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Intravascular Ultrasound Imaging of Angiographically Normal Coronary Arteries: An In Vivo Comparison With Quantitative Angiography

FREDERICK G. ST. GOAR, MD, FAUSTO J. PINTO, MD, EDWIN L. ALDERMAN, MD, FACC, PETER J. FITZGERALD, MD, PHD,* MICHAEL L. STADIUS, MD, FACC, RICHARD L. POPP, MD, FACC

Stanford and San Francisco, California

Intravascular ultrasound, a new technique for real-time two-dimensional visualization of arteries and veins, delineates vessel wall morphology and measures luminal dimensions. This imaging method has been validated with in vitro systems and in peripheral vessels, but there are few in vivo coronary artery studies.

Twenty cardiac transplant recipients with no angiographic coronary artery disease were scanned with a 30-MHz intravascular ultrasound catheter from the left main coronary ostium to the mid-left anterior descending coronary artery. Simultaneous angiographic measurements were performed at 76 sites. Ultrasound end-diastolic diameters in two perpendicular axes were 3.8 ± 0.9 and 3.9 ± 0.6 mm, respectively, and mean diameter derived from an area determined by planimetry was 3.9 ± 0.9 mm. Angiographic coronary artery diameters measured with a computer-assisted edge detection system perpendicular to the long axis of the vessel and to the long axis of the catheter were 3.4 ± 0.8 and 3.6 ± 0.8 mm, respectively.

Luminal diameters measured with the two imaging systems correlated closely, with an r value of 0.86 when ultrasound was compared with the angiographic diameter measured perpendicular to the vessel and 0.88 when compared with the angiographic diameter measured perpendicular to the imaging catheter. Eighty-three percent of the ultrasound-measured diameters were above the line of identity when compared with the simultaneous angiographic measurement. The more the imaging catheter deviated from the long axis of the vessel, the greater was the discrepancy between the ultrasound and angiographic measurements.

In summary, in vivo intracoronary ultrasound measurements correlate closely with quantitative angiography, although ultrasound measurements tend to be slightly larger. Correlation is improved when the ultrasound catheter is parallel to the vessel long axis. Eccentric ultrasound catheter placement does not have a significant effect on measurements in coronary vessels. Intravascular ultrasound provides an accurate method to assess coronary dimensions as an alternative to quantitative angiography.

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Intravascular ultrasound, a new technique for real-time two-dimensional visualization of arteries and veins, has the ability to delineate vessel wall thickness and morphology and facilitate measurements of luminal dimensions (1-3). Recent studies (4-11) using in vitro models, animals and in vitro and in vivo human peripheral vessels have shown good correlations between vessel area and diameter measurements obtained by intravascular ultrasound and pathologic and angiographic measurements. Before intravascular ultrasound can be used for monitoring coronary artery dimensions and for more advanced purposes such as evaluating outcomes of interventional procedures, in vivo coronary studies comparing ultrasound-derived measurements with those determined by angiography are needed. Although angiography has acknowledged limitations as a reference standard of in vivo coronary dimensions, computer-assisted edge detection in angiographically normal vessels yields highly reproducible measurements (12,13)

The purpose of this study was to assess simultaneous in vivo intracoronary ultrasound and arteriographic vascular measurements in angiographically normal coronary vessels.

Methods

Study patients. The study group included 20 cardiac transplant recipients (17 men and 3 women) with a mean age of 49 ± 9 years (range 31 to 62). Patients were studied at the time of a routine coronary arteriogram obtained 3 weeks to 9 years (mean 3.1 years) after transplantation. No patient had angiographic evidence of coronary artery disease. All participants gave informed consent to the protocol approved by the Committee for the Protection of Human Subjects in Research at Stanford University Medical Center.

From the Division of Cardiovascular Medicine, Stanford University School of Medicine, Stanford, and *Department of Cardiology, University of California-San Francisco, San Francisco, California. Dr. Pinto was supported by a Research Fellowship of the Fundação Calouste Gulbenkian, Lisbon, Portugal.

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Address for reprints: Richard L. Popp, MD, Cardiology Division, CVRC, Stanford University Medical Center, Stanford, California 94305.

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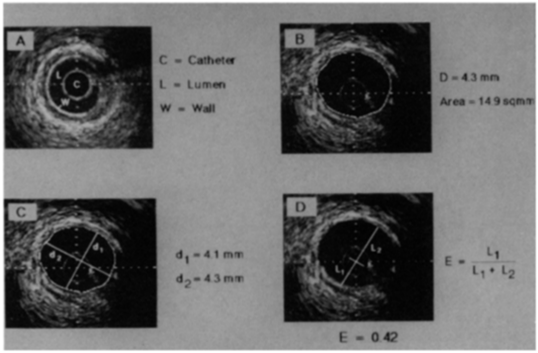
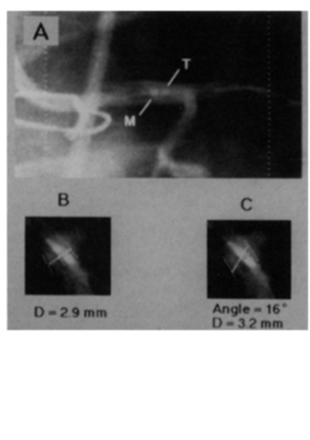


Figure 1. Intracoronary ultrasound. **A,** With imaging catheter (C) centered in the vessel lumen (L) and vessel wall (W). **B,** With planimetry-derived measurement of luminal area and a calculated mean diameter (D). **C,** With one diameter (d_1) measured through the center of the catheter to the nearest wall and one diameter (d_2) measured perpendicular to the mid-point of d_1. **D,** Showing calculation of eccentricity index (E): L_1/L_1+L_2, where L_1 = distance from center of the catheter to the nearest wall and L_2 = distance from center of the catheter to the farther wall.

Ultrasound transducer. The intracoronary imaging system includes a 30-MHz ultrasound transducer enclosed within an acoustic housing on the tip of a 5F, flexible, 135-cm long, rapid exchange catheter (CVIS). The ultrasound beam is reflected against an angulated mirror rotating at 1,800 rpm, creating a 360° cross-sectional image perpendicular to the catheter (Fig. 1A). A flexible drive cable through the length of the catheter is connected to a motor at the distal end that drives the mirror. At focal depth, axial resolution of the image is 150 μm and lateral resolution is 200 μm. The radius of penetration is approximately 5 mm. Images are acquired at 30 frames/s and recorded on 0.5-in. (1.27 cm) videotape for subsequent off-line analysis. The catheter lumen accommodates a 0.014-in. (0.036 cm) coronary guide wire that exits the catheter centrally, distal to the transducer, by means of a flexible tapered tip. The outer diameter of the catheter is 0.078 in. (0.198 cm) and fits easily through a large lumen, 8F guiding catheter (internal diameter 0.082 in. [0.208 cm]), permitting adequate contrast injections through the guiding catheter for visualization (Fig. 2A).

Ultrasound data analysis. After full anticoagulation with 10,000 U of intravenous heparin, transplant recipients underwent scanning with the ultrasound catheter from the ostium of the left main coronary artery to the mid-portion of the left anterior descending artery. Seventy-six coronary sites (mean 3.8 sites/patient) were measured with near simultaneous ultrasound and angiography. Ultrasound gain settings were adjusted for optimal visualization of the vessel-lumen interface and images were digitized onto a 512 × 512 × 8-bit matrix in 34-frame sequences, obtained at 30 frames/s by an image-processing computer (Dextra Medical, Inc.) dedicated to echocardiographic analysis. All patients had a heart rate at rest >60 beats/min (mean 84 ± 11) and thus at least one cardiac cycle was digitized. The largest lumen from the cardiac cycle immediately before the injection of contrast medium was obtained for analysis because contrast medium can obscure the ultrasound vessel lumen. The ultrasound measurements were performed by one of two

Figure 2. Angiography. A, Ultrasound transducer housing in the left main coronary artery imaged in the right anterior oblique caudal projection. T = ultrasound transducer directed proximally toward a rotating angulated mirror (M). B, Computer-assisted edge detection diameter (D) at the ultrasound catheter site measured perpendicular to the longitudinal axis of the vessel. C, Computer-assisted edge detection diameter at the ultrasound catheter site measured perpendicular to the longitudinal axis of the imaging catheter (16° angle deviation from the vessel long axis).



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investigators (F.G.S.G., F.J.P.) without knowledge of the angiographic data. The cross-sectional luminal area was obtained by planimetry of the vessel-lumen interface with previously validated software. The mean diameter was calculated from the planimetry-determined area (diameter = 2 $[\text{area}/\pi]^{1/2}$) (Fig. 1B). A diameter was also measured on each image as a line through the center of the imaging catheter to the nearest vessel wall. A second diameter was measured perpendicular to the mid-point of this line to examine the elliptic shape of the vessel (Fig. 1C) The distance from the center of the catheter to the nearest wall divided by the diameter measured in the same line was used as an index of axially eccentric catheter position (Fig. 1D).

Angiographic quantitative measurements. Angiographic analysis was performed by an investigator (E.L.A.) who had no knowledge of the ultrasound data. Contrast cineangiography of the left anterior descending artery with the imaging catheter in place was recorded in the right anterior oblique caudal position. Cineangiographic films were analyzed by automatic computer-assisted edge detection with use of a 35-mm cine film transport mechanism. The coronary quantitation system optically magnifies selected portions of the cine frame with use of a lens turret system housed in a Vanguard projector. A Vidicon video image processor digitizes the magnified image such that an average 3-mm vessel diameter is represented by 30 pixels. After an initial calibration obtained with use of the known dimension of the guiding catheter, the coronary segment at the tip of the ultrasound catheter was centered in the image field. An end-diastolic frame was digitized with a video processor (model 5524, De Anza Systems). The length of the coronary artery segment of interest was indicated with a marking pen, and an automatic edge-finding algorithm drew and smoothed the edges defined as the maximal derivatives of the density profile perpendicular to the manually defined margins (Fig. 2, B and C). When the computer algorithm was unable to resolve vessel boundaries in the areas of angiographic artifact or vessel crossings (approximately 5% of the measurements), manual editing of short segments was performed. The coronary artery diameter perpendicular to the long axis of the vessel was measured through a computer-constructed center line at the imaging catheter mirror tip (Fig. 2B). A second diameter was also obtained with use of the same vessel boundaries and measured through the catheter mirror, but perpendicular to the long axis of the catheter (Fig. 2C). The angle between the long axis of the vessel and the long axis of the catheter was measured as an index of catheter angulation.

To examine for angiographic measurement artifacts possibly produced by the ultrasound catheter, repeat measurements were made at 14 ultrasound sites in five patients with use of angiograms obtained immediately after withdrawal of the imaging catheter.

Statistics. Data are expressed as mean values ± 1 SD. Quantitative angiographic and ultrasound diameter measurements were compared with use of simple linear regression analysis. Linear regression analysis was also used to assess 1) the influence of catheter angulation on vessel dimensions measured by ultrasound, 2) the influence of the axial ultrasound eccentricity index on the difference in diameters between the two imaging systems, and 3) the difference in perpendicular ultrasound diameters. A level of significance of $p < 0.05$ was established.

Intraobserver and interobserver variability. Two ultrasound sites from 10 patients (n = 20) were randomly selected and measured by one observer at two separate times and once by a second observer. These measurements were then used to evaluate interobserver and intraobserver variability. These were expressed as a linear regression between the two observations and as a percent error, derived as the absolute difference between observations (14).

Table 1. Diameter Measurements by Intravascular Ultrasound (IVUS) and Angiography (Angio) in 20 Patients

Angio perpendicular to vessel (mm)	3.4 ± 0.8
Angio perpendicular to imaging catheter (mm)	3.6 ± 0.8
IVUS to nearest wall (mm)	3.8 ± 0.9
IVUS perpendicular to nearest wall (mm)	3.9 ± 0.6
IVUS derived from area (mm)	3.9 ± 0.9

Results

Quantifiable ultrasound images were obtained in all 20 patients. The average imaging time/patient was 13 ± 4 min. One patient had vessel spasm distal to the imaging catheter that resolved with sublingual nitroglycerin. No other complications occurred.

Dimensional correlates (Tables 1 and 2, Fig. 1 to 4). The mean angiographic diameter perpendicular to the vessel long axis was 3.4 ± 0.8 mm (range 2 to 5.2) and the angiographic diameter perpendicular to the long axis of the ultrasound catheter was 3.6 ± 0.8 mm. The mean ultrasound-measured diameter based on the distance from catheter to the vessel wall nearest the catheter was 3.8 ± 0.9 mm (range 2.1 to 5.7) and the mean diameter perpendicular to this first measurement was 3.9 ± 0.6 mm. The greatest difference between the perpendicular measurements was 0.7 mm (mean difference 0.2). The ultrasound-measured diameter obtained by planim-

Table 2. Percent of Ultrasound Measurements Above the Identity Line

	Angio Perpendicular to Vessel	Angio Perpendicular to Imaging Catheter
IVUS measured (%)	83	76
IVUS derived (%)	92	89
IVUS measured with cath perpendicular to vessel (%)	88	—
IVUS derived with cath perpendicular to vessel (%)	78	—

Cath = ultrasound imaging catheter; other abbreviations as in Table 1.

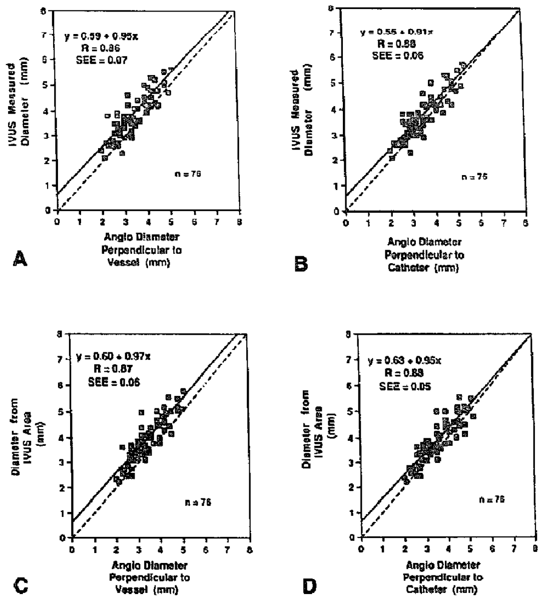

Figure 3. Linear correlations. **A,** Intravascular ultrasound (IVUS)-measured diameter and the angiographic (Angio) diameter measured perpendicular to the vessel long axis at 76 sites. **B,** Intravascular ultrasound-measured diameter and the angiographic diameter measured perpendicular to the imaging catheter. **C,** Mean vessel diameter derived from the area determined by planimetry from the ultrasound image and the angiographic diameter measured perpendicular to the vessel long axis. **D,** Mean vessel diameter derived from the area determined by planimetry from the ultrasound image and the angiographic diameter measured perpendicular to the imaging catheter.

etry area was 3.9 ± 0.9 mm. The luminal diameters measured by angiography and intracoronary ultrasound were closely correlated. The plots and r values are shown in Figure 3.

As shown in Table 2, 83% of the ultrasound-measured diameters lie above the line of identity when compared with the simultaneous angiographic measurement; the mean difference between the ultrasound and angiographic diameters is 0.5 ± 0.4 mm. When compared with the angulated angiographic measurement, 76% of the ultrasound-measured diameters still lie above the identity line; the mean difference between these values is 0.3 ± 0.4 mm. The diameters derived from the ultrasound areas showed a similar trend (Table 2). The mean deviation of the imaging catheter from the long axis of the vessel was 15° (range 0° to 29°). The more the catheter deviated from the vessel long axis, the greater was the discrepancy between the ultrasound measurement and the angiographically measured diameter perpendicular to the vessel walls ($p = 0.0001$) (Fig. 4).

The influence of catheter angulation and eccentric axial position of the catheter is shown in Table 3. Although the catheter angulation has a significant effect on the difference between the ultrasound diameter measurement and the angiographic diameter perpendicular to the vessel, in the coronary vessels, most likely because of their small dimensions, increasing catheter angles does not produce a significant elliptic distortion (that is, difference between perpendicular ultrasound measurements). An axially eccentric catheter position, whether or not the catheter is parallel to the vessel long axis, also does not influence elliptic shape or correlate with differences between ultrasound and angiographic diameter measurements (Fig. 5).

In 18 of the 76 measurements, the ultrasound catheter was exactly parallel to the longitudinal axis of the lumen. The mean angiographic diameter in these vessels was 3.02 ± 1.1 mm and the ultrasound-measured diameter was 3.04 ± 1 mm ($r = 0.90$). The diameter derived from the ultrasound area was 3.03 mm, with an r value of 0.91 when compared with the angiographic measurement.

To examine the direct influence of the imaging catheter on angiographic dimensions, 14 angiographic measurements repeated at the same site with and without the catheter were

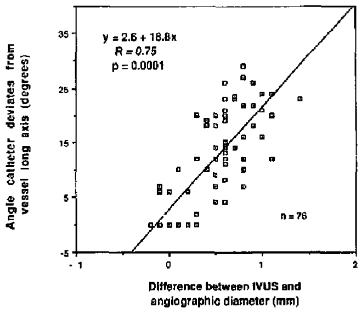

Figure 4. Linear correlation of the difference between the intravascular ultrasound (IVUS) measured diameter and the angiographic diameter measured perpendicular to the vessel long axis and the angle the ultrasound catheter deviated from the vessel long axis.

highly reproducible (r = 0.97). The measurements performed on the ultrasound images to examine interobserver and intraobserver variability demonstrated excellent reproducibility. The interobserver variability for the mean diameter derived from the area determined by planimetry as used in this study was 3.3%, (r = 0.97). The intraobserver variability for the derived diameter was 2.7% (r = 0.98).

Discussion

Previous study. Intravascular ultrasound measurements of luminal dimensions were initially validated against phantom models and excised vascular sections. Nishimura et al. (6), using a Plexiglas well, showed that ultrasound and direct area measurements were identical when the ultrasound imaging catheter was centered within the phantom. Pandian et al. (7) demonstrated excellent correlation between intravascular ultrasound and anatomic measurements of animal arterial lumen area (r = 0.98) and vessel diameter (r = 0.97) in vitro. Potkin et al. (8) performed a validation study in 21 human necropsy coronary arteries. They demonstrated a good correlation between ultrasound measurements and measurements performed at the time of histologic analysis (r = 0.85). The histologic area was smaller than the corresponding ultrasound area in 43 (80%) of 54 coronary segments; the average difference in areas was 10 ± 13%. This consistent discrepancy was attributed to vessel shrinkage occurring at the time of vessel fixation (8). Using a synthetic aperture ultrasound imaging catheter, Nissen et al. (9) compared measurements of peripheral vessels in experimental animals with those provided by direct cineangiography. They demonstrated a close correlation of vessel diameter

Table 3. Correlation Coefficients of Catheter Angle in Vessel and Eccentricity Index Versus Ultrasound-Angiographic Diameter Difference and Difference Between Two Perpendicular Ultrasound Measurements

	Ultrasound-Angiographic Diameter Difference	Difference Between Perpendicular Ultrasound Diameters
Catheter angle in vesse.	0.75*	0.14
Index of catheter eccentricity	0.03	0.04

*p < 0.05.

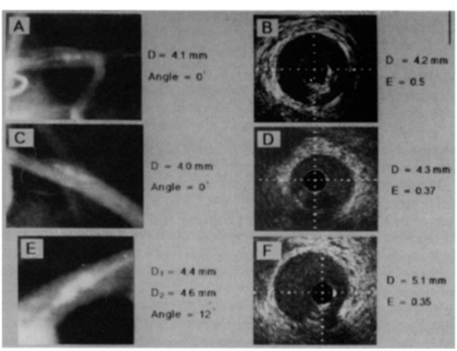

Figure 5. A, Ultrasound catheter parallel to vessel long axis and centered in lumen with (B) corresponding ultrasound image. C, Ultrasound catheter parallel to vessel long axis and eccentric in lumen with (D) corresponding ultrasound image. E, Ultrasound catheter at angle to vessel long axis and eccentric in lumen with (F) corresponding ultrasound image. D = diameter; E = eccentricity index.

measurements between ultrasound and cineangiography ($r = 0.9$) and also showed an interobserver and intraobserver variability of <0.13 mm.

Recently, Davidson et al. (10) performed an in vivo comparison of intravascular ultrasound and digital subtraction angiography in 86 human noncoronary arterial segments. Their data demonstrated a good correlation between the two imaging methods ($r = 0.97$ for diameter measurements and SEE = 1.83 mm for all sites studied, with an SEE of only 1.2 mm in arterial segments <10 mm in diameter).

The present study examined patients with angiographically normal coronary vessels, attempting to avoid the potential error eccentric atherosclerosis may add to measurements. Our data demonstrate a close correlation between angiographic and intravascular ultrasound diameters measured both directly and calculated from an ultrasound area determined by planimetry. However, this study also shows a small but consistent discrepancy between values from the two measuring systems, with a tendency for ultrasound measurements to be slightly larger.

Technical factors influencing ultrasound measurements. McKay et al. (11) described technical factors that influence intraluminal ultrasound images. They showed that angulation of the imaging catheter by as little as 10° could cause a definable increase in ultrasound measurement of luminal area. The study of Nishimura et al. (6) demonstrated that dimension measurements were unaffected by eccentric catheter placement within phantoms. This observation is in agreement with the present in vivo coronary artery study, in which axial eccentricity of the intravascular imaging catheter did not affect luminal measurements. Nishimura et al (6) also showed that when the catheter was angulated off the longitudinal axis of the phantom, the circular shape of the well was distorted and appeared elliptic. This distortion occurs because the plane of the ultrasound beam is no longer perpendicular to the wall. The present study shows that there is no statistically significant elliptic distortion in small coronary vessels despite some catheter angulation, suggesting that the small size of the coronary lumen relative to the catheter size mitigates the effect of this potential problem. Angulation of the imaging catheter does influence intravascular area measurements; the more the imaging catheter varies from the longitudinal axis of the vessel, the larger is the discrepancy between the angiographic and ultrasound measurements.

Intravascular ultrasound minimally but consistently measured a larger luminal diameter than that obtained with a computer-assisted angiographic edge detection system, even when the angiographically determined lumen was measured perpendicular to the imaging catheter. This difference also occurred when the imaging catheter was exactly parallel to the long axis of the vessel. Possible explanations for this discrepancy include incorrect intrinsic measurements by the ultrasound system or incorrect calibration, or both. This possibility is unlikely, however, because the ultrasound imaging was initiated in the guiding catheter and the known internal dimension of this catheter was reproducibly confirmed by measurements with the imaging system. Another possibility is that the axial position of the catheter in three-dimensional space was measured only in the right anterior oblique caudal angiographic view. In this study, the catheter was typically aligned near or along the anterosuperior aspect of the left anterior descending coronary artery. Thus, in the orthogonal, left anterior oblique view, the catheter was consistently coaxial in seven of eight patients in whom this second view was observed.

Comparison of quantitative angiography and ultrasound measurements. The reproducibility of the computer-assisted angiographic edge detection system has been confirmed with phantoms of known dimensions and with in vivo coronary artery studies (15), and the computer-assisted edge detection system used in our study is state of the art. Although this system defines the luminal edge as the maximal derivative of the contrast density profile, there is predictable contrast density drop-off at the outside edge of the projected image of the lumen, leading to an undersized absolute measurement. This is especially true with an in vivo system in which vessel wall-contrast interface produces nonlaminar flow at the external edge of the lumen. Thus, the angiographic algorithm used to define the luminal diameter may be a significant factor in the consistently smaller angiographic measurements compared with those produced with ultrasound.

The nonlaminar contrast flow could be exacerbated by the presence of the imaging catheter within the vessel, compromising opacification and further decreasing the angiographic measurement. The high reproducibility between the angiographic measurements performed with and without the imaging catheter in the vessel does not support this theory. Another possible explanation for the consistent discrepancy is ultrasound near field dropout, but the consistent validation of the system in the guiding catheter and optimization of the ultrasound image compression and time-gain control make this doubtful.

Conclusions. This study shows that in vivo intravascular ultrasound measurements of coronary artery lumen dimensions are highly reproducible and correlate closely with those of quantitative angiography, although ultrasound measurements tend to be slightly larger. Correlation is improved when the ultrasound catheter is parallel to the long axis of the vessel lumen. The effect of eccentric catheter position on luminal measurements within small coronary vessels did not reach statistical significance in this study. This series also demonstrates the safety of intracoronary ultrasound in cardiac transplant recipients. Finally, the consistent discrepancy between simultaneous measurements obtained with intracoronary ultrasound and angiography, even when the catheter is parallel to the vessel long axis, adds more substantive data to the ongoing controversy as to the true reference standard for coronary artery measurements (16–18).

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