Use of a New Device for Measurement of the Diameter of the Coronary Lumen Pre and Post Stenting

A primary experience in Argentina

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Background

Ten patients with coronary artery disease (CAD) subject to Percutaneous Transluminal Coronary Angioplasties (PTCA) with Stenting were enrolled in the Department of Interventional Cardiology at our Institution in order to perform the measurement of the coronary lumen with a new system: The Metricath™ System of Angiometrx Inc. (Vancouver, British Columbia, Canada).

The Metricath System

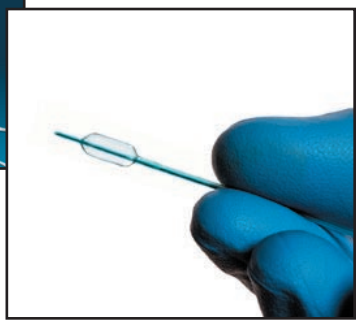
The Metricath™ System is a medical device that precisely measures cross sectional area and diameter of a short section of artery.

The Metricath System consists of two components, the Metricath 1000 Console (Fig. 1) and the Metricath Balloon Catheter (Fig. 2).

The Metricath Console consists of a syringe pump and pressure transducer that monitors both pressure and volume of the attached Metricath Balloon Catheter. The Metricath Balloon Catheter used in this preliminary experience a monorail design with a 3.6mm diameter balloon with 7mm length. The system inflates and deflates the balloon catheter to a low pressure (260mmHg, <1/3 ATM) and uses the measurement of volume and pressure to measure the cross sectional area and diameter. The System is intended to measure arterial morphology adjacent to a lesion, or within a stented section of an artery.

The Metricath Balloon Catheter can then be positioned within the area of interest of the vasculature using standard techniques and the Metricath System acquires measurements in approximately thirty (30) seconds from the time the measure button is pressed on the Metricath Console. The Metricath System allows the user to make multiple measurements with the same catheter within the same patient. This permits the user to "map" the vascular sections of interest; furthermore, it allows the user to measure the vasculature both pre and post stent deployment, which helps verify proper stent deployment.

The Metricath 1000 Console



The Metricath Balloon Catheter

The "Metricath equation", which describes the calculations performed by the Metricath 1000 Console software, is explained below.

$$A = \Pi(Dballoon)2/4 - (Vc-Vm)$$

A = Cross sectional area of what is being measured

$D_{balloon}$ = Balloon outside diameter (unrestrained), (Determined during manufacturing)

Vc = Calibration volume of fluid infused at pressure P P=250mmHg)

Vm = Measurement volume, volume of fluid infused at pressure P (P= 250mmHg)

L = Length of the balloon (Determined during manufacturing of the Metricath Balloon Catheter)

The variables $D_{balloon}$ and L are determined for each individual catheter during the manufacturing of the balloon catheter. Hence, one only needs the pressure-volume curves to obtain Vc & Vm, and to be able to calculate cross sectional area and diameter.

To make a cross sectional area measurement, the balloon is first inflated in an unrestrained area (ex vivo calibration curve of pressure vs. volume) and then in vivo at the desired measurement site (measurement curve). Multiple measurements can be made after the calibration curve is generated. From the calibration curve and each measurement curve, the computer determines the volume of fluid (Vc & Vm) infused at the measurement pressure P, and then uses these values to solve the equation for cross sectional area.

Diameter of the artery is calculated from the area by the equation:

$$D = (4\ A/\Pi)^{1/2}$$

Validation of the Metricath Measurement

The Metricath System has been extensively tested in bench testing, animal models and in humans to show the resolution of its measurement accuracy and equivalence to Intravascular Ultrasound (IVUS).

Bench testing was performed in vessels of known size showed that the Metricath System has a resolution of less than ± 0.10mm diameter.

Animal tests have shown that Metricath is equivalent to IVUS and QCA in stented arteries. The results of this animal investigation showed a comparison of area measurements in 14 stents with no significant differences between the 3 methods (p=0.66).[1] Various in vitro and animal studies have demonstrated that the arterial lumen measurements made with the Metricath™ System were more comparable to IVUS measurement than to those made with QCA. Other studies have shown that Metricath™ diameter measurements have a very high level correlation with the IVUS diameter and area measurement.

Material and Method

Study Population

All the patients enrolled signed an inform consent form authorizing the use of this new interventional device during their PTCA catheterization.

Within the ten patients, twenty arterial segments were subject to PTCA, stenting and measurements with Metricath. Three patients had obstruction in one vessel, four patients had obstructions in two vessels and three patients had obstruction in three vessels. Three lesions were located on a curved section of artery. The lesions were located: Ostial, 1 artery; proximal segment, 9 lesions; mid segment, 9 lesions; and distal segment, 1 lesion. The lesions were localized as follows, ten (10) in the Left Anterior Descending (LAD), six (6) in the Right Coronary Artery (RCA), and four (4) in the Circumflex Artery (LCx). The severity of the lesions in the arteries was 95% in 5 lesions, 90% in 7 lesions, 85% in 6 lesions and 80% in 2 lesions.

The length of the lesions ranged between 10 mm and 22 mm and the diameter of the vessel proximal and distal to the lesion were evaluated by means of the angiography software Laboratory BioImage S.A of Argentina, measurements ranged between 2.8mm and 3.5mm proximal to the obstruction and between 2.5 and 3.3 mm distal to the obstruction.

The QCA measurements were carried out by three medical operators.

All the patients were subjected to previous angiographic control and a measurement with the Metricath was made before the therapeutic procedure. In 14 lesions an intra-coronary injection of Nitroglycerine was made in typical doses previous to the beginning of the therapeutic procedure, a new measurement of the diameter of the vessel to be treated was performed on those patients

In all the cases we began the procedure with a measurement of the diameter of the vessel proximal and distal to the lesion, using the Bioimage software, and we then proceeded to insert into the coronary artery the Metricath™ Balloon Catheter to perform the corresponding measurement in the same locations proximal and distal to the lesion.

No complications were recorded and no difficulties were encountered when crossing the lesion with the balloon except for one case that could not be crossed with the Metricath™ Balloon Catheter due to the severity of the obstruction and calcification of the vessel. The diameter of this vessel was 2.5mm with an obstruction of more than 90%.

No difficulties were encountered when removing the Metricath™ Balloon Catheter after the measurements.

Following the pre-treatment measurement procedure, stents were implanted in the target vessels. In 9 lesions pre-dilatation was made with a 2.5mm balloon to 6 atmospheres of pressure and in 11 lesions we proceeded with "direct stenting" (without pre-dilatation). In all the patients we expanded the stent to the diameter measured by QCA and the stent was inflated to the corresponding diameter based on the compliance chart provided by the manufacturer on the stent's packaging. In fifteen cases, the diameter of stent was chosen based on the diameter of the artery measured distal to the lesion. In the cases of target lesions with a 20% or more difference between the proximal and the distal diameter we proceeded with a stent size that matched the proximal segment diameter size (five cases).

The stents used in the patients were the Blue Medical Gendyl, Hellistent Hexacath, Jomed and Carbo Stent Sorin.

After implantation of each stent, a new control angiogram with and without the injection of intracoronary nitroglycerine was made and a new measurement with the Metricath™ Balloon was made in locations proximal to the stent, in-stent and distal to the stent.

Basic Data

Estimates of lumen diameter in 10 patients (20 stents) undergoing stent-supported angioplasty were made by Quantitative Coronary Angiogram (QCA) and the Metricath System proximally and distally prior to nitroglycerin (NTG) administration. Estimates were made proximally on 14 arterial sections by both methods after NTG. The initial proximal diameter estimated for one patient was at the upper end of the specified measurement range for the Metricath measurement balloon catheter and data for that patient was not analyzed. A comparable distal measurement was not available for one other patient.

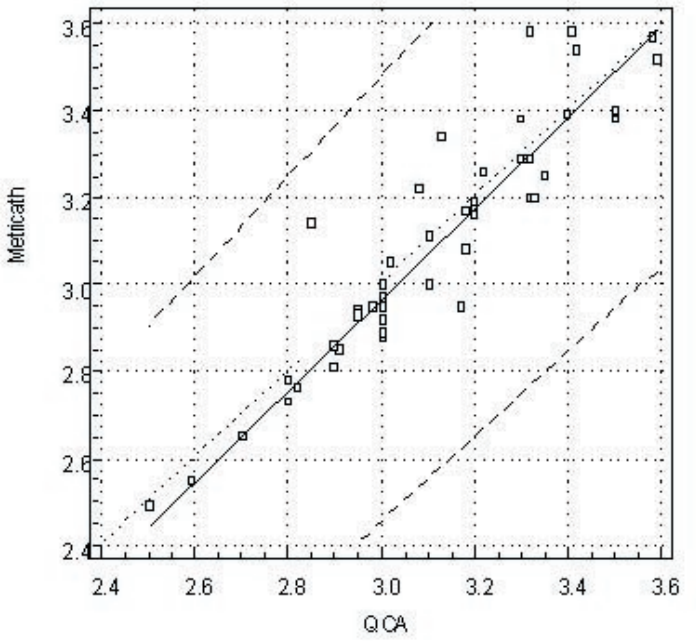
The average QCA diameter estimated at 19 positions proximal to the treated lesion was 3.13±0.244 mm over a range of 2.80 to 3.50 mm. For 19 positions distal to the treated lesion the average QCA diameter was 2.96±0.262 mm over a range of 2.50 to 3.33 mm. After administration of nitroglycerin, 13 proximal positions were estimated at 3.25±0.218 mm by QCA over a range of 2.85 to 3.59 mm. All 51 diameter estimates by QCA averaged 3.10±0.266 mm over a range of 2.50 to 3.59 mm.

The average diameter estimated by Metricath at the 19 proximal positions was 3.06±0.239 mm over a range of 2.73 to 3.40 mm. For the 18 distal positions the average diameter was 2.94±0.229 mm by Metricath over a range of 2.49 to 3.29 mm. After administration of nitroglycerin, 13 proximal positions were estimated at 3.34±0.198 mm by Metricath over a range of 3.05 to 3.58 mm. All 50 diameter estimates by Metricath averaged 3.09±0.273 mm over a range of 2.49 to 3.58 mm.

Data for the two methods to assess comparability was available in 50 separate observations (19 proximal and 18 distal before NTG and 13 proximal after NTG).

Metricath to QCA Comparison

Passing-Bablok regression analysis of the Metricath on the QCA diameter estimates (Fig. 3) demonstrated no significant deviation from linearity (p>0.10) between the comparison pairs, i.e. Y= -1.1850 +1.0500 X, and an obvious slight underestimation of the QCA-derived diameters by the Metricath estimates. The 95% confidence interval for the intercept, a, is moderately narrow at –0.4729 to 0.0447, as well as for the slope, b, between 0.9750 to 1.1429. The Pearson product moment correlation, r, between the comparable pairs was high at 0.9325 (p<0.0001) with the 95% confidence interval for r being 0.8834 to 0.9613.



QCA minus Metricath Diameter

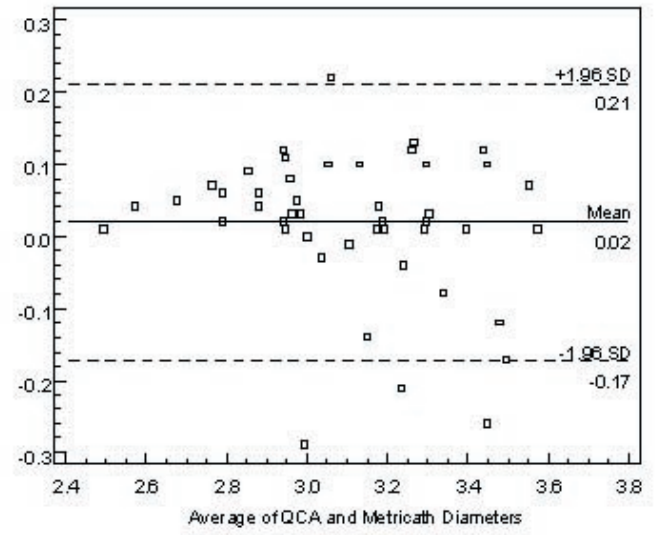


Figure 2—Bland-Altman Difference vs. Mean Plot of 50 Metricath to QCA Comparison Estimates.

The Bland-Altman analysis (Fig. 4) of all 50 Metricath to QCA comparable pairs shows a significant level of agreement between Metricath and QCA estimates with the 95% limits of agreement being ±0.19 between -0.17 mm to 0.21 mm around a mean difference of 0.02 mm. Apparently administration of nitroglycerin relaxed the vessels such that the Metricath balloon catheter overestimated lumen diameter after NTG when compared to the QCA estimates. Whereas, prior to administration of NTG, none of the Metricath estimates exceeded the QCA estimates. The seven greatest differences (that is, the ones shown at the bottom of Figure 4) all come from observations at the proximal position after NTG administration. If the 13 observations after NTG are removed and only the initial 37 estimates before NTG are considered, then the Bland-Altman analysis (Fig. 5) of the Metricath to QCA comparable pairs shows an even higher level of agreement between Metricath and QCA comparable pairs with the 95%

limits of agreement being ±0.095 between –0.03 mm to 0.16 mm around a mean difference of 0.06 mm.

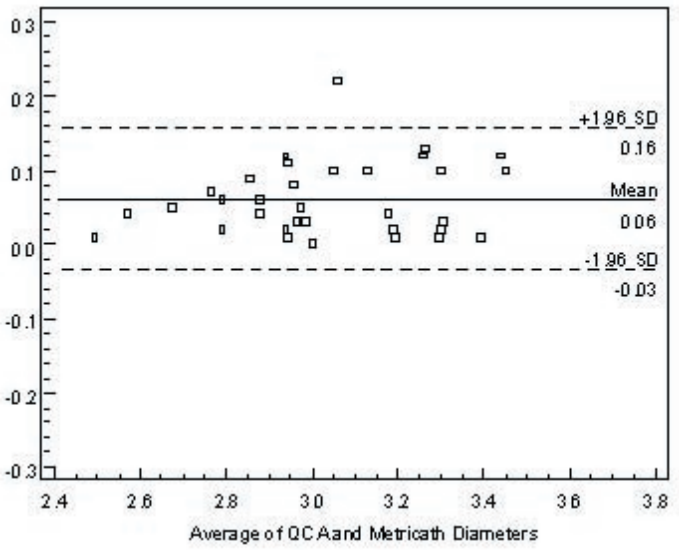


Figure 3—Bland-Altman Difference vs. Mean Plot of 37 Metricath to QCA Comparable Estimates Before Nitroglycerin Administration.

Significantly, all Metricath measurements in the native state of the vessel were at or below the diameters estimated by QCA. This analysis suggests that lumen diameter estimated by the Metricath System can be substituted for diameters derived by QCA with an accuracy of B10.16 mm.

Stent Under-Expansion

The Metricath device was used to evaluate the expansion of 19 stents. The diameter of the primary expansion was estimated according to the instructions for use for the 19 stents considering the expansion pressure. These estimates averaged 3.02±0.317 mm over a range of 2.50 to 3.52 mm. The Metricath in-stent diameter measurements of the 19 deployed stents averaged 2.46±0.303 mm over a range of 1.95 to 3.04 mm. The average difference between the primary expansion diameter and the Metricath measurement was 0.55±0.113 mm over a range of 0.38 to 0.76 mm. Percentage difference averaged 18.5B13.6% over a range of 13.1 to 23.0%. A secondary high-pressure expansion, typically >14 atmospheres pressure, of the 19 stents were estimated to average 3.30±0.334 mm over a range of 2.79 to 3.95 mm. The Metricath in-stent estimates of diameter of the 19 high-pressure expanded stents averaged 2.88±0.261 mm over a range of 2.43 to 3.20 mm. The average difference between the secondary high-pressure expansion diameter and the Metricath measurement was 0.42±0.158 mm over a range of 0.15 to 0.76 mm. Percentage difference averaged 13.0±3.4% over a range of 5.9 to 19.2%.

Conclusions

The Metricath™ System has a good correlation with QCA, for the measurement of the diameter of the coronary arteries.

The Metricath™ System is an excellent method to evaluate the real expansion of the stent placed either "De Novo" or with pre-dilatation. The testing indicated that better expansion of these four types of stent occurred when pre-dilatation was performed in the calcified severely obstructed vessels.

Based on the findings that the difference between the measurements made by QCA and Metricath is more pronounced with the use of nitroglycerin, nitroglycerine response by the arterial wall and wall/plaque composition seems to play a role in the comparison of the two measurement methods.

Stents were implanted and expanded to the pressure indicated on the manufacturer's compliance chart and this size should have correlated with the size of vessel measured. However in all cases the stents were under expanded. This under expansion, was more pronounced when no pre-dilatation was performed, the stent under-expansion was identified using the Metricath™ System and comparing the Metricath™ measurements of the native artery proximal and distal to the in-stent measurements. After the high pressure stent dilatation was performed the arterial lumen evaluated using the Metricath™ System showed a satisfactory result and a proper stent expansion.

In conclusion, the measurement with the Metricath™ allowed for an improved final expansion of the stent, if the measurement had not been taken with Metricath™, the patients would have been left with a residual obstruction between 13% and 23% that could be prone to higher restenosis rates.

References

[1] van der Giessen W, Carlier S, Regar E, Beusekom H, Foley D, Feyter P, Verdouw P, Boersma E, Wolthuis R, Serruys P. A New Intracoronary Measurement Catheter, Metricath, Compared to Intravascular Ultrasound And Quantitative Coronary Angiography in a Stented Porcine Coronary Model. Catheterization and Cardiovascular Interventions 57 2-9 (2002)

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