30.0]% using CAAS-IV ($p < 0.01$).
Conclusions: CAAS-IV demonstrated reliable QCU with excellent agreement with previously validated software and the IVUS imaging console. Precision and reproducibility of measurements were high, proving CAAS-IV to be a valid option for QCU analysis in clinical practice and research. Interactive contour editing reduced analysis time by 20%.

1. Introduction

Intravascular ultrasound (IVUS) is a catheter-based invasive imaging technique that produces tomographic cross-sectional images of coronary artery lumen and wall, providing details on plaque burden and vascular dimensions [1]. IVUS is being increasingly used in the catheterization laboratory for assessment of coronary artery disease and guidance of percutaneous coronary intervention (PCI). In cases where coronary angiography fails to identify the hemodynamic significance of coronary lesions, e.g. in left main coronary artery (LMCA) disease, IVUS can provide guidance in decision making [2]. Moreover, IVUS can be performed to optimize percutaneous treatment strategy (e.g. adequate lesion preparation), device selection (e.g. sizing) and stent deployment, and to reduce complication rates such as suboptimal stent apposition and expansion which are known risk factors for stent thrombosis [3]. In addition, IVUS is frequently used for research purposes to evaluate the performance of new devices and the progression/regression of coronary atherosclerotic burden in patients on investigational medical treatment [4–8].

As the options for quantitative coronary ultrasound (QCU) analysis are often limited on the imaging consoles, several software packages are commercially available that enable more sophisticated off line analysis of imaging data. These software packages provide semi-automatic contour detection of vessel compartments, reducing the time needed for pullback analysis and enabling volume calculations of coronary artery segments. Semi-automatic means that after initial manual input (i.e. a seed point) a contour tracing is performed which subsequently is fine-

Abbreviations: CAAS-IV, CAAS IntraVascular; CSA, Cross-sectional area; EEM, External elastic membrane; ICC, Intraclass correlation coefficients; IVUS, Intravascular ultrasound; LMCA, Left main coronary artery; MLA, Minimal lumen area; MSA, Minimal stent area; PCI, Percutaneous coronary intervention; QCU, Quantitative coronary ultrasound.

☆ Conflict of interest: KH & TS are employed at Pie Medical Imaging.

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* Corresponding author at: Department of Cardiology, University Medical Center Utrecht, Heidelberglaan 100, room E.04.210, 3584 CX, Utrecht, The Netherlands. Tel.: +31 88 755 6717; fax: +31 88 755 5427.
E-mail address: p.agostoni@umcutrecht.nl (P. Agostoni).

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tuned manually by the user again. Recently, new QCU software has been launched under the name of 'CAAS IntraVascular' (Pie Medical Imaging, Maastricht, The Netherlands).

The aim of this study is to validate CAAS IntraVascular (CAAS-IV) in the clinical setting through assessment of intraobserver and interobserver variability for grey scale QCU measurements in diseased human coronary arteries, and comparing these measurements with those obtained by established and already validated QCU software (intersoftware variability) and the IVUS imaging console (interplatform variability).

2. Material and methods

2.1. IVUS image acquisition

All IVUS images were provided by the University Medical Center Utrecht and retrospectively selected after review for sufficient image quality. The IVUS studies were derived from daily clinical practice and were performed at discretion of the operators (mainly to guide LMCA in our center). Fifteen random IVUS pullbacks, obtained in 10 individual patients, were selected for this study. The IVUS investigations comprised 10 pullbacks prior to PCI and 5 after PCI (all including stent implantation).

Each IVUS study was conducted using the mechanical Volcano s5 console (Volcano Corp., CA, USA) equipped with a 45-MHz Revolution transducer catheter. Image acquisition was performed without electrocardiographic (ECG) gating, following intracoronary administration of 200 μg nitroglycerine at an automated pullback speed of 0.5 mm/s. All images were stored on the console and transferred to CD-ROM for offline-analysis.

2.2. IVUS analysis software

CAAS IntraVascular is a recently released software package that provides offline semi-automatic quantitative analysis of IVUS images. The user interface renders one cross-sectional and two orthogonal longitudinal views of the coronary artery that allow for delineation of three compartment outlines: lumen, external elastic membrane (EEM) and stent. After initial automatic contour tracing by the software, manual adjustments can be made in both longitudinal and cross-sectional views. In the longitudinal view, an infinite number of points can be added to correct for errors in the automatic contour analysis. In the cross-sectional view, 8 points are used to delineate compartment contours by default (Fig. 1A), which can be relocated exclusively along the radius of the vessel. Freely movable points can be added on a per frame basis, if required for delineation of complex contours (e.g. in the case of erosions, ruptured plaques or dissections). Manual correction of irregularities in the cross-sectional and longitudinal contours is facilitated by interactive contour editing. This software feature provides the propagation of single manual contour adjustments to a modifiable number of neighboring frames through local reiteration of the automatic contour detection algorithm, reducing the need for frame by frame correction of erroneous initial tracings.

Curad Vessel Analysis (Curad, Curad BV, Amsterdam, The Netherlands) is established and validated software for quantitative analysis IVUS analysis [9], that has been previously used in several studies [10,11]. This software package offers semi-automatic contour delineation that is comparable with CAAS-IV. Manual corrections can also be applied in both cross-sectional (Fig. 1B) and longitudinal views, but once adjustments to the cross-sectional contours have been made, the longitudinal contours will be disabled to further changes. This restriction is imposed

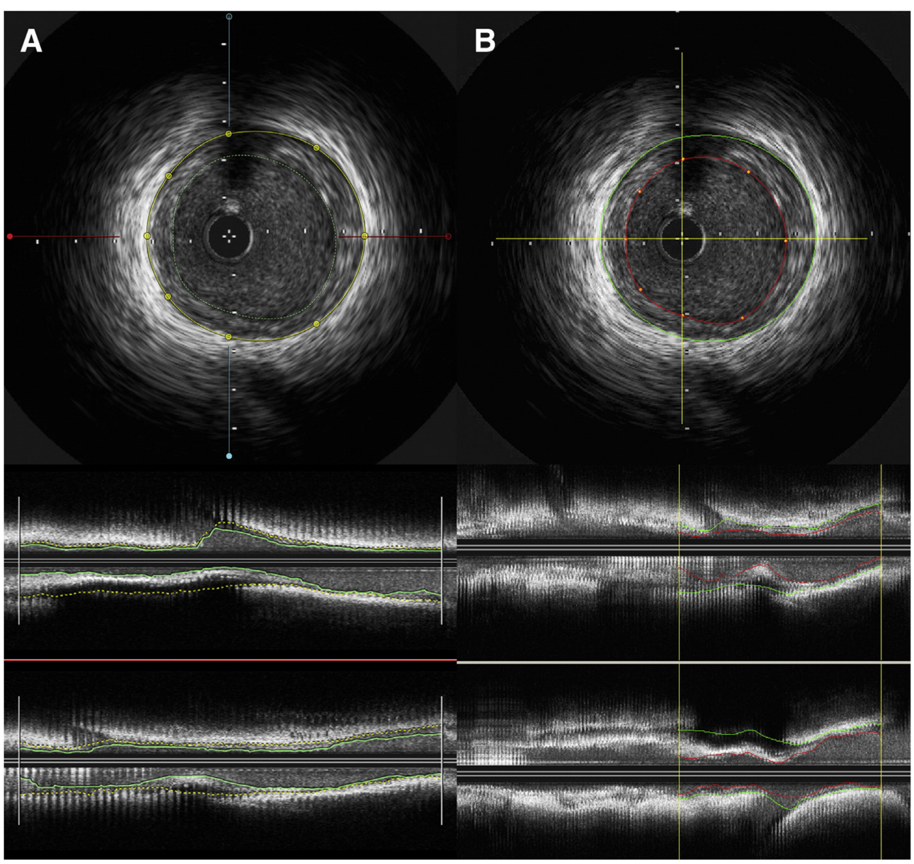

Fig. 1. Example of IVUS cross-sectional and longitudinal views in CAAS-IV and Curad. (A) The CAAS-IV views for manual adjustment of contours. The 'active' cross-sectional contour shows the 8 points that can be repositioned along the radius of the vessel. Yellow line = EEM, dotted green line = lumen, cross with red and blue arms = orientation in longitudinal view. (B) The Curad views of the same IVUS frame. The 'active' cross-sectional contour demonstrates adjustable points randomly divided along the lumen circumference. Green line = EEM, red line = lumen, yellow armed cross = orientation in longitudinal view.