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ARTICLE

The Safety of Intracoronary Ultrasound

A Multicenter Survey of 2207 Examinations

Dirk Hausmann, Raimund Erbel, Marie-J. Alibelli-Chemarin, Wolfgang Boksch, Eugene Caracciolo, Joel M. Cohn, Stephen C. Culp, Werner G. Daniel, Ivan De Scheerder, Carlo DiMario, James J. Ferguson, III, Peter J. Fitzgerald, Guy Friedrich, Junbo Ge, Günther Görge, Peter Hanrath, John McB. Hodgson, Jeffrey M. Isner, Suresh Jain, Willibald Maier-Rudolph, Michael Mooney, Jeffrey W. Moses, Harald Mudra, Fausto J. Pinto, Richard W. Smalling, J. David Talley, Jonathan M. Tobis, Paul D. Walter, Franz Weidinger, Gerald S. Werner, Alan C. Yeung, and Paul G. Yock

ABSTRACT: *Background* Intracoronary ultrasound (ICUS) is increasingly used in clinical practice to study the natural history of coronary artery disease and to assess the effects of intracoronary, catheter-based interventions. However, the risk associated with the procedure is not well documented. *Methods and Results* ICUS studies performed in 28 centers were retrospectively included; these centers agreed to contribute to the study among a total of 60 centers initially invited. Among the 2207 ICUS studies, 505 (23%) were performed in heart transplant recipients and 1702 (77%) in nontransplant patients. Indication for ICUS was diagnostic imaging in

915 (41%), drug testing in 244 (11%), and guidance for intracoronary interventions in 1048 patients (47%). There were no complications in 2034 patients (92.2%). In 87 patients (3.9%), complications occurred but were judged to be “not related” to ICUS by the operator. In 63 patients (2.9%), spasm occurred during ICUS imaging. In 9 patients (0.4%), complications other than spasm were judged to have a “certain relation” to ICUS, including acute procedural events in 6 (3 acute occlusion, 1 embolism, 1 dissection, and 1 thrombus) and major events in 3 patients (2 occlusion and 1 dissection; all resulting in myocardial infarction). In 14 patients (0.6%), complications with “uncertain relation” to ICUS were recorded, including acute procedural events in 9 (5 acute occlusion, 3 dissection, and 1 arrhythmia) and major events in 5 patients (2 myocardial infarction and 3 emergency coronary artery bypass surgery). The incidence of acute procedural or major complications judged to be associated with ICUS (uncertain relation or certain relation to ICUS) was compared in different patient groups. The complication rate was higher in patients with unstable angina or acute myocardial infarction (2.1% events) as compared with patients with stable angina pectoris and asymptomatic patients (0.8% and 0.4%, respectively; $\chi^2=10.9$, $P<.01$). These complications were also more frequent in patients undergoing interventions (1.9%) as compared with transplant and nontransplant patients undergoing diagnostic ICUS imaging (0% and 0.6%, respectively; $\chi^2=13.5$, $P<.001$). Adverse events were few, and no association was detected between these events and the size or type of ICUS catheter used. *Conclusions* ICUS is associated with (but not necessarily the direct cause of) a minor acute clinical risk. Vessel spasm is the most frequent event occurring during ICUS. Other complications predominantly occur in patients with acute coronary syndromes and during guidance for intervention.

Key Words: ultrasonics ■ coronary disease ■ risk factors

Intracoronary ultrasound (ICUS) is a new technique that provides two-dimensional, tomographic views of the coronary vessel lumen and wall morphology in vivo.[1] Compared with contrast angiography, ICUS may have some advantages in the direct visualization of atherosclerotic plaque[2 3] and plaque calcification[4 5] as well as determination of residual lumen size and identification of dissections after catheter-based, intracoronary interventions.[4 5 6 7 8 9 10 11] Therefore, ICUS has the potential to be used in the clinical setting for the guidance of intracoronary interventions and to study the natural history of coronary atherosclerosis and transplant vasculopathy.[1 2 3 4 5 6 7 8 9 10 11]

Although ICUS is now increasingly used in practice,[2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18] the risk associated with the procedure is not well defined. Only a few studies have addressed complications associated with ICUS; these studies included relatively small numbers of patients from single centers.[2 12 13 14 15 16 19] Reports on complications other than vessel spasm[20] are extremely rare, and the overall incidence, type, and predictors of more serious complications are unknown. The purpose of the present retrospective multicenter study is, for the first time, to analyze acute complications associated with the clinical use of ICUS in a large number of patients.

METHODS

Study Protocol

ICUS examinations performed in 28 domestic and international centers were included. We attempted to identify all centers actively performing ICUS by contacting industry and academic sources. Among the 60 centers contacted, 15 declined to participate and 14 did not respond to the invitations; 3 other centers had <10 cases performed at that time and were excluded. All adequately documented studies performed in the centers before July 31, 1993, were retrospectively included. Cases during which the ICUS catheter was introduced into the coronary arteries were considered regardless of whether an adequate image could be obtained or not. Attempted ICUS studies were also included if at least the guide wire had been introduced into the vessel with the intention of performing an ICUS study. Studies performed with catheters that combine imaging and interventional capabilities were not considered for this study.

The data were collected from the centers using a uniform case record form. The patients' records were analyzed for demographic data, medical history, and clinical status at the time of the ICUS study. The coronary vessels were imaged, and the most distal position of the ICUS catheter in each vessel was recorded. The indications to perform the ICUS studies were categorized into diagnostic evaluation, drug testing, or guidance for a catheter-based intervention. If ICUS was performed during an intervention, the device type and the temporal relation between the intervention and the ICUS study were recorded. To estimate the experience of the operators for the ICUS study, the patients were categorized into different groups according to the number of prior ICUS studies performed by the center (<20, 21 to 100, and >100 studies). Informed consent and institutional review board approval was obtained according to the usual approach of the study centers and was not specifically reported for this study. Although the participating centers are identified in the

"Appendix," data registry and analysis were blinded with respect to the contributing centers.

By consensus of the investigators during the organization of the study, the size of the ICUS catheter but not the manufacturer was reported. Since each catheter type used in this study had a unique size, we chose the size to identify the catheter. Eight different catheter sizes were used, ranging in size from 3.5F to 5.5F. Three catheter types had solid-state design with a central coaxial guide wire lumen. The other five catheters were mechanical systems; these devices were either passed through a plastic introducing sheath (two types) or the catheter was introduced over a guide wire that was offset relative to the imaging core with a 1-cm (one type) or 30-cm (two types) guide wire sleeve. Complication rates were initially analyzed for catheter sizes <4.0F, 4.0F to 4.5F, and >4.5F, including all 2207 ICUS examinations. In addition, complications were analyzed separately for each of the eight catheter sizes in a subgroup of 1896 examinations that were performed by the centers agreeing on this type of analysis.

ICUS Complications

All cardiac complications occurring during and 24 hours after the procedure were reported with regard to the type of complication, required treatment, and final patient outcome. In all cases, the causal relation between the ICUS study and the complication was assessed by the operator. The potential causal relation between ICUS imaging and the complication was assigned to one of three predefined categories by the operator of the procedure: Events were characterized as having a "certain relation" to ICUS when the complication had causative and temporal relation to ICUS. If a complication could clearly be attributed to other procedures than ICUS, the association was considered as "not related" to ICUS.

When the events could have been caused by ICUS, by another procedure, or potentially occurred randomly, an “uncertain relation” to ICUS imaging was noted.

The type of complication was categorized according to the clinical relevance of the event into major complication, acute procedural complication, and vessel spasm. Major complications included nonfatal myocardial infarction, emergency coronary artery bypass surgery, or death. Acute procedural complications were considered as acute vessel occlusion (reopened during procedure), dissection, thrombus formation, embolism, or significant arrhythmias requiring immediate treatment and not resulting in major complications. These were acute events that had the potential to evolve into more severe clinical complications; however, appropriate therapy prevented major adverse outcomes. The types of the acute procedural complications were classified by the operators according to their individual judgment; standardized definitions for these events were not used. Vessel spasm (requiring intracoronary nitroglycerin administration) during ICUS imaging was also considered as an ICUS complication and categorized in a separate group. To avoid listing patients in different complication groups, for this report the events are categorized under their worst final outcome. Myocardial ischemia occurring while the ICUS catheter was advanced into a lesion was not considered as a complication when ischemia immediately disappeared after withdrawal of the ICUS catheter. Technical problems of the ICUS system were also reported but were not considered as clinical complications if the patients were not affected other than by prolongation of the procedure. The ultrasound recordings or angiograms of the studies with complications were not reviewed by the core center.

Study Centers

The 28 participating centers were located in Austria (2 centers), Belgium (1 center), France (1 center), Germany (7 centers), the Netherlands (1 center), and the United States (16 centers). The number of ICUS studies contributed by each center was <50 in 12 centers (43%), 50 to 100 in 8 centers (29%), 100 to 200 in 7 centers (25%), and >200 in 1 center (4%); the median number of patients studied by each center was 59. The ICUS studies were performed during a time period of 6 to 43 months (median, 15 months). Three ICUS studies (0.1%) were performed in 1989, 150 in 1990 (7%), 429 in 1991 (19%), 1196 in 1992 (54%), and 429 in 1993 (19%) (until July 31).

Statistical Analysis

Data are presented as mean±1 SD. Statistical analysis for differences between patients with and without complications was performed using the χ^2 test for nominal variables and the Mann-Whitney rank sum test for ordinal variables. Significances of multiple comparisons were confirmed by the method of Bonferroni-Holm. A value of $P<.05$ was considered significant.

RESULTS

Baseline Characteristics

In the 28 participating centers, 2207 patients were examined by ICUS, including 505 cardiac transplant recipients and 1702 nontransplant patients. Indication for the ICUS study was diagnostic imaging in 915 (41%), drug testing in 244 (11%), and guidance for an intervention in 1048 patients (47%). The baseline characteristics, the size of the ICUS catheters, and the coronary vessels studied by ICUS are listed in Table 1. The most distal location of the ICUS catheter was the proximal part of the vessel in 262 patients (12%), the

midvessel in 808 patients (37%), and the distal vessel in 764 patients (35%); branches were imaged in 32 patients (1%), and the location of the ICUS catheter was not exactly reported in 301 patients (14%).

Among the 1048 patients undergoing ICUS imaging during interventions, balloon angioplasty was performed in 687 (66%), directional atherectomy in 238 (23%), stent placement in 81 (8%), laser angioplasty in 31 (3%), rotational atherectomy in 6 (0.6%), and other techniques in 5 patients (0.5%). ICUS was performed only before the intervention in 104 patients (10%), only after in 429 (41%), and both before and after the procedure in 515 patients (49%).

Complications of ICUS

In the study group, 2034 of the 2207 patients (92.2%) had uncomplicated procedures, and 87 (3.9%) had complications that were judged to be not related to ICUS imaging. In 63 patients (2.9%), spasm occurred during ICUS imaging. All other complications that had either certain relation or uncertain relation to ICUS are listed in Table 2.

In 9 patients (0.4%), complications (other than spasm) were reported that had certain relation to the ultrasound procedure as judged by the operator. These complications were acute procedural complications in 6 patients (3 acute occlusion, 1 embolism, 1 dissection, and 1 thrombus) and major complications in 3 patients (2 occlusion and 1 dissection; all resulting in myocardial infarction). Table 3 lists individual data for these patients. Among the 3 patients suffering from myocardial infarction, 1 patient had acute occlusion after angioplasty and subsequent ICUS imaging; the patient was treated with recanalization and angioplasty. In one of the patients, the ICUS catheter possibly picked up a flap or entered a dissection plane after angioplasty; repeat angioplasty was required. In the third patient with ICUS-related myocardial infarction, an extensive dissection

remote from the previously dilated lesion in the right coronary artery occurred after ICUS imaging; angioplasty of the vessel was necessary.

In 14 patients (0.6%), complications were recorded that had uncertain relation to ICUS as judged by the operator. These events were acute procedural complications in 9 patients (5 acute occlusion, 3 dissection, and 1 arrhythmia) and major complications in 5 patients (2 myocardial infarction and 3 emergency coronary artery bypass surgery) (Table 4). In 9 of the 2207 patients (0.4%), the ICUS study was interrupted due to technical failure of the ICUS system, including 6 patients with guide wire winding and 3 patients with broken catheter; in none of these cases was the patient affected.

Factors Associated With ICUS Complications

In 2120 of the 2207 patients, possible factors associated with the occurrence of ICUS complications could be evaluated; the 87 patients with complications judged to be not related to ICUS were excluded for this analysis. As listed in Table 5, the incidence of spasm was not associated with any identifiable demographic, clinical, or procedural variables. The incidence of the other complications (acute procedural and major events) was significantly increased in 717 patients with unstable angina or acute myocardial infarction before the procedure. Complications occurred in 15 of these patients (2.1%) as compared with 5 of 608 patients (0.8%) with stable angina pectoris and 3 of 795 patients (0.4%) without or with unspecific symptoms (χ^2=10.9, *P*<.01). Acute procedural or major complications (except spasm) were noted in 19 of 975 patients (1.9%) undergoing ICUS during catheter-based interventions as compared with none of the cardiac transplant recipients and 4 of 650 nontransplant patients undergoing diagnostic ICUS only (χ^2=13.5, *P*=.001). Complications occurred in 1 of 619 patients (0.2%) undergoing ICUS before the intervention

compared with 18 of 944 undergoing ICUS after the procedure (1.9%; χ^2=8.1, *P*<.01). All other variables showed no significant association with the occurrence of acute procedural or major complications. Incidence of complications possibly associated with ICUS was also similar in patients undergoing balloon angioplasty (16 of 626 patients, 2.6%) or directional atherectomy (3 of 207 patients, 1.4%; *P*=NS). There was also no significant difference in the incidence of complications during ICUS imaging of proximal segments (3 of 262 patients, 1.1%), midsegments (12 of 808 patients, 1.5%), and distal coronary segments (5 of 764 patients, 0.7%). Although not statistically significant, there was a trend for decreasing incidence of acute procedural and major complications (other than spasm) with more advanced experience with the ICUS technique. The complications are categorized according to the number of cases done by the center or operator at the time the complications occurred. The incidence of complications for patients studied with early (≤20 ICUS studies performed), intermediate (21 to 100 studies), and advanced ICUS experience (>100 studies) was 1.6% (8 of 499 patients), 1.1% (12 of 1074 patients), and 0.5% (3 of 547 patients), respectively (χ^2=2.7, *P*=.26).

The incidence of ICUS complications was also similar for catheter size <4.0F, 4.0F to 4.5F, and >4.5F (Table 5). In addition to this analysis, 25 centers (contributing 1896 ICUS examinations) agreed to analyze complications separately for each of the eight different catheter types (Table 6). The incidence of minor and major ICUS complications during use of these catheters ranged between 0% and 1.9%; the complication rate was not significantly different for the various ICUS catheter sizes. An increased incidence of spasm (17.5%) was reported by a single center in a small number of

patients (n=40) in whom a catheter was used that is no longer commercially available.

DISCUSSION

Although several studies have shown that ICUS may be superior to contrast angiography in the direct visualization of plaque[2 3] and in the assessment of residual lumen and morphological changes after intracoronary interventions,[4 5 6 7 8 9 10 11] the clinical benefit of ICUS imaging has not been demonstrated in a randomized trial format. Therefore, it is of particular importance to determine potential complications that can result from this procedure. The present multicenter study is the first large survey of the clinical applications and complications of ICUS imaging.

Risks of ICUS

This retrospective study demonstrates that ICUS imaging is associated with (but not necessarily the direct cause of) a small acute clinical risk. Vessel spasm is the most frequent event, occurring in 2.9% of the studies. Acute procedural complications (other than spasm) with certain relation to ICUS imaging occurred in 0.3% and major complications in 0.1% of the ICUS studies. Complications with uncertain relation to ICUS were acute procedural events in 0.4% and major events in 0.2%. The risk for these complications was significantly increased in patients with acute coronary syndromes and in patients studied after intracoronary interventions. Complication rates of ICUS examinations performed for diagnostic reasons only or performed before interventions were relatively low. In this retrospective, nonrandomized survey, the size of the ICUS catheter and the center experience with the technique had no significant impact on the complication rates.

Several groups have reported their clinical experience with ICUS during the last few years.[2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18] Nevertheless, only limited information about acute complications of this procedure is available. Tobis et al[12] studied 27 patients after balloon angioplasty; 3 patients (11%) developed spasm, 4 patients (15%) had angina during ICUS imaging, and in 1 patient a dissection extended during ICUS imaging, requiring repeat balloon angioplasty. After balloon angioplasty, Nissen et al[14] observed spasm during ICUS in 5 of 51 patients (10%). Other groups reported no complications of ICUS imaging after balloon angioplasty[12] or during the use of a combined angioplasty/imaging catheter.[16] In a preliminary report from Erbel et al,[19] 11 of 229 ICUS studies (4.8%) could not be completed due to technical or patient-related complications. Recent data indicate that the risk of ICUS is lower with less severe coronary disease. No complications occurred in 20 patients with coronary stenoses <50% studied by Hodgson et al.[13] St. Goar et al[2] performed ICUS in 80 heart transplant recipients (75 with normal angiograms); the only complication was spasm occurring in 4 of the patients (5%).

The incidence of complications encountered in relation to the ICUS procedure is consistent with safety data from other intracoronary procedures. As might be expected, complications from therapeutic catheter interventions are generally higher than for ICUS imaging due to the greater extent of plaque disruption. During balloon angioplasty, death occurs in 0.1% to 1.0%, emergency coronary bypass surgery in 1.4% to 3.6%, and nonfatal myocardial infarction in 1.1% to 5.0% of the patients.[21 22 23 24] Among the minor complications during angioplasty, prolonged angina pectoris is observed in 4.7% to 6.8%, occlusion in 1.7% to 4.9%, and dissections in 3.2% to 4.8% of the procedures, whereas embolism, perforation, and tamponade are extremely rare events. The complication rate of directional

atherectomy is similar to balloon angioplasty; emergency bypass surgery, myocardial infarction, and death occur in 1.5% to 5.5%, 1.8% to 4.5%, and approximately 1.0% of the patients, respectively.[25] [26] Among diagnostic intracoronary catheters, safety data are available for the 1-mm intracoronary Doppler ultrasound catheter: 1.4% of patients studied by Wilson et al[27] had abrupt coronary occlusion probably related to catheter-induced vasospasm. The experience with intracoronary angioscopy is still limited, and representative data on complications from this method are currently not available.[28]

In the present study, acute occlusion after balloon angioplasty accounts for 10 of the 23 complications (43%) (except spasm) with certain or uncertain relation to ICUS. Vessel occlusion after angioplasty alone can be a delayed phenomenon, occurring in 50% of cases later than 10 minutes after completion of the procedure.[29] Since ICUS imaging delays the termination of the procedure, it is possible that some proportion of the closures attributed to ICUS may have occurred even without imaging.

Limitations of the Study

There are some significant limitations inherent in our retrospective study design.

(1) Most of the complications (19 of 23) possibly related to ICUS occurred in association with interventions. The cause of the complications often remained unclear with respect to the contribution of the ultrasound catheter. The design of the current study required operators to categorize the complications as certain relation, uncertain relation, or not related to the ICUS procedure. Clearly, there is no external, objective standard to differentiate certain relation and uncertain relation to ICUS. It is also possible that complications judged by the operator to be not related to ICUS were in fact

influenced by the imaging procedure. To properly assess the incremental risk of ICUS after interventions would require a randomized study comparing interventions with ICUS imaging (but without change of decisions by ICUS results) with those without ICUS.

(2) A related problem with our retrospective analysis is that the ICUS complication rates were relatively small as compared with the historical event rates in patients with acute coronary syndromes and/or those undergoing interventions. It is therefore not clear whether the events that were designated as related to ICUS in the present study in fact have a causal relation to this procedure or only coincide with ICUS imaging.

(3) Some details of the ICUS studies (duration of ICUS imaging, prophylactic use of nitroglycerin, and so forth) were not adequately reported by all centers and are not included in the analysis.

(4) The effective operator experience from the standpoint of safety of ICUS imaging is determined by multiple factors (general interventional experience, number of prior ICUS studies). In the present study, the number of prior ICUS studies was considered as the only marker for the experience.

(5) Cases from the early phases of ICUS technology development were included in this study. Complication rates were therefore assessed in a developing rather than a stable phase of the technique. Although there was no statistically significant difference in complication rates as a function of catheter size in this study, a trend toward lower rates in both acute procedural/major complications and spasm was seen with the smallest catheters in this study. As still smaller catheters enter clinical use, the risk profile for ICUS imaging may be lower than the overall rates reported in this study.

(6) The selection of the study centers may have affected the results of the study. The 29 centers that declined or did not respond to the invitation might have a higher complication rate than reported in the present study.

(7) Inadequate ICUS images were considered as a complication in the present study; this is arguable since some users may consider inadequate recordings in a costly and potentially harmful diagnostic procedure as a complication.

Beyond the type of complications documented in this study, it is also possible that intracoronary manipulation of the ICUS catheter causes endothelial damage, which could accelerate the atherosclerosis process. We did not attempt to assess this issue in the present study. In transplant recipients restudied 1 year after ICUS imaging, Pinto et al[30] found no significant difference in change of vessel diameters (by quantitative coronary angiography) between the instrumented and noninstrumented arteries. The long-term consequences of intravascular imaging will need to be assessed in larger studies, perhaps with repeat ICUS imaging for plaque quantitation.

Conclusions

This retrospective study shows that ICUS is associated with (but not necessarily the direct cause of) a minor acute clinical risk. Spasm occurred in 2.9% of all ICUS studies. Other acute procedural and major complications that were judged to have certain relation to ICUS occurred in 0.3% and 0.1% of the patients, respectively. Complications with uncertain relation to ICUS occurred in 0.4% (acute procedural complications) and 0.2% (major complications) of the patients. ICUS complications (other than spasm) were related to the presence of acute coronary syndromes and to simultaneous coronary interventions but unrelated to catheter size or center experience.

Prospective, randomized studies will be needed to better determine the risk of intracoronary interventions with and without ICUS imaging.

APPENDIX A

Main Investigators and Institutions

Marie-J. Alibelli-Chemarin, MD; Jacques Puel, MD; Hospital Rangueil, Toulouse, France; Satish K. Choudhary, MD; J. David Talley, MD; Miodrag Stikovac, MD; Patty Hamilton, RN; University of Louisville, Louisville, Ky; Stephen C. Culp, MD; Duke University Medical Center, Durham, NC; Werner G. Daniel, MD; Andreas Mügge, MD; Medizinische Hochschule, Hannover, Germany; Ivan De Scheerder, MD; Universitaire Ziekenhuizen, Leuven, Belgium; Raimund Erbel, MD; Junbo Ge, MD; Günther Görge, MD; Gutenberg Universität, Mainz, Germany; James J. Ferguson III, MD, Texas Heart Institute, Houston, Tex; Guy Friedrich, MD; Nico Moes, MD; Volker Mühlberger, MD; Universitätsklinik Innsbruck, Innsbruck, Austria; Peter Hanrath, MD; E.R. Schwarz, MD; Medizinische Fakultät der RWTH, Aachen, Germany; John McB. Hodgson, MD; Helen Sheehan, RN; University Hospitals of Cleveland, Cleveland, Ohio; Jeffrey M. Isner, MD; St Elizabeth's Hospital, Boston, Mass; Morton J. Kern, MD; Eugene Caracciolo, MD; University Medical Center, St Louis, Mo; Willibald Maier-Rudolph, MD; Werner Rudolph, MD; Deutsches Herzzentrum, Munich, Germany; Michael Mooney, MD; Minneapolis Heart Institute, Minneapolis, Minn; Jeffrey Moses, MD; Lenox Hill Hospital, New York, NY; Harald Mudra, MD; Ludwig-Maximilians-Universität, Munich, Germany; Richard L. Popp, MD; Fausto J. Pinto, MD; Stanford University, Stanford, Calif; Michael Schartl, MD; Wolfgang Boksch, MD; Freie Universität, Berlin, Germany; Patrick W. Serruys, MD; Carlo Di Mario, MD; Pim De Feyter, MD; Jose Baptista, MD; Thoraxcenter, Erasmus Universiteit, Rotterdam, the

Netherlands; Richard W. Smalling, MD; University of Texas Medical School, Houston, Tex; Jonathan M. Tobis, MD; University of California, Irvine, Calif; Paul D. Walter, MD; Cardiology Associates, Lubbock, Tex; Franz Weidinger, MD; Severin Schwarzacher, MD; Dietmar Glogar, MD; Universitätsklinik Wien, Wien, Austria; Gerald S. Werner, MD; Georg-August-Universität, Göttingen, Germany; Christopher J. White, MD; Suresh Jain, MD; Ochsner Foundation Hospital, New Orleans, La; Robert L. Wilensky, MD; Joel M. Cohn, MD; Indiana University, Indianapolis, Ind; Alan C. Yeung, MD; Todd J. Anderson, MD; Ian T. Meredith, MBBS, PhD; Brigham and Women's Hospital, Boston, Mass; Paul G. Yock, MD; Peter J. Fitzgerald, MD, PhD; Dirk Hausmann, MD; University of California, San Francisco, Calif.

Table 1. Baseline Characteristics of 2207 Patients (Table view)

	n	%
Male patients	1725	(70)
Age, y (mean±SD)	56±11	
Clinical presentation		
Transplant patients	505	(23)
Nontransplant patients		
Unstable angina/acute MI	768	(35)
Stable angina	626	(28)
Asymptomatic/other	308	(14)
Indication for ICUS study		
Transplant patients		
Diagnostic	345	(16)
Drug study	158	(7)
Intervention	2	(0.1)
Nontransplant patients		
Diagnostic only	570	(26)
Drug study	86	(4)
Intervention	1046	(47)
No. of vessels imaged per patient		

	n	%
1	2092	(95)
2	106	(5)
3	9	(0.4)
Type of vessel imaged		
LAD	1406	(60)
LCx	301	(13)
RCA	480	(21)
LMCA	25	(1)
Bypass graft	119	(5)
Size of ICUS catheter		
<4.0F	767	(35)
4.0F to 4.5F	898	(41)
>4.5F	542	(25)

MI indicates myocardial infarction; ICUS, intracoronary ultrasound; LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; and LMCA, left main coronary artery.

Table 2. Complications Judged to Have a Certain Relation or an Uncertain Relation to Intracoronary Ultrasound Imaging (Table view)

	Certain/Uncertain: Complications			
	Diagnostic ICUS in Transplant Patients (n=503)	Diagnostic ICUS in Nontransplant Patients (n=656)	ICUS During Interventions (n=1048)	All Patients (n=2207)
Spasm	15/0	21/0	27/0	63 (2.9%)/0
Acute procedural complications				
Acute occlusion	0/0	1/0	2/5	3/5
Dissection	0/0	0/0	1/3	1/3
Thrombus	0/0	1/0	0/0	1/0
Embolism	0/0	0/0	1/0	1/0
Arrhythmia	0/0	0/1	0/0	0/1
Total	0/0	2/1	4/8	6 (0.3%)/9 (0.4%)

	Certain/Uncertain: Complications			
	Diagnostic ICUS in Transplant Patients (n=503)	Diagnostic ICUS in Nontransplant Patients (n=656)	ICUS During Interventions (n=1048)	All Patients (n=2207)
Major complications				
Nonfatal MI	0/0	0/0	3/2	3/2
Emergency CABG	0/0	0/1	0/2	0/3
Death	0/0	0/0	0/0	0/0
Total	0/0	0/1	3/4	3 (0.1%)/5 (0.2%)

ICUS indicates intracoronary ultrasound; MI, myocardial infarction; and CABG, coronary artery bypass graft.

Table 3. Acute Procedural Complications of Intracoronary Ultrasound (Except Spasm) (Table view)

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	ICUS Complications	
					Complication	Treatment
Certain relation to ICUS						
273	48, M	SAP	Mid RCA	Post PTCA	Occlusion	PTCA
760	58, M	Other	Mid RCA	Post PTCA	Occlusion	PTCA
1011	51, M	Acute MI	Mid Cx	Diagnostic	Occlusion	PTCA
1088	57, M	SAP	Distal RCA	Post PTCA	Air embolism	NTG, flushing
1172	67, M	UAP	Distal RCA	Post PTCA	Dissection	PTCA
2057	65, F	UAP	Mid LAD	Diagnostic	Thrombus	Thrombolysis
Uncertain relation to ICUS						
390	49, M	SAP	Mid RCA	Post DCA	Dissection	PTCA
397	56, M	UAP	Mid LAD	Pre DCA	Occlusion	PTCA, DCA
467	60, M	UAP	Mid RCA	Post PTCA	Occlusion (thrombus)	Thrombolysis

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	ICUS Complications	
					Complication	Treatment
1155	66, M	UAP	Distal Cx	Post DCA	Dissection	PTCA
1292	66, F	Other	LMCA	Diagnostic	Ventricular tachycardia	Drugs
1581	33, M	SAP	Mid LAD	Post PTCA	Occlusion	PTCA
1630	50, M	UAP	Mid LAD	Post PTCA	Occlusion	PTCA
1964	44, M	UAP	Distal LAD	Post PTCA	Dissection	PTCA
1973	34, M	UAP	Mid LAD	Post PTCA	Occlusion	PTCA

ICUS indicates intracoronary ultrasound; SAP, stable angina pectoris; MI, myocardial infarction; UAP, unstable angina pectoris; RCA, right coronary artery; Cx, circumflex artery; LAD, left anterior descending coronary artery; LMCA, left main coronary artery; PTCA, percutaneous transluminal coronary angioplasty; DCA, directional coronary atherectomy; and NTG, nitroglycerin.

Table 4. Major Complications of Intracoronary Ultrasound (Table view)

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	Complications of ICUS		
					Complication	Treatment	Worst Clinical Outcome
Certain relation to ICUS							
268	52, M	UAP	LAD	Post PTCA	Occlusion	PTCA	MI
755	62, M	UAP	Prox LAD	Post PTCA	Occlusion	PTCA	MI
1320	82, M	UAP	Distal RCA	Post PTCA	Dissection	PTCA	MI
Uncertain relation to ICUS							
312	51, M	SAP	Mid RCA	Post PTCA	Dissection	Perfusion catheter	CABG
413	73, M	UAP	Prox LAD	Post DCA	Side branch occlusion	. . .	MI
468	62, F	UAP	Graft	Post PTCA	Thrombus, occlusion	Thrombolysis	MI

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	Complications of ICUS		
					Complication	Treatment	Worst Clinical Outcome
1409	50, F	SAP	Prox LAD	Diagnostic	Thrombus, occlusion	PTCA	CABG
2079	51, M	UAP	Mid LAD	Post PTCA	Dissection	CABG	CABG

ICUS indicates intracoronary ultrasound; UAP, unstable angina pectoris; SAP, stable angina pectoris; LAD, left anterior descending coronary artery; Prox, proximal; RCA, right coronary artery; PTCA, percutaneous transluminal coronary angioplasty; DCA, directional coronary atherectomy; CABG, coronary artery bypass graft; and MI, acute myocardial infarction.

Table 5. Incidence of Complications With Certain or Uncertain Relation to Intravascular Ultrasound Imaging: Correlation to Demographic, Clinical, and Procedural Variables (Table view)

Procedural	No.	Complications			
		Spasm		Acute+ Major	
		No.	(%)	No.	(%)
All patients[1]	2120	63	(3.0)	23	(1.1)
Male patients	1657	52	(3.1)	21	(1.3)
Age, y (mean±SD)	56.2±11.3	53.7±13.1		56.0±11.5	
Presentation					
Unstable angina/acute MI	717	22	(3.0)	15	(2.1)[4]
Stable angina	608	13	(2.1)	5	(0.8)
Asymptomatic/other	795	28	(3.5)	3	(0.4)
Indication for ICUS study					
Diagnostic in transplants	495	15	(3.0)	0	(0)
Diagnostic in nontransplants	650	21	(3.2)	4	(0.6)
Interventions	975	27	(2.8)	19	(1.9)[4]
Coronary vessel imaged[2]					
Left anterior descending artery	1360	43	(3.2)	11	(0.8)
Left circumflex artery	288	5	(1.7)	2	(0.7)
Right coronary artery	452	14	(3.1)	8	(1.8)
Other	139	2	(1.4)	2	(1.4)
Size of ICUS catheter					
<4.0F	734	20	(2.7)	10	(1.2)

Procedural	No.	Complications			
		Spasm		Acute+ Major	
		No.	(%)	No.	(%)
4.0F to 4.5F	855	26	(3.0)	10	(1.2)
>4.5F	531	17	(3.2)	3	(0.6)
Center experience (No. of cases)[3]					
1 to 19	499	14	(2.8)	8	(1.6)
20 to 100	1074	28	(2.6)	12	(1.1)
>100	547	21	(3.8)	3	(0.5)

MI indicates myocardial infarction; ICUS, intracoronary ultrasound.
[1] Eighty-seven patients with complications unrelated to ICUS imaging were excluded for this analysis;
[2] including patients with >1 vessel imaged;
[3] complications are categorized according to the number of cases done by the center at the time the complication occurred;
[4] *P*<.01.

Table 6. Incidence of Complications With Certain or Uncertain Relation to Intravascular Ultrasound Imaging: Importance of Catheter Size (Table view)

Catheter Size	No.	Complications			
		Spasm		Minor+ Major	
		No.	(%)	No.	(%)
All sizes	1896	57	(3.0)	20	(1.1)
3.5F	459	7	(1.5)	5	(1.1)
3.9F	219	9	(4.1)	4	(1.8)
4.3F	776	26	(3.4)	9	(1.2)
4.5F	3	0	(0)	0	(0)
4.8F	261	7	(2.7)	1	(0.4)
4.9F	40	7	(17.5)[1]	0	(0)
5.0F	54	0	(0)	1	(1.9)
5.5F	84	1	(1.2)	0	(0)

Twenty-five centers contributing 1896 ultrasound examinations agreed to analyze complications separately for each catheter size.
[1] *P*<.001.

ARTICLE INFORMATION

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Correspondence

Correspondence to Paul G. Yock, MD, Division of Cardiovascular Medicine, Stanford University School of Medicine, 300 Pasteur Dr, H3554, Stanford, CA 94305.

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REFERENCES

1. Yock PG, Johnson EL, Linker DT. Intravascular ultrasound: development and clinical potential. *Am J Card Imaging.* 1988;*2*:185-193.
2. St. Goar FG, Pinto FJ, Alderman EL, Valantine HA, Schroeder JS, Gao SZ, Stinson EB, Popp RL. Intracoronary ultrasound in cardiac transplant recipients: in vivo evidence of 'angiographically silent' intimal thickening. *Circulation.* 1992;*85*:979-987. Crossref. PubMed.
3. Anderson TJ, Meredith IT, Uehata A, Mudge GH, Selwyn AP, Ganz P, Yeung AC. Functional significance of intimal thickening as detected by intravascular ultrasound early and late after cardiac transplantation. *Circulation.* 1993;*88*:1093-1100. Crossref. PubMed.
4. Honye J, Mahon DJ, Jain A, White CJ, Ramee SR, Wallis JB, Al-Zarka A, Tobis JM. Morphological effects of coronary balloon angioplasty in vivo assessed by intravascular ultrasound imaging. *Circulation.* 1992;*85*:1012-1025. Crossref. PubMed.
5. Mintz GS, Douek P, Pichard AD, Kent KM, Satler LF, Popma JJ, Leon MB. Target lesion calcification in coronary artery disease: an intravascular ultrasound study. *J Am Coll Cardiol.* 1992;*20*:1149-1155. Crossref. PubMed.
6. The GUIDE Trial Investigators. Discrepancies between angiographic and intravascular ultrasound appearance of coronary lesions undergoing intervention: a report of Phase I of the GUIDE Trial. *J Am Coll Cardiol*. 1993;21;118A. Abstract.
7. Werner GS, Sold G, Buchwald A, Kreuzer H, Wiegand V. Intravascular ultrasound imaging of human coronary arteries after percutaneous transluminal angioplasty: morphologic and quantitative assessment. *Am Heart J.* 1991;*122*:212-220. Crossref. PubMed.
8. Davidson CJ, Sheikh KH, Kisslo KB, Phillips HR, Peter RH, Behar VS, Kong Y, Krucoff M, Ohman EM, Tcheng JE, et al. Intracoronary ultrasound evaluation of interventional technologies. *Am J Cardiol.* 1991;*68*:1305-1309. Crossref. PubMed.

9. Tenaglia AN, Buller CE, Kisslo KB, Stack RS, Davidson CJ. Mechanisms of balloon angioplasty and directional coronary atherectomy as assessed by intracoronary ultrasound. *J Am Coll Cardiol.* 1992;*20*:685-691. Crossref. PubMed.
10. Gerber TC, Erbel R, Görge G, Ge J, Rupprecht HJ, Meyer J. Classification of morphologic effects of percutaneous transluminal coronary angioplasty assessed by intravascular ultrasound. *Am J Cardiol.* 1992;*70*:1546-1554. Crossref. PubMed.
11. Hodgson JM, Reddy KG, Suneja R, Nair RN, Lesnefsky EJ, Sheehan HM. Intracoronary ultrasound imaging: correlation of plaque morphology with angiography, clinical syndrome and procedural results in patients undergoing coronary angioplasty. *J Am Coll Cardiol.* 1993;*21*:35-44. Crossref. PubMed.
12. Tobis JM, Mallery J, Mahon D, Lehmann K, Zalesky P, Griffith J, Gessert J, Moriuchi M, McRae M, Dwyer ML, et al. Intravascular ultrasound imaging of human coronary arteries in vivo: analysis of tissue characterization with comparison to in vitro histological specimens. *Circulation.* 1991;*83*:913-926. Crossref. PubMed.
13. Hodgson JM, Graham SP, Savakus AD, Dame SG, Stephens DN, Dhillon PS, Brands D, Sheehan H, Eberle MJ. Clinical percutaneous imaging of coronary anatomy using an over-the-wire ultrasound catheter system. *Int J Card Imaging.* 1989;*4*:187-193. Crossref. PubMed.
14. Nissen SE, Gurley JC, Grines CL, Booth DC, McClure R, Berk M, Fischer C, DeMaria AN. Intravascular ultrasound assessment of lumen size and wall morphology in normal subjects and patients with coronary artery disease. *Circulation.* 1991;*84*:1087-1099. Crossref. PubMed.
15. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty: an observational study using intravascular ultrasound. *Circulation.* 1992;*86*:64-70. Crossref. PubMed.
16. Violaris AG, Linnemeier TJ, Campbell S, Rothbaum DA, Cumberland DC. Intravascular ultrasound imaging combined with coronary angioplasty. *Lancet.* 1992;*339*:1571-1572. Crossref. PubMed.
17. Potkin BN, Keren G, Mintz GS, Douek PC, Pichard AD, Satler LF, Kent KM, Leon M. Arterial responses to balloon coronary angioplasty: an intravascular ultrasound study. *J Am Coll Cardiol.* 1992;*20*:942-951. Crossref. PubMed.
18. Hermiller JB, Tenaglia AN, Kisslo KB, Phillips HR, Bashore TM, Stack RS, Davidson CJ. In vivo validation of compensatory enlargement of atherosclerotic coronary arteries. *Am J Cardiol.* 1993;*71*:665-668. Crossref. PubMed.
19. Erbel R, Ge J, Gerber T, Görge G, Rupprecht HJ, Meyer J. Safety and limitations of intravascular ultrasound: experience with 325 consecutive procedures. *Circulation*. 1992;86(suppl I):I-195. Abstract.

20. Alfonso F, Macaya C, Goicolea J, Iniguez A, Hernandez R, Banuelos C, Castillo JA, Zarco P. Angiographic changes induced by intracoronary ultrasound imaging before and after coronary angioplasty. *Am Heart J.* 1993;*125*:877-880. Crossref. PubMed.

21. Detre K, Holubkov R, Kelsey S, et al. Percutaneous transluminal coronary angioplasty in 1985 and 1977-1981: the National Heart, Lung, and Blood Institute Registry. *N Engl J Med.* 1988;*318*:265-270. Crossref. PubMed.

22. Tuzcu EM, Simpfendorfer C, Badhwar K, Chambers J, Dorosti K, Franco I, Hollman J, Whitlow P. Determinants of primary success in elective percutaneous transluminal coronary angioplasty for significant narrowing of a single major coronary artery. *Am J Cardiol.* 1988;*62*:873-875. Crossref. PubMed.

23. Cowley MJ, Dorros G, Kelsey SF, van Raden M, Detre KM. Acute coronary events associated with percutaneous transluminal coronary angioplasty. *Am J Cardiol.* 1984;*53*:12C-16C. Crossref. PubMed.

24. Bredlau CE, Roubin GS, Leimgruber PP, Douglas JS, King SB, Grüntzig AR. In-hospital morbidity and mortality in patients undergoing elective coronary angioplasty. *Circulation.* 1985;*72*:1044-1052. Crossref. PubMed.

25. Ellis SG, DeCesare NB, Pinkerton CA, Whitlow P, King SB, Ghazzal ZMB, Kereiakes DJ, Popma JJ, Menke KK, Topol EJ, et al. Relation of stenosis morphology and clinical presentation to the procedural results of directional coronary atherectomy. *Circulation.* 1991;*84*:644-653. Crossref. PubMed.

26. Safian RD, Gelbfish JS, Eray RE, Schnitt SJ, Schmidt DA, Baim DS. Coronary atherectomy: clinical, angiographic, and histologic findings and observations regading potential mechanisms. *Circulation.* 1990;*82*:69-79. Crossref. PubMed.

27. Wilson RF, Laughlin DE, Ackhell PH, Chilian WM, Holida MD, Hartley CJ, Armstrong ML, Marcus ML, White CW. Transluminal, subselective measurement of coronary artery blood flow velocity and vasodilator reserve in man. *Circulation.* 1985;*72*:82-92. Crossref. PubMed.

28. Mizuno K, Satomura K, Miyamoto A, Arakawa K, Shibuya T, Arai T, Kurita A, Nakamura H, Ambrose JA. Angioscopic evaluation of coronary-artery thrombi in acute coronary syndromes. *N Engl J Med.* 1992;*326*:287-291. Crossref. PubMed.

29. Ellis SG, Roubin GS, King SB, Douglas JS, Weintraub WS, Thomas RG, Cox WR. Angiographic and clinical predictors of acute closure after native vessel coronary angioplasty. *Circulation.* 1988;*77*:372-379. Crossref. PubMed.

30. Pinto FJ, St. Goar FG, Gao SZ, Chenzbraun A, Fischell TA, Alderman EL, Schroeder JS, Popp RL. Immediate and one year safety of intracoronary ultrasonic imaging: evaluation with serial quantitative angiography. *Circulation.* 1993;*88*:1709-1714. Crossref. PubMed.

Sections

Table 1. Baseline Characteristics of 2207 Patients

	n	%
Male patients	1725	(70)
Age, y (mean±SD)	56±11	
Clinical presentation		
Transplant patients	505	(23)
Nontransplant patients		
Unstable angina/acute MI	768	(35)
Stable angina	626	(28)
Asymptomatic/other	308	(14)
Indication for ICUS study		
Transplant patients		
Diagnostic	345	(16)
Drug study	158	(7)
Intervention	2	(0.1)
Nontransplant patients		
Diagnostic only	570	(26)
Drug study	86	(4)
Intervention	1046	(47)
No. of vessels imaged per patient		
1	2092	(95)
2	106	(5)
3	9	(0.4)
Type of vessel imaged		
LAD	1406	(60)
LCx	301	(13)
RCA	480	(21)
LMCA	25	(1)
Bypass graft	119	(5)
Size of ICUS catheter		
<4.0F	767	(35)
4.0F to 4.5F	898	(41)
>4.5F	542	(25)

MI indicates myocardial infarction; ICUS, intracoronary ultrasound; LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; and LMCA, left main

coronary artery.

Table 2. Complications Judged to Have a Certain Relation or an Uncertain Relation to Intracoronary Ultrasound Imaging

	Certain/Uncertain: Complications			
	Diagnostic ICUS in Transplant Patients (n=503)	Diagnostic ICUS in Nontransplant Patients (n=656)	ICUS During Interventions (n=1048)	All Patients (n=2207)
Spasm	15/0	21/0	27/0	63 (2.9%)/0
Acute procedural complications				
Acute occlusion	0/0	1/0	2/5	3/5
Dissection	0/0	0/0	1/3	1/3
Thrombus	0/0	1/0	0/0	1/0
Embolism	0/0	0/0	1/0	1/0
Arrhythmia	0/0	0/1	0/0	0/1
Total	0/0	2/1	4/8	6 (0.3%)/9 (0.4%)
Major complications				
Nonfatal MI	0/0	0/0	3/2	3/2
Emergency CABG	0/0	0/1	0/2	0/3
Death	0/0	0/0	0/0	0/0
Total	0/0	0/1	3/4	3 (0.1%)/5 (0.2%)

ICUS indicates intracoronary ultrasound; MI, myocardial infarction; and CABG, coronary artery bypass graft.

Table 3. Acute Procedural Complications of Intracoronary Ultrasound (Except Spasm)

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	ICUS Complications	
					Complication	Treatment
Certain relation to ICUS						
273	48, M	SAP	Mid RCA	Post PTCA	Occlusion	PTCA
760	58, M	Other	Mid RCA	Post PTCA	Occlusion	PTCA
1011	51, M	Acute MI	Mid Cx	Diagnostic	Occlusion	PTCA
1088	57, M	SAP	Distal RCA	Post PTCA	Air embolism	NTG, flushing
1172	67, M	UAP	Distal RCA	Post PTCA	Dissection	PTCA
2057	65, F	UAP	Mid LAD	Diagnostic	Thrombus	Thrombolysis
Uncertain relation to ICUS						
390	49, M	SAP	Mid RCA	Post DCA	Dissection	PTCA
397	56, M	UAP	Mid LAD	Pre DCA	Occlusion	PTCA, DCA
467	60, M	UAP	Mid RCA	Post PTCA	Occlusion (thrombus)	Thrombolysis
1155	66, M	UAP	Distal Cx	Post DCA	Dissection	PTCA
1292	66, F	Other	LMCA	Diagnostic	Ventricular tachycardia	Drugs
1581	33, M	SAP	Mid LAD	Post PTCA	Occlusion	PTCA
1630	50, M	UAP	Mid LAD	Post PTCA	Occlusion	PTCA
1964	44, M	UAP	Distal LAD	Post PTCA	Dissection	PTCA
1973	34, M	UAP	Mid LAD	Post PTCA	Occlusion	PTCA

ICUS indicates intracoronary ultrasound; SAP, stable angina pectoris; MI, myocardial infarction; UAP, unstable angina pectoris; RCA, right coronary artery; Cx, circumflex artery; LAD, left anterior descending coronary artery; LMCA, left main coronary artery; PTCA, percutaneous

transluminal coronary angioplasty; DCA, directional coronary atherectomy; and NTG, nitroglycerin.

Table 4. Major Complications of Intracoronary Ultrasound

Patient No.	Age, y, Sex	Clinical Presentation	Vessel	Purpose of ICUS	Complications of ICUS		
					Complication	Treatment	Worst Clinical Outcome
Certain relation to ICUS							
268	52, M	UAP	LAD	Post PTCA	Occlusion	PTCA	MI
755	62, M	UAP	Prox LAD	Post PTCA	Occlusion	PTCA	MI
1320	82, M	UAP	Distal RCA	Post PTCA	Dissection	PTCA	MI
Uncertain relation to ICUS							
312	51, M	SAP	Mid RCA	Post PTCA	Dissection	Perfusion catheter	CABG
413	73, M	UAP	Prox LAD	Post DCA	Side branch occlusion	. . .	MI
468	62, F	UAP	Graft	Post PTCA	Thrombus, occlusion	Thrombolysis	MI
1409	50, F	SAP	Prox LAD	Diagnostic	Thrombus, occlusion	PTCA	CABG
2079	51, M	UAP	Mid LAD	Post PTCA	Dissection	CABG	CABG

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MI indicates myocardial infarction; ICUS, intracoronary ultrasound.

1 Eighty-seven patients with complications unrelated to ICUS imaging were excluded for this analysis;

2 including patients with >1 vessel imaged;

3 complications are categorized according to the number of cases done by the center at the time the complication occurred;

4 *P*<.01.

Table 6. Incidence of Complications With Certain or Uncertain Relation to Intravascular Ultrasound Imaging: Importance of Catheter Size

Catheter Size	No.	Complications			
		Spasm		Minor+ Major	
		No.	(%)	No.	(%)
All sizes	1896	57	(3.0)	20	(1.1)
3.5F	459	7	(1.5)	5	(1.1)
3.9F	219	9	(4.1)	4	(1.8)
4.3F	776	26	(3.4)	9	(1.2)
4.5F	3	0	(0)	0	(0)
4.8F	261	7	(2.7)	1	(0.4)
4.9F	40	7	(17.5)[1]	0	(0)
5.0F	54	0	(0)	1	(1.9)
5.5F	84	1	(1.2)	0	(0)

Twenty-five centers contributing 1896 ultrasound examinations agreed to analyze complications separately for each catheter size.

[1] $P<.001$.