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Benefit of Intracoronary Ultrasound in the Deployment of Palmaz-Schatz Stents

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Objectives. This study was designed to evaluate the changes in intrastent and angiographic dimensions when intravascular ultrasound imaging is used to direct the deployment of balloonexpandable Palmaz-Schatz stents in coronary arteries and saphenous vein grafts.

Background. Intravascular ultrasound provides more information than angiography in the imaging of intravascular structures. Previous studies have shown that obtaining a larger lumen (greater "acute gain") with coronary interventions such as stenting leads to less restenosis and subacute thrombosis. It is not clear whether the information obtained by intravascular ultrasound can be used to obtain a greater acute gain in lumen dimensions.

Methods. Forty consecutive patients undergoing Palmaz-Schatz stent implantation had intravascular ultrasound imaging performed after a good angiographic appearance was obtained. If the stent did not appear adequately expanded by intravascular ultrasound, or if the struts were poorly apposed to the arterial wall,

Intracoronary placement of metallic stents has been used to improve the results of balloon angioplasty and to salvage acute or threatened occlusions from large dissections (1-3). Estimates of the arterial angiographic dimensions are used during the procedure to choose the size of the balloon and to determine that the stent is successfully deployed. Other studies (5-12) have described observations with intravascular ultrasound before and after stent insertion but have not demonstrated how the information obtained could be clinically useful. In our institution, 40 patients had intravascular ultrasound imaging performed after standard angiographic guidance of intracoronary stent insertions to determine whether adequate placement of the stent had been achieved or to direct further therapy if the results were not satisfactory. This report docufurther stent dilation with larger balloons or higher pressure inflations were performed. Twenty-nine patients had subsequent intravascular ultrasound imaging. Intrastent diameters and areas were compared from the initial to the final intravascular ultrasound studies.

Results. Of the 40 patients studied, only 5 (13%) had an adequate result by intravascular ultrasound despite an acceptable angiographic appearance in all patients. Six additional patients did not undergo subsequent intravascular ultrasound imaging. The other 29 patients all demonstrated a significant increase in intrastent minimal diameter (mean 19%), major diameter (11%) and cross-sectional area (34%) (p < 0.001 for all measurements).

Conclusions. The use of intravascular ultrasound imaging in the deployment of balloon-expandable Palmaz-Schatz stents leads to a significant increase in intrastent dimensions (greater "acute gain").

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ments how therapy was significantly altered by the results of intravascular ultrasound imaging in guiding the placement of intracoronary stents and provides a retrospective analysis of angiographic and ultrasound dimensions.

Methods

Forty patients underwent Palmaz-Schatz stent implantation using previously described techniques (3,4). After the stent was in place, a balloon 0.5 mm greater than the estimated lumen diameter of the angiographically normal-appearing segment was used. When the angiogram demonstrated successful deployment of the stent, the procedure was considered complete; only then was intravascular ultrasound imaging performed. The coronary artery was imaged with a 25-MHz, 3.9F catheter (Interpret System, InterTherapy/CVIS, Inc.). This system uses a protective monorail sheath with a manual pullback rotating drive shaft (13,14). The imaging probe was positioned distal to the stent and pulled back manually through the stented segment, as previously described (15).

The lumen minimal and major diameters and crosssectional area were measured from the intravascular ultrasound images during the procedure (16). Lumen and vessel diameters were also measured immediately proximal and distal

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to the stented segments. Vessel diameters were defined as media to media, with vessel area defined as the area inside the adventitia. If incomplete stent expansion or poorly apposed struts were appreciated on the ultrasound images, further balloon dilation was performed using larger balloons until the balloon size approximated the intravascular ultrasoundmeasured average vessel diameter of the reference segments. If the balloon diameter was as large as the vessel diameter, then dilations were performed at higher pressures rather than with a larger balloon. To avoid inflating the balloon outside the stented segment of the vessel, a short 10-mm long balloon (Short Speedy, Schneider Europe, Zurich, Switzerland) was used for the final dilation whenever possible. Intravascular ultrasound imaging was repeated until complete and uniform stent expansion was achieved or no further improvement could be demonstrated. The intravascular ultrasound criteria for an optimal stent deployment were as follows: 1) The stent was completely expanded, and there was no free space between the stent struts and the intimal surface; 2) the stent was uniformly expanded with the ratio of the minor diameter divided by the major diameter >0.8; and 3) an attempt was made to maximize the intrastent lumen cross-sectional area to approximate that of the reference artery lumen.

If the initial intravascular ultrasound image demonstrated optimal stent deployment, the procedure was terminated. In this report, the results are presented for the measurements made after the first (when "angiographic success" was attained) and final (after all dilations were performed) intravascular ultrasound procedures.

Angiographic measurements were made retrospectively by an observer in blinded manner using hand calipers and the guiding catheter as a reference. The view with the tightest stenosis was selected for measurements. The closest proximal normal-appearing segment was used as the reference lumen.

Intravascular ultrasound measurements were performed during the procedure from videotape using previously described techniques (14). The stented segment of the vessel with the smallest intrastent diameter on the initial ultrasound examination was selected for measurement. The cursor was placed at the midaspect of the brightly reflective echoes of the stent, and the minimal and major diameters were measured. The major diameter was defined as the diameter perpendicular to the minimal diameter. Intrastent cross-sectional area measurements were performed using a trackball to trace over the stent. Vessel measurements were performed by placing the cursor at the distal border of the echolucent ring of the media. Where the media was in part obscured by shadowing from calcified plaque or stent echoes, or both, the closest adjacent segment of visible media proximal and distal to stented segments was identified on the videotape and used as a reference (17).

When repeat intravascular ultrasound images were performed after further interventions, care was taken to identify the same location in the stented segment of the vessel for measurements. This was achieved by identifying unique reflective structures in the plaque, such as the position of calcified deposits. Alternatively, the tightest point identified by intravascular ultrasound within the stent segment was used as the site of measurement. Although this does not guarantee that the identical point was selected for each intravascular ultrasound measurement, this approach ensures that differences in dimensions will tend to be underestimated rather than exaggerated.

Statistics. The data are expressed as mean value \pm SD. The values for each variable were analyzed by a two-tailed, paired Student *t* test and by repeated-measures analysis of variance with posttest contrast when more than two measurements were performed. Differences were considered statistically significant at p < 0.05. Comparison among groups was performed using analysis of variance for repeated measures, with post hoc pairwise comparisons using least significant differences.

Results

Forty patients received Palmaz-Schatz stents during a 3-month period (37 men, 3 women; mean [\pm SD] age 57.5 \pm 9.4 years). The indications for stent insertion were elective in 36 patients (90%) and emergent in 4 patients (10%). The distribution of vessels treated was left anterior descending coronary artery in 21 patients (53%), left circumflex coronary artery in 9 (22%), right coronary artery in 8 (20%) and a saphenous vein graft in 2 (5)%.

In addition to the standard-length (15 mm) Palmaz-Schatz stents, the short (7 mm), hemiarticulated version of the Palmaz-Schatz stent, as well as 10-mm biliary and renal Palmaz stents, were used (18). Twelve (30%) patients had a single stent implanted, and 28 (70%) received multiple stents.

Exclusions. Twenty-nine of the 40 patients underwent further balloon dilation with subsequent ultrasound examinations. Of the 11 patients who did not have a second intravascular ultrasound study, 5 (13%) were considered to have an adequate result on the first ultrasound examination, and no further interventions were performed. In two patients, difficulty in passing the ultrasound catheter prevented repeat imaging. In an additional two patients, early in the experience the operator elected not to repeat the ultrasound examination because of time constraints. Two patients underwent surgery and did not have a second ultrasound study. One of these patients had elective surgery after the initial ultrasound showed a very small lumen and attempts at further dilations were unsuccessful. One patient developed vessel rupture requiring immediate operation and is described in more detail later.

Findings. In all patients, stents were successfully delivered and deployed at the stenosis site, with significant angiographic improvement. Table 1 shows the angiographic results. By angiography, the average lumen diameter before angioplasty was 0.9 ± 0.5 mm. The stented lesion diameter with angiographic guidance was 3.15 ± 0.33 . This increased significantly to 3.7 ± 0.4 mm with ultrasound guidance (p < 0.001 for repeated-measures analysis of variance as well as between the dimensions after angiographic vs. ultrasound guidance).

Table 1		Angiographic	M	leasurement	S
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	Predilation (mean ± SD)	Angiographic Guidance* (mean ± SD)	IVUS Guidance† (mean ± SD)
MLD (mm)	0.90 ± 0.50	3.15 ± 0.33	3.70 ± 0.40
Stenosis (%)	74 ± 12	8 ± 7	-6 ± 14
Reference lumen diameter (mm)	3.50 ± 0.30		

*Measurements made at the first intravascular ultrasound (IVUS) procedure. \pm final measurements, p < 0.001 between ineasurements, as analyzed by repeated-measures analysis of variance; posttest pairwise comparisons revealed this level of significance for all comparisons. MLD = minimal lumen diameter.

The angiographic percent diameter stenosis at baseline was 74 \pm 12%. After the initial stent deployment with an apparent successful angiographic result, the mean percent stenosis was 8 \pm 7%; after further balloon dilation based on intravascular ultrasound guidance, the residual diameter at the treated site was larger than the reference diameter, with a negative "residual stenosis" of $-6 \pm 14\%$. The average balloon size with angiographic guidance was 3.76 \pm 0.32 mm, which increased to 4.21 \pm 0.44 mm when ultrasound guidance was used (p < 0.001).

Intravascular ultrasound measurements of the tightest section through the stented segment are shown in Table 2. The ultrasound minimal lumen diameter inside the stent was 2.76 ± 0.49 mm after angiographic guidance. After further dilations based on ultrasound imaging, the mean minimal lumen diameter was 3.25 ± 0.48 mm by intravascular ultrasound, a 19% increase compared with the initial measurement (p < 0.0001). The major lumen diameter increased from 3.30 ± 0.46 to 3.66 ± 0.47 mm (p < 0.001). The ratio of the minimal lumen diameter divided by the major diameter was 0.84 after the initial dilation and increased to 0.89 after the final treatments (p = NS). The minimal lumen cross-sectional area, measured by intravascular ultrasound, increased 34% to 9.31 ± 2.49 mm² after the final balloon dilation from $7.36 \pm$ 1.51 mm² at the time of the first ultrasound image (p < 0.001).

The following examples demonstrate how this method was used in specific situations. The associated angiographic and ultrasound images illustrate how a stented segment of vessel can appear fully expanded by angiography but not by intravascular ultrasound imaging.

Table 2. Intravascular Ultrasound Measurements

	Initial (mean ± SD)	Final (mean ± SD)	Increase
Intrastent minimal diameter (mm)	2.8 ± 0.5	3.3 ± 0.5	19%
Intrastent major diameter (mm)	3.3 ± 0.5	3.7 ± 0.5	11%
Intrastent area (mm ²) Balloon size (mm)	7.4 ± 1.5 3.8 ± 0.3	9.3 ± 2.5 4.2 ± 0.4	34% 12%

p < 0.001 between initial and final measurements for all categories.

Representative examples. Patient 1. A 56-year old man with stable angina pectoris after a myocardial infarction had an ostial stenosis of the left anterior descending coronary artery (Fig. 1A). A Palmaz-Schatz stent was delivered over a 2.5-mm balloon with an adequate angiographic result. Intravascular ultrasound demonstrated an intrastent diameter of 2.5 mm; however, the vessel diameter (media to media) was measured at 4.0 mm (Fig. 1B). Further inflations were performed with 3.0- and 3.5-mm balloons, and the angiographic result appeared excellent. However, intravascular ultrasound continued to demonstrate a stent that was not fully expanded to the arterial wall (Fig. 1B). After a 4.0-mm balloon was used, no change in the angiographic appearance or measurement could be appreciated; however, ultrasound identified an intrastent diameter of 4.0 mm with the stent fully apposed to the arterial wall. The intrastent lumen area increased from 5.3 mm² after the initial 2.5-mm balloon to 10.6 mm² after the 4.0-mm balloon. This represents a 100% increase in cross-sectional area.

Patient 2. A 53-year old man presented with angina after a myocardial infarction, and coronary angiography revealed single-vessel disease with a subtotal occlusion of the mid-right coronary artery. Balloon angioplasty was performed with a 4.0-mm balloon, but the result was inadequate on both angiography and intravascular ultrasound imaging. Stent implantation was performed with three short stents with increasing balloon sizes up to 4.0 mm (Fig. 2A). Intravascular ultrasound revealed a portion of the distal stent that was partially compressed by plaque, preventing complete stent expansion (Fig. 2B). The reference vessel diameter was measured at 4.8 mm. On the basis of this ultrasound appearance, a 4.5-mm balloon was used to expand the stent further. Repeat ultrasound imaging did not demonstrate a significant change, so a 5.0-mm balloon was used. Intravascular ultrasound now showed an increase in stent dimensions with evidence of full expansion. Because short balloons in the 4.5- and 5.0-mm size were not available, a standard 20-mm length balloon was used, which led to dilation of the nonsegmented proximal segment of the artery. Angiography demonstrated a dissection and intramural hematoma proximal to the stent (Fig. 2A). Follow-up angiography the next day demonstrated resolution of the dissection with no change in the lumen dimensions.

Patient 3. A 50-year old man with unstable angina and stenosis in the proximal left anterior descending coronary artery underwent stent insertion, which was expanded with a 4.0-mm balloon (Fig. 3A). Intravascular ultrasound showed suboptimal intrastent dimensions of 3.3×2.7 mm (Fig. 3B). The reference vessel measured 4.7×4.1 mm. A 4.5-mm balloon was inflated to 6 atm without significant improvement in the intrastent dimensions. Because the vessel diameter measurements by ultrasound were close to 4.5 mm, use of a larger balloon was not attempted. Instead, repeat inflations were performed with a 4.5-mm balloon, but at a higher pressure of 12 atm. This resulted in an improved ultrasound appearance with intrastent diameters of 3.9×3.9 mm and a 66% increase in area from 6.2 to 10.3 mm².



Figure 1. Angiograms and intravascular ultrasound images of ostial left anterior descending coronary artery from Patient 1. A, Angiograms before (Baseline) and after placement of the stent and dilation with 2.5-, 3.0-, 3.5- and 4.0-mm balloons. Arrow identifies the lesion. B, Intravascular ultrasound appearance after each balloon size. V = vessel diameter.

Patient 4. A 62-year old man presented with unstable angina 5 years after coronary artery bypass surgery. Balloon angioplasty was performed for a stenosis in the left anterior descending coronary artery immediately distal to the anastamosis of a saphenous vein graft. The angiographic results after balloon angioplasty were suboptimal, and a stent was inserted and dilated with a 3.0-mm balloon. Angiographically, the result appeared adequate (Fig. 4A). However, intravascular ultrasound demonstrated a lumen diameter of 1.5 mm, with compression of a short segment of the stent by a dense fibrous plaque (Fig. 4B). The reference vessel distal to the stent measured 2.5 mm in diameter. Despite this small measurement of the vessel (media to media) diameter, a 3.5-mm followed by a 4.0-mm balloon was inflated because of the inadequate lumen diameter. The proximal aspect of the balloon was carefully placed inside the larger saphenous vein graft. Slight indentation of the balloons was noted when they were inflated (Fig. 4C). After the 4.0-mm balloon dilation, there was angiographic evidence for vessel rupture with contrast extravasation into the pericardium (Fig. 4C). Emergency pericardiocentesis was attempted, and the patient underwent emergency coronary artery bypass graft surgery. Although hemodynamic function was preserved, he succumbed to incessant ventricular arrhythmias after surgery.

Discussion

The observations from this study demonstrate that intravascular ultrasound imaging provides more information than is obtained by angiography for assessing intrastent dimensions along the segment of artery where a stent is used. This study indicates that relative obstruction within the stent may be more prevalent than is appreciated with standard angiography. These intrastent stenotic areas may not only predispose to subacute thrombosis but also provide a reduced initial gain, which may influence the restenosis rate. Although it remains to be proved that full stent expansion using ultrasound criteria is less prone to subacute closure or restenosis, data from Kuntz et al. (19,20) suggest that larger increases in acute gain for an intervention based on angiographic results are associated with lower rates of restenosis. Their studies showed that restenosis after coronary interventions varied directly with the lumen diameter at the end of the procedure, although others (21) have challenged this concept. Also, data from several centers (22-27) suggest that the risk of subacute thrombosis is increased when smaller final lumen sizes are achieved.

In our series of 40 patients, only 5 (13%) had adequate expansion of the stent by ultrasound imaging despite an acceptable angiographic appearance in all of them. On the basis of these findings, 29 of the patients underwent at least one more balloon dilation and repeat intravascular ultrasound. This resulted in an average 19% increase in minimal intrastent diameter and a 34% increase in intrastent cross-sectional area, which were both statistically significant. Because a small increase in the radius of the vessel will lead to a sizable increase in flow, as described by Poisseuille's law, the larger vessel dimensions resulting from further expansion will substantially improve flow through the vessel (28). Our hypotheses are that larger lumens achieved with ultrasound guidance will minimize the likelihood of subacute thrombosis and that the improvement in acute gain will lower the rate of restenosis after stent insertion. Large randomized clinical outcome trials will be required to demonstrate whether these hypotheses are valid.



Inadequate stent expansion. Inadequate stent expansion may be caused by a balloon that is too small for the artery or by compression of the stent by plaque. The example of Patient 1 illustrates how the angiogram provides less accurate estimations of vessel size than intravascular ultrasound, which may lead to an inappropriate choice of balloon size and insufficient stent expansion. A common reason for inadequate stent expansion as demonstrated by intravascular ultrasound was a smaller cross-sectional area than expected based on the initial balloon size used. The average balloon size before intravascular ultrasound imaging was 3.76 ± 0.36 mm, which has an expected lumen cross-sectional area of 11.3 mm². This is a larger balloon than that used in other published studies on stent deployment (29,30). The average lumen cross-sectional area by intravascular ultrasound after the initial imaging was 7.4 mm², which represents only 65% of the expected lumen cross-sectional area if full balloon expansion has occurred. It is not clear whether this is a result of inadequate balloon expansion within the stent because of resistance from plaque or whether what appears on angiography to be complete balloon inflation is followed by elastic recoil despite the

presence of the stent. Asymmetric stent expansion. An unexpected observation from ultrasound imaging was that balloon inflation did not produce a uniform expansion of the stent. The ratio of the minor lumen to the major lumen diameter was 0.84 even after maximal balloon inflation. Fibrocalcific plaque may be a cause of inadequate stent expansion, as suggested by the examples of Patients 2 and 3. Fracture of the plaque may be attempted in these cases by oversizing the balloon or using a higher inflation pressure. A larger balloon provides greater leverage for plaque fracture. Because the stent is in place, the risk of dissection is diminished, and a greater acute gain becomes possible. However, overdilation of adjacent nonstented segments needs to be avoided to prevent dissection. Short balloons that are inflated only inside stented portions of vessel are very useful for this purpose.

Balloon sizing. Intravascular ultrasound also provides an estimation of the upper limit of acceptable balloon sizes. As illustrated by Patient 4, the use of a larger balloon than was appropriate for the measured diameter by intravascular ultrasound led to the serious complication of vessel rupture. In contradistinction to this episode, the example of Patient 3 demonstrates how optimal balloon sizing with higher inflation pressures was used advantageously in subsequent cases. In this patient, an incompletely expanded stent persisted despite sizing up to a larger balloon (4.5 mm). Because the reference vessel measured 4.1×4.7 mm on ultrasound, there was concern with using a larger balloon. Therefore, repeat inflation with a 4.5-mm balloon was performed but at a higher pressure of 12 atm. This led to a marked improvement in stent expansion, with a 66% increase in vessel area.

Angiography versus intravascular ultrasound. We believe that the main reason for the discrepancy between angiographic assessment and intravascular ultrasound measurements is the insufficient information provided by a projection imaging technique, such as angiography. The ultrasound images frequently demonstrated that the stenotic segment within the stent was very short, 1 to 2 mm in length, which could be missed unless the angiographic projection was directly perpen-

Figure 3. Angiograms and intravascular ultrasound images of the left anterior descending coronary artery from Patient 3. A, Angiograms before stent implantation (Baseline), after stent insertion and inflation of a 4.0-mm balloon and after inflation of a 4.5-mm balloon at 6 atm (ATM) and a 4.5-mm balloon at 12 atm. Arrow points to the lesion. B, Intravascular ultrasound images after stent insertion and dilation with a 4.0-mm balloon. a 4.5-mm balloon at 6 atm and a 4.5-mm balloon at 12 atm. See text for details. CSA = cross-sectional area.



 $CSA = 6.2 \text{ mm}^2$ Vessel: 4.7 x 4.1 mm В

 $CSA = 7.0 \text{ mm}^2$

Intra-stent: 3.9 x 3.9 mm CSA = 10.3 mm²

dicular at that site of the artery. The radiographic point spread function and focal spot of the X-ray imaging chain may produce blooming of contrast in short stenoses, which could result in underestimation of stenosis severity in short narrowed sections. Imaging from within the artery is not subject to this misrepresentation (31). Although there are potential artifacts produced by intravascular ultrasound imaging, the quality of the images obtained in the majority (95%) of our patients was adequate to perform measurements of lumen diameters and cross-sectional area within the stented segments. Intravascular ultrasound can also provide excellent quantitative information on the plaque cross-sectional area, which is unavailable from angiographic imaging (32,33). However, once a stent is inserted, the dense reflections from the metallic struts decrease the ability to make accurate measurements of plaque dimensions behind the stent in many cases.

Limitations. Although this study demonstrates significant improvements in intrastent dimensions when intravascular ultrasound is used to guide therapy, this study was not designed

to show an improvement in clinical outcomes based on this strategy. In addition, one must be cautious with this approach because one of the 40 patients had a severe complication that would not have occurred if intravascular ultrasound had not been performed and acted on (Patient 4). In this instance, only part of the information obtained from the ultrasound images was utilized; that is, an unacceptable minimal lumen diameter <2 mm. If the choice of balloon size had been limited on the basis of measurements of the reference vessel dimension from the ultrasound images, it is possible that the complication would not have occurred. Although this study documented that larger lumen dimensions may be obtained when intravascular ultrasound information is added to the stenting procedure, the small numbers and lack of randomization preclude drawing conclusions with regard to the clinical benefit of this approach.

The criteria for adequacy of stent expansion as defined for this study have not been validated as clinically useful. No other criteria for adequate stent expansion as assessed by intravas-



Α

B

С

Stent compressed



1.5 mm X 2.3 mm CSA: 3.0 mm²





Vessel = 2.5 mm X 2.5 mm CSA: 5.50 mm²



2.2 mm X 2.4 mm CSA: 4.0 mm²





Figure 4. Angiograms and intravascular ultrasound images from Patient 4. A, Angiogram of a saphenous vein graft and its insertion into the left anterior descending coronary artery before and after deployment of a stent and dilation with a 3.0-mm balloon in the native vessel. Arrow points to the lesion. B, Intravascular ultrasound appearance of a short segment of stent being compressed by plaque, a reference vessel immediately distal to the stent with a vessel diameter of 2.5 mm and a segment of stent with more complete expansion. Arrows point to plaque compressing the stent. C, 4.0-mm balloon inside the artery with a persistent indentation ("waist") in the balloon; pericardial staining is seen after the final dilation. Large arrow points to indentation in the balloon. Small arrows point to pericardial staining.

cular ultrasound have previously been defined. Refinements in establishing guidelines for intravascular ultrasound evaluation of stent deployment are likely to develop with further studies.

Conclusions. This study demonstrates that information derived from angiography is often limited in providing an accurate assessment with regard to vessel size, plaque calcification, or stent deployment. Use of vascular dimensions from intravascular ultrasound may assist in the optimal choice of balloon size. Ultrasound imaging after stent insertion is useful in documenting satisfactory stent expansion. Inadequate expansion may result from suboptimal balloon size selection or plaque compression of the stent. This preliminary experience demonstrates that intravascular ultrasound is an important, novel method to establish proper stent placement and that guidance with ultrasound imaging may be superior to angiography alone. The results of this study are encouraging and suggest that it would be appropriate to perform a randomized clinical outcome trial to determine whether the effects of this approach with intravascular ultrasound guidance can be used to decrease the subacute thrombosis and restenosis rates after intracoronary stent implantation.

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