Accuracy and Reproducibility of Quantitative Coronary Arteriography Using 6 and 8 French Catheters with Cine Angiographic Acquisition

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To determine the suitability of 6 French catheters for quantitative coronary arteriography, the relative accuracy and reproducibility of one type of these catheters was compared to that obtained with standard 8 French catheters in 20 stenoses. Duplicate injections with polyurethane 6 French catheters were obtained using hand and power injection technique with cineangiographic acquisition (four 6 French catheter injections total per stenosis). Measurements of both percent diameter stenosis and absolute dimensions were compared to those obtained with hand injection and cine acquisition using 8 French catheters as a "gold standard." While the reproducibility of dimension determination with the 6 French catheter was generally similar to that obtained with the 8 French catheter (0.27 ± 0.23 mm for absolute diameter and 8.1 ± 7.4% for percent diameter stenosis), accuracy was significantly less for the 6 French catheter for measurement of absolute dimensions. Thus, while apparently well suited for serial measurements of the same stenoses, 6 French catheters may not be as accurate in the determination of absolute artery dimensions as 8 French catheters.

Key words: quantitative arteriography, angiography

INTRODUCTION

Assessment of coronary artery dimensions has been found to have physiologic and prognostic importance in several clinical settings [1–4]. In fact, it has been suggested that change in dimensions be an appropriate surrogate endpoint for clinical events in studies such as interventions on coronary artery disease progression so as to decrease the substantial cost of such trials [5].

The usual manner of clinical assessment of coronary disease severity, visual estimation of percent stenosis from coronary arteriograms obtained during hospitalization, is neither accurate nor precise [6,7], thus leading to the development of quantitative computer techniques to assess disease severity [8–10]. The cost of such procedures could be minimized by the use of outpatient catheterization. However, the accuracy and reproducibility of coronary angiography obtained using 5 French catheters has been questioned [11–14], and that of 6 French catheters that might also facilitate outpatient catheterization is not known. If such catheters could be utilized, the cost of intervention trials could be decreased and the number of patients who are willing to participate might be increased.

PATIENTS AND METHODS
Study Population

Fifteen patients without renal disease (serum creatinine <2.0 mg) or resting ischemia referred for diagnostic coronary arteriography comprised the study population. All patients were selected prior to knowledge of coronary anatomy and no patients were rejected from the study once they had given informed consent. All patients were studied with standard cine angiophic techniques using 8 French catheters (Cordis Corp., Miami, FL) with hand injection technique immediately prior to the study. All stenoses estimated to reduce normal vessel diameter by ≥20% that were well visualized without foreshortening

or branch vessel overlap and a single best projection were then selected by the investigator (G.B.J.M. or S.G.E.) for study evaluation.

Radiographic Technique

All arteriography was performed with commercially available radiographic units (Siemens BiCor Pandoros 1200A, Erlangen, West Germany; Philips Optimus M100, Eindhoven, The Netherlands). The radiographic tubes used a 1.0 and 0.6 mm nominal focal spot. Coronary imaging was performed using a 17 cm field of view at 30 frames per second. Five to 10 ml of Renografin 76 (E.R. Squibb & Sons, Princeton, NJ) was injected manually by an experienced angiographer, or using a Medrad Mark IV power injector (Pittsburgh, PA) set to deliver 6–8 ml at 5 ml/sec with a 0.5 sec ramp for the left coronary artery system and 4–6 ml at 3 ml/sec with a 0.5 sec ramp for the right coronary artery. Automatic brightness control by the X-ray generators adjusted the tube potential from 70 to 100 kV and the pulse width between 2 and 10 msec. The nominal X-ray exposure at the image intensifier input was 25 microRoentgen per frame.

Each stenosis was sequentially imaged using the 8 French catheter (internal diameter = .056 in.) and hand injection technique onto cine film, and the 6 French catheter (polyurethane construction, internal diameter = .048 in., American Edwards Laboratories, Irvine, CA) with hand or power injections onto cine film in random order and following intracoronary instillation of 250 μg nitroglycerin.

Collimation and imaging technique were optimized by the angiographer, but was unchanged for each study injection. Care was taken to ensure that both the stenosis and the angiographic catheter were within the central portion of the radiographic field to minimize the possible effects of pincushion distortion. Each injection was performed in duplicate.

Cineangiogram Technique

Cineangiograms were obtained on conventional 35 mm film (Kodak CFR, Rochester, NY). Processing was performed according to manufacturer's specifications and quality control standards.

Image Interpretation

Cine images were examined and processed by a single observer. For analysis, optimal images were projected on a Vanguard cine projector (Model XR-35, Melville, NY) which was optically coupled to a video camera. Using 2.4:1 optical magnification, the resulting video signal corresponding to a subregion of the 35 mm frame was digitized at .512 × 512 × 8 bit resolution onto angiographic computer system. The video noise of this method of digitization was reduced by averaging 25 video frames prior to storage of each image.

All images were analyzed using a previously described and validated automatic coronary quantitation program [10]. A calibration factor was obtained by imaging and measuring the catheter.

Statistical Analysis

Results are expressed as mean ± 1 standard deviation, unless otherwise indicated.

Reproducibility (mean of absolute differences between measurements) was assessed by comparison of the first and second injections with each technique, with the first injection serving as a "gold-standard." Statistical analysis was performed using paired Student's t-tests.

Relative accuracy (regression slope and mean difference between measurements) was determined by comparison of the results with the first of two injections using the 6 French catheter with those from the second 8 French cine angiogram hand injection, using the first 8 French cine angiogram hand injection as the "gold-standard." Slopes and standard errors of the estimate for each comparison were determined and tested for statistically significant differences between injection techniques using linear regression models wherein the 8 French data were added to the 6 French data to ascertain if they added significantly to the estimate of the "gold-standard."

RESULTS

There were 14 males and 1 female in the study population. The stenoses evaluated were located as follows: 3 proximal left anterior descending, 3 mid-distal left anterior descending, 2 proximal circumflex, 3 distal circumflex, 5 proximal right coronary artery, and 4 mid-distal right coronary artery. The mean stenosis diameter = 1.64 ± 0.83 mm and the percent diameter stenosis using an adjacent "normal" arterial segment as reference = 53.9 ± 18.7%. Catheter instability (tendency to recoil from the ostium) was noted in 4/60 6 French injections and 0/30 8 French injections, p = NS. Clinically important contrast streaming was observed in 6/60 6 French injections and 1/30 8 French injections (p = NS). The results for reproducibility are shown in Table I and for relative accuracy in Table II and Figure 1.

DISCUSSION

Accurate and reproducible quantitative coronary angiography has been achieved using 8 French catheter sys-

TABLE I. Reproducibility of Repeated Measurements

Absolute Diameter (n = 20)			
Catheter	Injection	Absolute differences between repeated measurements (mm)	p value
8 French	Hand	.27 ± .23	—
6 French	Power	.33 ± .28	NS
6 French	Hand	.30 ± .21	NS

Percent Stenosis (n = 20)			
Catheter	Injection	Absolute difference between repeated measurements (% diam. stenosis)	p value
8 French	Hand	8.1 ± 7.4	—
6 French	Power	8.5 ± 7.1	NS
6 French	Hand	5.5 ± 5.0	NS

TABLE II. Relative Accuracy of Measurements*

Absolute Diameter (n = 20)						
Catheter	Injection	Slope	Constant	SEE (mm)	R	p value[a]
8 French	Hand[b]	.87	.11	.33	.92	—
6 French	Power	.84	.23	.38	.90	0.06
6 French	Hand	.80	.24	.38	.89	0.05

% Diameter Stenosis (n = 20)						
Catheter	Injection	Slope	Constant	SEE (% diameter)	R	p value[a]
8 French	Hand[b]	.78	12.2	10.4	.84	—
6 French	Power	.79	10.6	10.3	.84	NS
6 French	Hand	.90	6.1	8.1	.91	NS

*First 8 French hand injection used as "gold standard."
[a]For additional information supplied by second 8 French injection to first 6 Fr injection as an estimate of dimensions assessed by first 8 Fr injection.
[b]Second 8 French hand injection used as reference.

tems and with strict attention to the details of central catheter and stenosis placement in the field of view, avoidance of vessel foreshortening, and proper injection technique, as well as the technical concerns of pincushion distortion and X-ray beam divergence [15]. The variability of repeated measurements has been reported to be as low as ± 3% for percent diameter stenosis and ±0.1 mm for minimal lesion diameter [16,17]. If similar results could be obtained with smaller 5 or 6 French catheters, patient acceptance of the follow-up catheterization required for coronary artery disease intervention studies could be optimized. Limited data suggest that this may not be possible with 5 French catheters [11–14].

In this study, 20 mild to moderately severe stenoses from 15 patients enrolled prospectively were sequentially interrogated using standard 8 French catheter techniques and 6 French catheters using hand and power injection, and cine acquisition. Statistically nonsignificant trends in

catheter stability and contrast streaming were noted in favor of the 8 French catheters. Duplicate injections using standard 8 French catheter technique yielded variabilities of .27 ± .23 mm for absolute stenosis diameter and 8.1 ± 7.4% in the measurement of diameter stenosis. For the 6 French catheter these values with hand and power injection were .30 ± .21 mm, .33 ± .28 mm, and 5.5 ± 5.0%, 8.5 ± 7.1%, respectively. There was no difference between the reproducibility of 6 French catheter techniques and 8 French catheter techniques. For the parameter of relative accuracy, however, while the results with 6 French catheter techniques were equivalent to 8 French catheter techniques for the measurement of percent diameter stenosis (standard error of the estimate 8.1 to 10.3% r = .84–.91), there was a definite trend for lessened accuracy with the 6 French catheters when absolute stenosis diameter was measured [.38 mm and r = .89–.90 vs .33 mm and r = .92 for 8 French catheters (p = 0.05 and = 0.06% for hand and power injections, respectively)].

The relative inaccuracy of measuring absolute dimensions contrasts with apparent accuracy measuring percent diameter stenosis and suggests that a possible difficulty with the use of these catheters lies in the somewhat inexact or variable measurement of their diameter as a point of reference rather than their inability to allow adequate vessel contrast opacification for the technique evaluated. The general positive constants in regression equations relating absolute dimensional results of 6 to 8 French catheter measurements suggest that this may have resulted from a systematic overestimation of the catheter dimension by the computer edge tracking system. This difficulty may vary with catheter composition [18]. This study is limited by the relatively small number of stenoses interrogated, and in that generalization to results with catheters of different internal dimensions, composition, or with different methods of digital analysis cannot be presumed. However, catheters of polyurethane construction such as those tested have been shown to have measured size, image contrast, and average brightness gradient along the edges of the catheter equal to or superior to those of woven dacron, polyvinylchloride, or nylon composition [18].

Based upon these results, we would conclude that accurate measurement of percent diameter stenosis using these high flow 6 French catheters is possible, but that perhaps due to their relative lack of radiolucency compared to 8 French catheters, their use to measure absolute dimensions of stenoses may be questioned. However, since reproducibility with these 6 French catheters was not inferior to that with 8 French catheters, the use of the smaller catheters in serial studies appears justified. Improvements in catheter design that would allow better edge detection of the external dimensions of the catheter
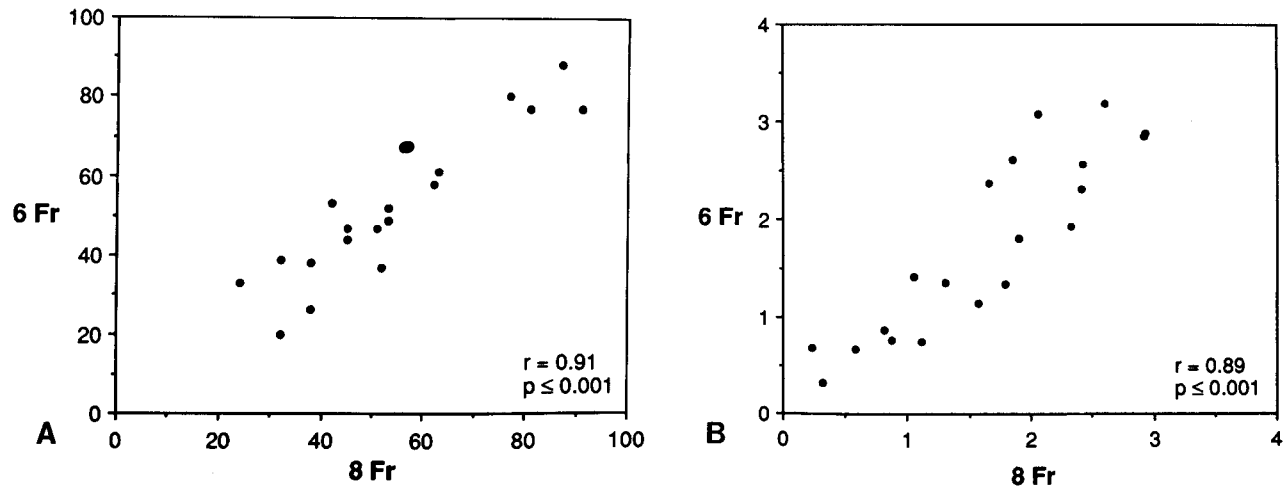
Fig. 1.   Comparison of measurements of percent diameter stenosis (A) and of absolute steno-sis dimension (B) using 8 and 6 French catheters and hand injection technique.

without compromise of luminal flow would be desirable. These results may have important implications for patient follow-up in studies investigating coronary artery disease treatment.

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