Final Results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) Study

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Background—Intravascular ultrasound (IVUS) can assess stent geometry more accurately than angiography. Several studies have demonstrated that the degree of stent expansion as measured by IVUS directly correlated to clinical outcome. However, it is unclear if routine ultrasound guidance of stent implantation improves clinical outcome as compared with angiographic guidance alone.

Methods and Results—The CRUISE (Can Routine Ultrasound Influence Stent Expansion) study, a multicenter study IVUS substudy of the Stent Anti-thrombotic Regimen Study, was designed to assess the impact of IVUS on stent deployment in the high-pressure era. Nine centers were prospectively assigned to stent deployment with the use of ultrasound guidance and 7 centers to angiographic guidance alone with documentary (blinded) IVUS at the conclusion of the procedure. A total of 525 patients were enrolled with completed quantitative coronary angiography, quantitative coronary ultrasound, and clinical events adjudicated at 9 months for 499 patients. The IVUS-guided group had a larger minimal lumen diameter (2.9±0.4 versus 2.7±0.5 mm, P<0.001) by quantitative coronary angiography and a larger minimal stent area (7.78±1.72 versus 7.06±2.13 mm², P<0.001) by quantitative coronary ultrasound. Target vessel revascularization, defined as clinically driven repeat interventional or surgical therapy of the index vessel at 9 month-follow-up, occurred significantly less frequently in the IVUS-guided group (8.5% versus 15.3%, P<0.05; relative reduction of 44%).

Conclusions—These data suggest that ultrasound guidance of stent implantation may result in more effective stent expansion compared with angiographic guidance alone. (Circulation. 2000;102:523-530.)

Key Words: stents ■ coronary disease ■ ultrasonics ■ angiography ■ restenosis

Coronary stenting has evolved into the most common catheter-based treatment of coronary artery disease.1–3 Early in the clinical experience with stenting, intravascular ultrasound (IVUS) played a key role in refining appropriate stent deployment strategies. IVUS studies demonstrated that incomplete deployment of stents occurred in up to 80% of patients at nominal pressures (8 to 12 atm). This insight helped usher in the use of high pressure (>12 atm) techniques and emphasized the need for careful attention to maximizing target segment expansion.

The role of IVUS in the current, high-pressure era of stenting has not been clearly defined. Several studies have shown that IVUS is more accurate than angiography in determining in-stent dimensions and is better able to detect subtle findings such as incomplete apposition of the stent to the vessel wall and dissections at the stent margins.4–9 Recently, several single-center studies have demonstrated that the IVUS measurement of minimal stent area (MSA) is the single most powerful predictor of long-term patency and clinical outcome.10–13 No previous study, however, has directly addressed whether IVUS-guided stenting leads to improved results than stenting with angiographic guidance alone.

The CRUISE study (Can Routine Ultrasound Influence Stent Expansion) was designed to compare IVUS-guided

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CRUISE was a substudy of the Stent Anti-thrombotic Regimen Study (STARS), in which the use of IVUS or angiography was assigned on a center-by-center basis. The primary end point of the study was the postprocedure minimal stent dimensions as determined by angiography and intravascular ultrasound. The secondary end point was major cardiac events (death, Q-wave myocardial infarction (MI), and target vessel revascularization, TVR) at 9 months as a function of IVUS versus angiographic guidance.

Methods

Study Design

The STARS trial was designed as a prospective, randomized study to compare 3 antithrombotic regimens (aspirin alone, aspirin and ticlopidine, and aspirin and cumarin). Patients from 45 US sites were enrolled, with a primary end point of major cardiac end points (death, Q-wave MI, and TVR) at 30 days.

For the CRUISE substudy, 16 centers were selected on the basis of experience with IVUS imaging in previous trials. To avoid influencing the primary randomization of the STARS trial to these angiographic protocols, the use of IVUS was assigned on a center-by-center basis (ie, each center performed either IVUS or angiographic optimization). In the angiographic-guidance centers, a blinded (documentary) IVUS examination was performed after final stent optimization. Seven centers participated in the IVUS-documentary group and 9 centers were designated as the IVUS-guided group. The centers and respective principal investigators are listed in the Appendix.

The primary end point of the CRUISE trial was the postprocedure measure of minimal stent dimensions by angiography (diameter) and ultrasound (area, minimal diameter). The secondary end point was independently adjudicated major cardiac events (death, MI, and TVR) determined by follow-up at 9 months.

Patient Selection

Inclusion criteria included symptomatic ischemic heart disease, new lesions or restenotic lesions of the native coronary circulation, and planned stent implantation with up to 2 stents deployed per patient. Only Palmaz-Schatz balloon-expandable stents were deployed. Patients were excluded from the study if any of the following conditions occurred: (1) the patient required revascularization of lesions other than the stented lesion; (2) use of aspirin, ticlopidine, or cumarin was contraindicated; (3) the presence of a left main coronary
artery lesion; (4) an MI within the past 7 days; (5) occurrence of a stroke/transient ischemic neurological attack within the past 3 months.

Stent Implantation Procedure
In the IVUS-documentary group (angiographic guidance), the protocol included standard high-pressure stent deployment until angiographic success was achieved (defined as diameter stenosis <10% by visual assessment). After the final balloon inflation, a blinded IVUS was performed within the target segment. This included a slow manual or motorized pullback from ≥10 mm beyond the stent, through the stent, and then through the proximal 10-mm reference segment. Because the IVUS examination was blinded, there was no operator response to the IVUS information.

In the IVUS-guided group, after angiographic success, iterative IVUS was performed within the target segment, and the operators used this information to optimize stent deployment. For example, the operators could perform additional inflations with the use of higher pressure, larger balloons, and/or additional stents based on iterative IVUS pullbacks.

Postprocedure Medication Protocol
After stent implantation, with or without IVUS guidance, patients were randomly assigned to one of the following antithrombotic regimens: aspirin alone (long-term aspirin, 325 mg), aspirin and ticlopidine (long-term aspirin, 325 mg, and 250 BID ticlopidine for 1 month), or aspirin and cumarin (long-term aspirin, 325 mg, and adequate cumarin to maintain INR between 2.0 to 2.5 for 4 weeks).

Quantitative Coronary Angiography
All cineangiograms were analyzed by the Washington Hospital Center Angiographic Core Laboratory (Washington, DC) by analysts blinded to the guidance method and postprocedure medication protocol. Cine frames were selected from 2 views before intervention, after stent deployment, and after final balloon inflation. These frames were digitized and analyzed with the use of an automated edge-detection algorithm (CAAS-II). Image calibration was performed with the use of contrast-filled catheters as the reference standard. The minimal lumen diameter inside and outside the stent and reference diameter were used to calculate the percent diameter stenosis before intervention, after stent deployment, and after the final balloon dilatation.

IVUS Imaging Protocol
A commercially available system (CVIS/Boston Scientific Corp) was used for all IVUS studies. The catheter contains a single-element, 30-MHz transducer mounted on the tip of a flexible shaft and rotating at 1800 rpm within a 2.9F, rapid-exchange/common distal lumen imaging sheath, or within a 3.2F, short monorail imaging sheath. IVUS imaging was performed after achievement of angiographic success, and images were recorded on half-inch, high-resolution Super-VHS (S-VHS) videotape for off-line quantitative analysis.

IVUS Analysis
All ultrasound images were reviewed and evaluated for both qualitative and quantitative parameters by an independent core laboratory at the Center for Research in Cardiovascular Interventions, Stanford University Medical Center (Stanford, Calif). The images were digitized to perform morphometric analysis with commercially available systems.
available planimetry software (TapeMeasure, Indec Systems, Inc). Quantitative parameters consisted of stent and reference lumen cross-sectional areas; stent and reference lumen minimal diameters; and stent and reference vessel cross-sectional areas. The vessel area was defined as the area within the media/adventitial border (that is, including lumen, plaque, and media). Plaque area was calculated as vessel area minus lumen or stent area.

IVUS measurements were performed at 5 cross sections in the target segment: the tightest segment within the stent; the proximal and distal stent edges (measured within ~1 mm of the proximal and distal stent ends); and the proximal and distal reference segments (defined as the location in the native vessel with the least amount of disease within 5 mm of the proximal and distal stent edges and before the emergence of any major side branches) (Figure 1). For the purposes of quantification, when 2 stents in a vessel overlapped, they were treated as a single stented segment. However, 2 nonoverlapping stents in a single vessel were treated as 2 individually stented segments. In cases in which the stent was placed in an ostial position, no efforts were made to measure proximal reference segments.

Clinical Follow-Up
Clinical follow-up was obtained at 9 months after stent implantation for the occurrence of major cardiac events (death, MI, or TVR). TVR was defined as clinically driven repeat revascularization of the initially treated target vessel. Clinical data were independently adjudicated at the Cardiovascular Data Analysis Center at the Beth Israel Deaconess Medical Center (Boston, Mass).

Statistical Analysis
All clinical, angiographic, and ultrasound data were submitted to the Cardiovascular Data Analysis Center. Quantitative data were presented as a mean value±SD and qualitative data were presented as frequencies. Continuous variables were compared by means of paired or unpaired t tests. Binary variables were examined by use of Fisher’s exact and x² tests. Predictors of TVR were examined by use of multivariate logistic models. Significance was defined at a threshold of P=0.05. All statistical analyses were performed with the SAS for Windows version 6.12 (SAS Institute).

Results

Patient Characteristics
During the 13-month enrollment phase (from April 1996 to May 1997), 525 patients were enrolled in CRUISE. Two hundred twenty-nine patients in the IVUS-documentary group and 270 patients in the IVUS-guided group had completed case-report forms at 9-month follow-up and image quality deemed acceptable by both the angiographic and ultrasound core laboratories (Washington Hospital Center and Stanford University). All of these 499 patients had complete adjudication for clinical follow-up. Baseline demographics and clinical data are shown in Table 1. The clinical profile showed a significantly lower percentage of history of MI and a significantly higher percentage of single vessel disease in the IVUS-guided group. Baseline angiographic characteristics are shown in Table 2.

Procedure Characteristics
Procedure characteristics are listed in Table 3. Before IVUS imaging, the average balloon size and pressure used in the documentary group was similar to the IVUS-guided group (balloon size 3.34±0.43 versus 3.28±0.47 mm, P=NS; balloon pressure 15.62±2.29 versus 15.91±2.70 atm, P=NS). However, at the end of the procedure, larger balloon and higher inflation pressure were used in the IVUS-guided group (3.88±0.51 versus 3.69±0.59 mm, 18.0±2.58 versus 16.6±3.01 atm, respectively, both P<0.001). In the IVUS-guided group, 36% of the patients received additional therapy based on IVUS information. In this subgroup, MSA increased from 6.25±1.39 mm² to 7.14±1.47 mm². For these patients, the operators chose to use higher pressure in 59.0% of patients, larger balloon in 33.7%, and an additional stent in 7.3%.

Case Examples
Figure 2 is an example of an IVUS-documentary case. After high-pressure stent deployment, the angiogram illustrates adequate stent expansion in the mid left circumflex artery (Figure 2A). However, IVUS reveals an MSA of only 5.41 mm² (Figure 2B), which is underdilated compared with a reference segment lumen area of 10.40 mm² (Figure 2C). In contrast, in an IVUS-guided case shown in Figure 3, in a mid right coronary artery, the angiographic image after high-pressure stent deployment appears adequate (Figure 3A). However, on review by IVUS, the operators deemed stent expansion not acceptable (Figure 3B) and proceeded to use a
0.5-mm larger balloon size at 18 atm within the stent, achieving a nearly 3-mm\textsuperscript{2} improvement in MSA (Figure 3C).

**Angiographic and IVUS Results**

Angiographic and IVUS results are shown in Table 4. Angiographic core laboratory analysis showed a significantly larger postprocedure minimal lumen diameter and a significantly lower residual diameter stenosis in the IVUS-guided group (2.9±0.4 versus 2.7±0.5 mm; \(P<0.001\), 7.6±10.4% versus 9.8±11.2%; \(P<0.05\), respectively). IVUS core laboratory analysis also showed a significantly larger postprocedure minimal lumen area and minimal lumen diameter in the IVUS-guided group (7.78±1.72 versus 7.06±2.13 mm\textsuperscript{2}, 2.96±0.55 versus 2.59±0.43 mm, respectively; both \(P<0.001\)).

**Clinical Outcome at 9 Months**

Clinical outcomes at 9 months are shown in Table 5 and illustrated in Figure 4. There were no differences in the incidence of death and MI during follow-up. However, the incidence of TVR was 44% lower in the IVUS-guided group (8.5% versus 15.3%; \(P<0.05\)). Interestingly, in the 64% of the patients not receiving additional therapy in the IVUS-guided group, TVR occurred in 18 of 173 or 10.4%, which trended lower than the IVUS-documentary group but did not reach statistical significance (\(P=0.15\)). The potential predictors of TVR at 9-month follow-up were entered into multivariable regression models including multivessel disease and history of MI (which had different incidences in the 2 baseline groups; see Table 1) are shown in Table 6. The only significant predictor of TVR was postprocedure in-stent size.

**Discussion**

In this multicenter, prospective study, IVUS-guided stent implantation resulted in larger stent areas, as measured by both qualitative coronary angiography (QCA) and qualitative coronary ultrasound (QCU). Although in the IVUS-guidance cohort only 36% of patients underwent a change in deployment strategy on the basis of IVUS information, this change resulted in a 44% composite relative reduction in TVR in the entire IVUS-guided group compared with the IVUS-documentary group. There were no statistical differences between the 2 groups with respect to Q-wave MI or death. The data for the CRUISE trial suggest that the use of

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**TABLE 4. Quantitative Angiographic and Ultrasound Analysis (After Procedure)**

<table>
<thead>
<tr>
<th></th>
<th>Guided (n=290)</th>
<th>Documentary (n=253)</th>
<th>(P)</th>
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</thead>
<tbody>
<tr>
<td><strong>Quantitative angiographic analysis</strong></td>
<td></td>
<td></td>
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<tr>
<td>Reference segment diameter, mm</td>
<td>3.1±0.5</td>
<td>3.0±0.5</td>
<td>NS</td>
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<tr>
<td>In-lesion minimal lumen diameter, mm</td>
<td>2.5±0.5</td>
<td>2.4±0.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>In-lesion diameter stenosis, %</td>
<td>18.8±13.0</td>
<td>20.6±12.7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>In-stent minimal lumen diameter, mm</td>
<td>2.9±0.4</td>
<td>2.7±0.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-stent diameter stenosis, %</td>
<td>7.6±10.4</td>
<td>9.8±11.2</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>Quantitative ultrasound analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal reference area, mm\textsuperscript{2}</td>
<td>8.68±2.79</td>
<td>9.01±3.37</td>
<td>NS</td>
</tr>
<tr>
<td>Proximal reference area, mm\textsuperscript{2}</td>
<td>9.92±2.94</td>
<td>9.62±3.12</td>
<td>NS</td>
</tr>
<tr>
<td>Minimal stent area, mm\textsuperscript{2}</td>
<td>7.78±1.72</td>
<td>7.06±2.13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Minimal lumen diameter, mm</td>
<td>2.96±0.55</td>
<td>2.59±0.43</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
IVUS in conjunction with the angiogram allowed the operator to define a subgroup of patients with suboptimal stent geometry, who required additional therapy and ultimately achieved an improved clinical outcome. To our knowledge, this is the first multicenter study to demonstrate the benefits of IVUS-guided stenting for improved TVR.

There are several possible reasons for the improved acute morphometric outcomes observed in the IVUS-guided cohort. Vessel overlap, tortuosity, and complex lesion morphology may mask subtle changes in luminal dimensions on the angiogram. In stented lesions, the metal of the struts or irregularities in the stented segment may cause QCA overestimation compared with QCU. Hoffmann et al15 showed that in 71 patients who had Palmaz-Schatz stent implantation, QCA overestimated acute lumen gain (QCA-IVUS; 0.33±0.39, P<0.0001). Blasini et al8 showed in 225 patients with Palmaz-Schatz stent implantation after low-pressure dilatation that angiography overestimated the minimal lumen diameter relative to IVUS imaging by a mean of 0.4±0.4 mm. Additionally, several studies have demonstrated that visual angiographic estimation of stenosis severity in nonstented segments results in both overestimation before intervention and underestimation after intervention.16,17 Thus operators using visual angiographic end points in the catheterization laboratory alone may tend to conclude that certain lesion subsets may be aggressively treated with balloon sizes that traditionally would be thought too injurious. Thus, iterative IVUS guidance during stent deployment augments the angiographic information and adds lesion-specific information to more efficiently “fine tune” the stent geometry for a particular lesion segment.

Recently, in the high-pressure era, several single-center studies have examined stent geometry and clinical follow-up. de Feyter et al12 showed an inverse relation between MSA as tracked by IVUS after angiographically successful deployment and TVR. In a larger single center study, Moussa et al11 also showed an inverse relation between MSA and angiographic restenosis with 425 consecutive patients (496 lesions). These data were corroborated by a further single-center study by Hoffmann et al,13 who showed that IVUS after interventional stent dimensions was one of the most consistent predictors of angiographic in-stent restenosis.

The ability to optimize stent deployment may not only improve clinical benefits but may translate to an overall cost-saving benefit at 1 year (even with the “up-front” cost of an IVUS catheter). In a recent article by Ellis et al,19 a reduction in an absolute 10% of restenosis was projected to yield an overall savings of nearly a billion dollars in the United States alone. This degree of savings could potentially justify inexpensive “on-board” guidance strategy with IVUS during initial stent placement for the coronary artery.

Even with IVUS-guided stenting, vessel size, plaque composition, and especially plaque burden limit optimal achievement of acute lumen gain. One way to achieve a larger relative lumen gain may be to debulk the lesion (directional coronary atherectomy or rotational coronary atherectomy) before stenting. Several single-center studies have shown excellent results with a combination of debulking followed by a stent.20,21 The Stenting after Optimal Lesion Debulking (SOLD) pilot study, which tested a directional coronary atherectomy before stent deployment protocol, showed an angiographic restenosis rate of 4.9% at 6-month follow-up.22 This technique may not only increase lumen gain but may also allow optimal stent expansion with low deployment pressures—capitalizing on the change in vessel compliance after primary debulking therapy.

**Study Limitations**

One clear limitation of the present study is the center-based assignment to IVUS guidance as opposed to a direct randomization. This strategy was selected because of the economy and efficiency of using a relatively large trial apparatus (STARS) to provide additional information without disrupting the primary randomization scheme. There was no clear difference in prior experience with stenting or volume of cases performed in the centers assigned for angiographic or IVUS guidance.

A second limitation was that the optimization strategy was not standardized and was left to the discretion of the individual institutional practice. However, in this study, the incidence of IVUS-guided additional therapy (36% of patients) is consistent with recent studies (Angiography Versus Intravas-
circular Ultrasound Directed Coronary Stent Placement [AVID] 31%, Albiero et al 44%).10,23 It is interesting to note that TVR was less (but the difference did not reach statistical significance) in the IVUS-guided group not receiving additional therapy compared with the IVUS-documentary group. This may represent bias (ie, the group assigned to IVUS may be better “stenters” as a result of their continued IVUS experience) or underscore the value of IVUS in recognizing severely underdeployed stents in the setting of adequate angiographic representation. Although this study cannot address this issue, it is an important consideration in the design of future IVUS trials.

Finally, the incidence of previous MI and triple-vessel disease was lower in the baseline IVUS-guided group than in the IVUS-documentary group. However, in multivariate regression analysis, these factors were not significant predictors of clinical outcome.

Conclusions
In the CRUISE trial, centers that used IVUS guidance achieved significantly larger minimal stent dimensions than centers that used angiographic guidance alone. This difference was associated with a 44% lower rate of TVR but no difference in mortality or MI.

Appendix
The following institutions and investigators participated in the CRUISE Trial: University of Texas Health Science Center, San Antonio, Tex: Steven R. Bailey; Beth Israel Hospital, Boston, Mass: Donald S. Baim; Yale University Hospital, New Haven, Conn: Michael W. Cleman; New York Hospital, Cornell Medical Center, New York, NY: Ezra Deutsch; Georgetown University Medical Center, Washington, DC: Daniel J. Diver; Washington Hospital Center, Washington, DC: Martin B. Leon; Lenox Hill Hospital, New York, NY: Jeffrey W. Moses; Stanford University, Stanford, Calif: Stephen N. Oesterle; Lubbock Medical Center, Lubbock, Tex: Paul A. Overlie; University of Florida, Gainesville: Carl J. Pepine; William Beaumont Hospital, Royal Oak, Mich: Robert D. Safian; Maimonides Medical Center, Brooklyn, NY: Jacob Shani; Cardiovascular Consultant, Inc, Kansas City, Mo: Thomas M. Shimshak; The Sanger Clinic, Charlotte, NC: Charles A. Simonton; University of Texas, Houston: Richard W. Smalling; Scripps Clinic, La Jolla, Calif: Paul S. Teirstein; and Duke University Medical Center, Durham, NC: James P. Zidar.

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References

TABLE 6. Univariate and Multivariate Predictors of Target Vessel Revascularization

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Univariate Results</th>
<th>Multivariate Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of MI</td>
<td>−0.0334 ± 0.2932</td>
<td>−0.1207 ± 0.3175</td>
</tr>
<tr>
<td>STARS assignments</td>
<td>0.0472 ± 0.4047</td>
<td>−0.2646 ± 0.4915</td>
</tr>
<tr>
<td>Single vessel</td>
<td>−0.3022 ± 0.2844</td>
<td>−0.2227 ± 0.3108</td>
</tr>
<tr>
<td>IVUS-guided</td>
<td>−0.6768 ± 0.2919</td>
<td>−0.3334 ± 0.3161</td>
</tr>
<tr>
<td>Final in-stent minimal lumen diameter</td>
<td>−1.3747 ± 0.3641</td>
<td>−1.2581 ± 0.3760</td>
</tr>
</tbody>
</table>


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