Catheterization and Cardiovascular Diagnosis 33:55–60 (1994)

Technical Notes

Radiological Quality of Coronary Guiding Catheters: A Quantitative Analysis

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Quantitative coronary angiography (QCA) is a validated and widely accepted method to investigate changes in arterial dimension over time. Calibration of measurements is enabled by the use of the coronary catheter as a scaling device. The dimensions and laminar composition of coronary catheters, however, have changed significantly over recent years and the suitability of the current generation of coronary catheters for calibration purposes has not been validated. We therefore recorded 57 coronary guiding catheters on cinefilm, and compared their automated quantitative measurements (Cardiovascular Angiography Analysis System, CAAS) with their true values (precision micrometer). We found an overall underestimation of quantitatively derived dimensions, ranging from −8.9 to +4% for water-filled catheters and from −15.5 to −3.9% for contrast-filled catheters. In conclusion, while the current generation of coronary guiding catheters shows a wide variety in radiological quality, it can be clearly detected by the CAAS system, and is suitable for calibration of QCA measurements (with the exception of the DVI atherectomy catheter), provided that calibration is done on contrast-empty catheters. © 1994 Wiley-Liss, Inc.

Key words: coronary arteriography, quantitative coronary angiography analysis, edge detection, automated algorithm, cardiac catheterization, coronary guiding catheter

INTRODUCTION

Quantitative coronary angiography (QCA) is increasingly being used for both on-line analysis to guide interventional procedures as well as for off-line analysis in the study of restenosis and progression/regression. Despite the widespread and long-standing use of coronary angiography, as well as recent improvement in radiographic acquisition, the interpretation of angiograms in clinical practice has changed little over the years and is still assessed visually. Visual assessment, however, is subjective with a large inter- and intraobserver variability and should therefore not be incorporated in scientific research of restenosis prevention and progression–regression [1–3]. Computer-assisted or automated QCA is not only objective but also has the advantage of being more accurate and reproducible than visual or hand-held calliper measurements.

At the Thoraxcenter, the computer-assisted Cardiovascular Angiography Analysis System (CAAS) using an automated edge detection technique was developed and has recently been updated [4]. The CAAS has been used in the angiographic "core laboratory" in several multicenter pharmacological and device studies [5–7]. In order to obtain reliable and reproducible quantitative measurements of coronary cine-angiograms, variations in data acquisition associated with the use of different coronary guiding catheters must be minimized. The actual size of individual catheters often differs significantly from the nominal size stated by the manufacturer. In order to obtain the true external diameter of the catheter, all catheters are measured by a digital micrometer, with a high degree of accuracy and precision (0.001 mm) [8]. This provides an accurate basis for calibration of the measurements of the catheter image obtained by QCA.

Combining micrometer measurements and radiologi-

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Received February 10, 1994; revision accepted April 18, 1994.

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TABLE I. Summary of the Manufacturer, Composition of Material, Number, and Sizes of the Catheters Studied

Material	*N*	Size (Fr)	Manufacturer
Teflon/Polyurethane/Ultrax	7	9.5/11	DVI
Polyurethane/Steel braid/Teflon	6	8/10	Medtronic
Teflon/Steel braid/Polyurethane	13	7–10	Schneider
Teflon/Steel braid/Trilon	9	7/8	Scimed
Teflon/Kevlar braid/Pebax	12	7/8	Bard
Trilon/Steel braid/Nylon	10	6/8	Cordis

cal size results in a calibration factor (mm per pixel) which allows objective and absolute measurements of coronary artery dimensions. Consequently, QCA measurements based on catheter calibration have been previously shown to be highly reproducible [9].

The automated QCA measurement of a guiding catheter and the subsequent calibration factor are significantly influenced by the material of the catheter, the presence of radiographic contrast in the catheter lumen, and the settings of the X-ray equipment. QCA validation studies of previously available catheters have been reported [10–14] but the recent development of catheters of new materials in trilaminar composition with altered radiopacity made reinvestigation of the radiographic quality of coronary guiding catheters necessary.

METHODS

Catheters

Mid-portions of a total of 57 coronary guiding catheters (Table I) were filmed. We selected frequently used and commonly available catheters from Scimed (Triguide series), Medtronic (Sherpa), Bard (Illumen), Cordis (6Fr Diaventional and 8 Fr Brite tip), Schneider (Soft touch), and DVI (atherectomy catheters).

Image Acquisition and Processing

A monoplane Philips Poly Diagnost C2 machine equipped with an MCR X-ray tube and powered by an Optimus CP generator (Philips Medical Systems International BV, Best, The Netherlands) was used for all radiographic imaging. The 5-inch (12.5-cm) field mode of the image intensifier (focal spot 0.5 mm) was selected. Catheters were taped on a block of polymethylmethacrylate (PMMA or perspex) $25 \times 250 \times 250$ mm, and filmed in the isocenter of the X-ray system. The distances from X-ray source to catheter and from X-ray source to the image intensifier were 75 and 100 cm, respectively.

Each catheter was filmed at two kilovolt levels. The X-ray system automatically adjusts the kilovoltage level to 60 and 90 kV upon the interposition of 125 or 250 mm PMMA blocks, respectively. The incorporation of the PMMA blocks results in more appropriate kilovolt levels and a scatter medium which more closely imitates the X-ray scatter in the human thorax during cine-angiography.

Catheters were filmed at two filling conditions: filled with water and filled with 100% radiographic contrast (lopamidol 755;370 mg iodine/ml, Bracco, Italy). A centimeter grid was filmed in exactly the same plane for scaling purposes.

All catheters were imaged and acquired on 35-mm cinefilm (CFE Type 2711, Kodak, Paris, France) at a frame rate of 12.5 images/sec, using an Arritechno 90 cine camera (Arnold & Richter, Munich, Germany) with an 85-mm lens. The cinefilms were processed by a Refinal developer (Agfa-Gavaert, Leverkusen, Germany) for 4 min at 28°C. The film gradient was measured in all cases to ensure that the optical densities of interest were on the linear portion of the sensitometric curve.

QCA Edge Detection

For each individual catheter 8 cineframes were quantitatively analysed (water/60 kV, water/90 kV, lopamiro/60 kV, lopamiro/90 kV, with two cineframes in each setting). All cineframes were analyzed using the new generation Cardiovascular Angiography Analysis System (CAAS II) (Pie Medical Maastricht, the Netherlands) [4]. The principles of computer-assisted quantitation of coronary cine-angiograms using this system have been previously described in detail [15]. Briefly, the selected cineframes were digitized by a high resolution digital camera. The calibration factor for this study was determined by a manual definition of three pairs of points on horizontal lines of a centimeter grid in the center of the image. The calibration factor is thus expressed in mm per pixel. Catheter contours are then determined automatically with the edge detection algorithm over a length of approximately 15 mm. This edge detection is based on the weighted sum of the first and second derivative functions applied to the digitized brightness profile information along scan lines perpendicular to the local centerline directions of the catheter. All contour positions were corrected for the pincushion distortion induced by the image intensifier.

Calibration

The true size of the catheter, was measured by an experienced analyst as the mean of two orthogonal measurements of each individual catheter by an electronic precision-micrometer (Mitutoyo OP-1HS Tokyo, Japan; accuracy 0.001 mm) [8].

Data Analysis

The mean ± standard deviation of the QCA measurements of cinefilm-recorded catheters was calculated for

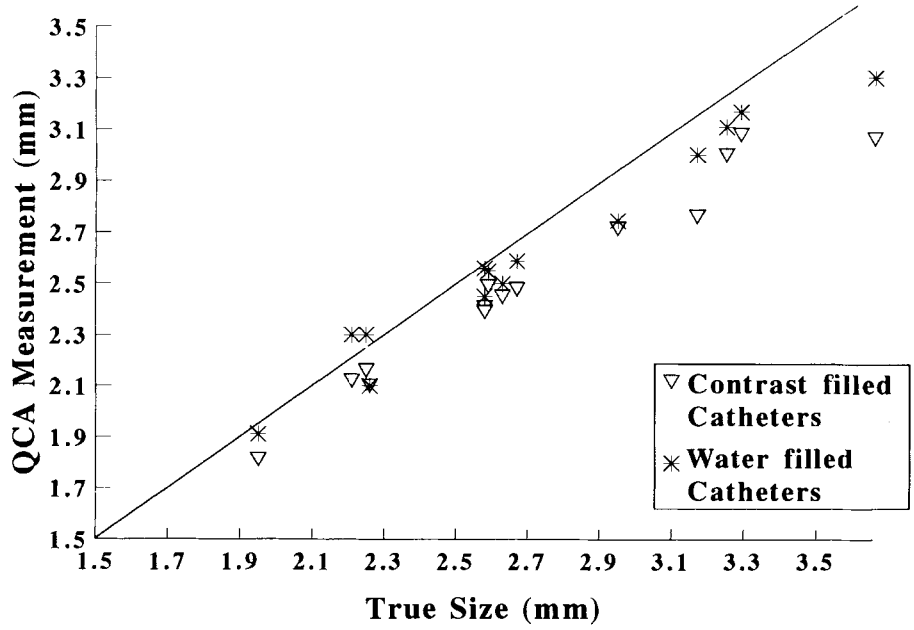

Fig. 1. QCA measurements plotted against the true size, as measured by a precision micrometer. Diameters of contrast-filled catheters are underestimated more than water filled catheters ($P<0.0001$).

each individual catheter from four cineframes comprising either contrast-filled catheters or water-filled catheters. This was averaged per French size and per manufacturer. The mean of two digital micrometer measurements was taken as the true size. Radiographically measured size was compared to the true size and expressed as percentage deviation, a positive percentage deviation meaning a larger QCA measurement compared to the true catheter size, and a negative percentage deviation meaning a smaller QCA measurement compared to the true catheter size.

RESULTS

The data are averaged over the 60 and 90 kV level and presented per manufacturer and french size, but subdivided in measurements of contrast-filled and contrast-empty catheters. Micrometer-derived diameters differed significantly from the manufacturer's nominal size. The micrometer measurements of the external diameter were on average 0.025 mm smaller than the nominal diameter listed by the manufacturer ($P<0.0001$).

Quantitative analysis of each catheter, either filled or empty of contrast, results in a lower value, compared to assessments by digital micrometer ($P<0.0001$) (Fig. 1). This deviation is less in water-filled catheters (ranging between -8.9 and $+4\%$), and more distinct in contrast-filled catheters (ranging between -15.5% and -3.9%). Overall the deviation results in an average weighted underestimation of -2.9% for catheters filled with water, and -7.1% for contrast-filled catheters, compared to micrometer measurements. Applying the edge detection procedure on water-filled catheters results consistently in a larger diameter (0.11 mm $\pm$ 0.07), when compared to analysis of contrast-filled catheters ($P<0.0001$) (Figs. 1 and 2) and thus generates less underestimation of the catheter diameter on cinefilm.

DISCUSSION

Assessment of the True Catheter Size

One of the vital components of the calibration process is an accurate micrometer measurement of the coronary guiding catheter [12,15,16]. This is a mandatory step in the calibration since actual sizes of the catheter often differ from the nominal catheter sizes specified by the manufacturer. In our study it appears that catheters are 0.025 mm smaller in diameter in comparison to the dimensions listed by the manufacturer ($P<0.0001$) (Table II). Very low standard deviations demonstrate the high reliability of the digital micrometer assessment. Previously, this method has been validated [14]. Interobserver variability between 3 analysts measuring a total of 96 catheters ranging from 6 to 9 French showed a mean

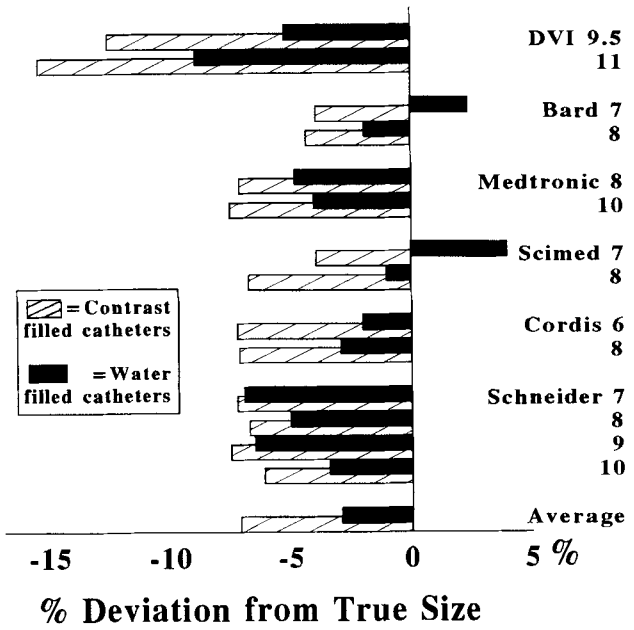

Fig. 2. Schematic presentation of the percentage deviation from the true size for contrast-empty and contrast-filled coronary guiding catheters per manufacturer and per French size.

difference of less than 0.03 mm and a standard deviation depending on the size between 0.00 and 0.04 mm. The intraobserver variability showed a mean difference of less than 0.01 mm and a standard deviation of the difference of less than 0.03 mm for all sizes. This indicates that it is possible to measure the true size of a catheter with a high degree of accuracy and precision [8].

Analysis of Contrast-Filled and Contrast-Empty Catheters

Additional reliability of calibration can be achieved by the acquisition of the catheter image after flushing with saline or filling with blood in the same projection and field of view of the image intensifier, positioning the catheter in the centre of the radiographic image and operating a correction for pincushion distortion [8]. In this study, overall deviation of angiographically measured dimensions of contrast-empty catheters was approximately -2.9% ($P<0.0001$, range -8.9% to $+4\%$) (Table II). When free of contrast, the edge detection algorithm reliably detects the external border of the guiding catheter. The weighted sum of the first and second derivative will result in a slightly smaller diameter than the true diameter. However, the presence of the misleading high density column of contrast medium inside the catheter lumen will cause a much higher underestimation of the catheter dimension since the edge detection will trace the contours of the contrast column, i.e., the internal diameter of the catheter, instead of the external diameter which is actually measured by the digital precision micrometer (Fig. 1). In our study, analysis of contrast-filled catheters resulted in an average underestimation of -7.8% (range -15.5 to -3.9%), and thus a subsequent overestimation of calibration factor and coronary dimensions of 8.5% ($[[100/(100-7.8)]-1]\times 100$). This clearly underlines the importance of calibration methodology, not only for longitudinal studies, but also for online clinical practice.

In a previous study we have compared quantitavely analyzed cineframes using contrast-filled catheters and water-filled catheters (either filled with blood or flushed with saline) for calibration [14]. The measured calibration factor was 0.156 ± 0.030 mm per pixel with the contrast-filled catheter, and 0.143 ± 0.020 mm per pixel with the catheter filled with saline or blood ($P<0.001$) [8,17]. The use of calibration obtained from contrast-filled catheters would have resulted in an average overestimation of 9.1% (range $-1\%/30\%$) of the measurements obtained from cineframes recording a contrast empty catheter.

Catheter Material and Composition

The use of catheters of low radiopacity should be avoided in QCA studies [12,16]. Our study has highlighted the wide variation in radiopacity of coronary guiding catheters. Every guiding catheter must possess a minimal degree of radiopacity, in order to be visible on fluoroscopic or cinefilm images. For calibration purposes, a sharp contrast gradient near the outer edge is vital for accurate contour detection. The outer layer of material must overcome the peak in the density profile caused by stainless steel braidings. Analysis of catheters with a highly radiopaque outer layer, or without the presence of a "distracting" stainless steel braiding in the middle layer (DVI and Bard), may result in less underestimation of the angiographic catheter size. Both may contribute to the low deviation from the true size, and even positive values in the Bard catheters. The atherectomy catheters, which also lack a steel braiding as well, introduce an extreme divergence in obtained values. These catheters, even filled with water, give a deviation of -5.2 to -8.9% depending on their French size. The consistently poor reproducibility of the computer-assisted measurements of each individual atherectomy catheter is expressed in a wide standard deviation, and is an indication for the relative radiolucency of the Ultrax outer layer. Average deviations from the true size of the remaining manufacturers were -4.2 and -5.9% for Medtronic and Schneider (polyurethane) catheters, and $+1.2$, $+0.3$, and -2.4% for Scimed (Trilon), Bard (Pebax), and Cordis (nylon) catheters, respectively, which is in concordance with the observations of Fortin et al. [18].

TABLE II. Catheter Dimensions and Average Deviation*

Material		Catheter Dimensions (mm) and average deviation (%)				
			Cine-film			
		Micrometer	Water-filled		Contrast-filled	
Size	*N*	(mm)	mm	%	mm	%
Teflon/PU/Ultrax						
9.5fr	3	3.17 ± 0.01	3.01 ± 0.06	−5.2	2.77 ± 0.08	−12.6
11fr	4	3.66 ± 0.02	3.32 ± 0.16	−8.9	3.08 ± 0.05	−15.5
PU/Steel/Teflon						
8fr	2	2.58 ± 0.02	2.45 ± 0.00	−4.8	2.39 ± 0.01	−7.1
10fr	4	3.25 ± 0.02	3.12 ± 0.01	−4.0	3.01 ± 0.02	−7.5
Teflon/Steel/PU						
7fr	3	2.26 ± 0.02	2.10 ± 0.01	−6.9	2.10 ± 0.03	−7.2
8fr	4	2.63 ± 0.01	2.50 ± 0.02	−5.0	2.45 ± 0.02	−6.7
9fr	5	2.95 ± 0.02	2.75 ± 0.03	−6.5	2.72 ± 0.03	−7.5
10fr	1	3.29	3.18 ± 0.03	−3.4	3.09 ± 0.00	−6.1
Teflon/Steel/Trilon						
7fr	4	2.21 ± 0.02	2.30 ± 0.05	4.0	2.12 ± 0.06	−3.9
8fr	5	2.58 ± 0.02	2.56 ± 0.06	−1.0	2.41 ± 0.07	−6.7
Teflon/Kevlar/Pebax						
7fr	6	2.25 ± 0.03	2.30 ± 0.02	2.4	2.16 ± 0.04	−3.9
8fr	6	2.59 ± 0.01	2.55 ± 0.02	−1.9	2.49 ± 0.02	−4.3
Trilon/Steel/Nylon						
6fr	5	1.95 ± 0.00	1.91 ± 0.01	−2.0	1.81 ± 0.02	−7.2
8fr	5	2.67 ± 0.01	2.59 ± 0.03	−2.9	2.48 ± 0.02	−7.1
Total	57	Guiding Catheters		−2.9%		−7.1%

*Micrometer (mm), catheter dimensions measured by a digital precision micrometer which is considered to be the true size; water-filled, QCA dimensions of water-filled catheters; contrast-filled, QCA dimensions of contrast-filled catheters. Materials: PU, polyurethane; Steel, stainless steel wire braid. The percentage deviation is the difference from QCA-derived dimensions in comparison to the true size ($P<0.0001$ for both filling states). Consistently the analysis of contrast-filled catheter image results in a significant smaller diameter ($P<0.0001$ vs water-filled).

We measured the shafts of coronary guiding catheters, according to the protocol used by Reiber et al. [12]. The rationale of this approach is the following: catheter material at the tip does not vary from the material used in the catheter shaft, with the exception of some diagnostic catheters [13]. In general it is the addition of barium sulphate or other radiopaque substances to the nylon and nylon-like compounds especially in the outer layer of the coronary catheters and not the compound itself that defines radiopacity and radiographic qualifications.

CONCLUSION

Correct acquisition of the angiographic catheter dimension is critical for reliable calibration of QCA measurements, but when these conditions are respected, this technique can give accurate and reproducible results. The use of coronary guiding catheters of poor radiographic quality, and catheters of different brands in a long-term angiographic follow-up study should be minimized. In a multicenter study, this issue is ideally standardized by providing each participating centre with similar guiding catheters, or diagnostic catheters of high quality which are used before and after angioplasty, as well as during the follow-up catheterization procedure.

We conclude that coronary guiding catheters can be analyzed reliably only when recorded in a contrast-empty state. Although the rationale for calibrating angiographic cine-images on a contrast-empty catheter is evident, some angiographic core-labs persist in calibrating their cine-images on a contrast-filled catheter. The reason for this practice is apparently that these angiographic core-labs are using a QCA system, which is unable to detect the edge of an empty catheter. This inability is related to the lack of resolution and potentially to the algorithm used in this system.

ACKNOWLEDGMENTS

We gratefully acknowledge the technical support of J.M.R. Ligthart, technician in the Thoraxcenter catheterization laboratory, and the help of Diny Amo and Jaap Pameyer for quantitative catheter measurements. Dr. David Keane is a recipient of a travel grant from the Peel Medical Research Trust, U.K.

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