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# High Pressure Assisted Coronary Stent Implantation Accomplished Without Intravascular Ultrasound Guidance and Subsequent Anticoagulation

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***Objectives.*** **The purpose of this study was to determine the efficacy of treatment with antiplatelet therapy and no anticoagulation after high pressure assisted coronary stent implantation performed without intravascular ultrasound (IVUS) guidance.**

***Background.*** **Previous studies have shown that during IVUS-guided Palmaz-Schatz coronary stenting, it is safe to withhold anticoagulation when stent expansion has been optimized by high pressure balloon dilation.**

***Methods.*** **Patients that had successful coronary stenting without IVUS guidance were treated with ticlopidine, 500 mg/day, and aspirin, 325 mg/day, for 1 month and then received only aspirin, 325 mg/day, indefinitely. Patients were not treated with warfarin (Coumadin) or heparin after successful stenting. Clinical and angiographic events were assessed at 1 month.**

***Results.*** **A total of 201 intracoronary stents were implanted in 127 patients with 137 lesions. The average number of stents per lesion was 1.4 ± 0.8, and the average number of stents per patient was 1.6 ± 1.1. Stent deployment was performed for elective indications in 79% of procedures and for emergency indications in 21%. There were four stent thrombosis events for a per patient event rate of 3.1% and a per lesion event rate of 2.9%.**

***Conclusions.*** **After high pressure assisted stenting performed without IVUS guidance, there was an acceptable incidence of 3.1% of stent thrombosis with the combination of short-term ticlopidine and aspirin therapy and no anticoagulation. Although the study involved only 127 patients, the results support the relative safety of stenting without IVUS guidance and with antiplatelet therapy only in comparison to historical trials on stenting performed with postprocedure anticoagulation.**

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Coronary stent implantation has been shown to reduce the morbidity of acute or threatened vessel closure after coronary angioplasty (1,2). The Belgian Netherlands Stent study (BENESTENT) and Stent and Restenosis Study (STRESS) randomized trials comparing stents to angioplasty in the treatment of de novo coronary lesions demonstrated a significant reduction in the angiographic restenosis and late ischemia driven clinical events in the group treated with stents (3,4). The BENESTENT trial also demonstrated a reduction in major clinical events after coronary stent implantation in comparison with coronary angioplasty (3). These contributed to a marked increase in the use of intracoronary stents for the treatment of symptomatic coronary artery disease. The utility of stent implantation, however, continues to be limited by a stringent postprocedure anticoagulation regimen that increases vascular and bleeding complications without providing sufficient protection against stent thrombosis (5–8).

A cause of stent thrombosis was proposed to be stent underexpansion after a study of intravascular ultrasound (IVUS) evaluation after stent deployment demonstrated that 80% of stents were underexpanded when the final result was judged only with angiographic assessment (9,10). In a subsequent prospective study on IVUS-guided coronary stent implantation in which stent expansion was optimized with the use of high pressure balloon dilations, there was a 1.1% stent thrombosis rate in 321 patients treated only with antiplatelet therapy after a successful procedure (11,12).

The strategy of stent implantation with IVUS guidance and elimination of postprocedure anticoagulation therapy also resulted in a reduction in hospital stay (12). However, this strategy adds to the expense and increases procedure time of the stent implantation procedure. Thus, the purpose of the present study was to evaluate the safety and efficacy of treatment with combination ticlopidine and aspirin after a successful stent implantation procedure guided by an angiographic assessment only, without IVUS evaluation.

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**Abbreviations and Acronyms**

| | | |
|---|---|---|
| ACT | = | activated clotting time |
| BENESTENT | = | Belgian Netherlands Stent study |
| ECG | = | electrocardiographic, electrocardiogram |
| IVUS | = | intravascular ultrasound |
| STRESS | = | Stent Restenosis Study |
| TIMI | = | Thrombolysis in Myocardial Infarction |

## Methods

From October 26, 1993 to October 25, 1994, 132 patients underwent successful high pressure assisted intracoronary stent implantation without IVUS guidance. A total of 127 patients (91 consecutive patients in Villa Bianca Hospital, Bari, Italy, and 36 selected patients in Columbus Clinic, Milan, Italy) had a successful coronary stent implantation and did not receive anticoagulation after the stent procedure. The patients from the Columbus Clinic were not a consecutive series of patients because of the general policy of performing stent implantation with IVUS guidance. These patients, however, were not specifically or exclusively low risk patients. In this last group of patients IVUS was not performed because of severe proximal tortuosity in 12 patients (33%) or because of significant angulation (>45°) at the lesion site after placement of a stent with a coil design (Gianturco-Roubin, Wiktor, Cordis stents) in 10 patients (28%).

In these patients the indication for stent implantation was emergent (acute or threatened closure) in eight lesions (22%) and nonemergent (chronic occlusions) in five lesions (14%). These indications are comparable to the ones reported for the entire group.

The entry criteria for the study were evidence of coronary artery disease manifested by clinical symptoms or objective evidence of myocardial ischemia or exercise testing, nuclear scintigraphy or pharmacologic stress echocardiogram, and angiographic evidence of single- or multiple-vessel disease with a target lesion stenosis of >70% by visual assessment. Specific exclusion criteria included 1) small vessels <2.5 mm by visual estimate; 2) angiographically diffuse distal disease that might compromise outflow after stent insertion; 3) patients who were taking Coumadin before the stent procedure and who required anticoagulation with Coumadin for other medical reasons; and 4) suboptimal angiographic results due to residual dissection or suboptimal expansion at the end of the stent procedure that was thought to require continued short-term anticoagulation therapy with Coumadin for 1 month. During the course of this investigation five patients had successful stent implantation without IVUS guidance and received Coumadin therapy after the stent procedure for poor distal run off (n = 2), compromised side branch (n = 2) or residual dissection (n = 1). There were no complications of stent thrombosis in these five patients.

**Stent implantation procedure.** Patients received aspirin, 325 mg, and calcium antagonists before the stent procedure. All coronary tent implantation procedures were performed from the standard femoral artery approach using an 8F or 9F guiding catheter. A bolus of 10,000 U of heparin was administered after insertion of the femoral sheath. A repeat bolus of 5,000 U of heparin was given to maintain an activated clotting time (ACT) >250 s or if the procedure was longer than 3 h. Patients did not receive dextran or dipyridamole (Persantine) before, during or after the stent procedure. After appropriate baseline angiograms were obtained, lesion predilation was performed. There were five different types of stents deployed during this study: the Palmaz-Schatz stent (Johnson and Johnson Interventional Systems Co.), the Gianturco-Roubin stent (Cook Cardiology), the Wiktor stent (Medtronic), the Micro stent (Applied Vascular Engineering) and the Cordis stent (Cordis Corp.). Palmaz-Schatz stents were hand-crimped on balloons and delivered bare as previously described (12). There was no balloon size selection protocol for the stent optimization. Each operator selected an appropriate balloon size based on his or her visual assessment of the angiographic reference diameter. Typically, noncompliant balloons (NC Shadow, SCIMED Life Systems, or High Energy, Mansfield) were used for final high pressure dilations.

The indications for stent deployment were defined as follows. *Acute occlusion* stent implantation was performed to relieve ischemia associated with complete vessel closure (100%) after angioplasty with Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 or 1. *Threatened closure* stent implantation was performed when the angioplasty was complicated by a longitudinal or spiral dissection associated with >50% lumen encroachment (with or without compromised flow) and symptomatic or electrocardiographic (ECG) evidence of ischemia. *Suboptimal result* stent placement was defined as insertion of a stent for a focal dissection or significant vascular recoil after angioplasty that resulted in >50% lumen narrowing not associated with ischemia. *Restenosis* stent implantation was performed for lesions with a history of restenosis after one or more previous angioplasty procedures. *Chronic occlusion* stent insertion was performed after reopening a vessel that had been occluded for longer than 2 months. *Elective stenting* was performed as the intention to stent de novo lesions before the procedure. *Emergency stent implantation* was considered stent implantation performed for acute or threatened closure and acute myocardial infarction.

**Postprocedure medication protocol.** A decision to treat with only antiplatelet therapy at the completion of the stent procedure required angiographic success, defined as the achievement of <20% residual stenosis and no evidence of untreated residual dissection by visual assessment at the time of the stent implantation procedure. After a successful stent implantation procedure, no further heparin was infused. Femoral sheaths were removed when the ACT dropped below 150 s. When a stent procedure was completed in the evening, intravenous heparin was infused until the following morning before being discontinued with subsequent sheath removal. Ticlopidine was not administered before or during the stent procedure but was initiated after a successful procedure.

Antiplatelet therapy with ticlopidine, 500 mg in two equal doses per day, and aspirin, 325 mg/day, was initiated after a successful stent procedure and continued for 1 month. After 1 month, ticlopidine was discontinued and patients were treated with aspirin, 325 mg/day, indefinitely.

**Quantitative angiographic measurements.** Quantitative coronary angiographic analysis was performed using digital calipers by experienced angiographers not involved in the stent procedure. Angiographic measurements were obtained during diastole. The lesions were measured from an optically magnified image in a single, matched "worst" view using digital calipers (Brown and Sharp) using the guiding catheter as the reference object for magnification calibration. Previous studies have shown that digital calipers correlate closely with computer-assisted methods with a low interobserver and intraobserver variability (13,14). Measurements of the reference vessel diameters, minimal lumen diameter and diameter stenosis were obtained on the baseline and final angiograms. The average of the proximal and distal reference vessel diameters was used as the index reference vessel diameter for percent diameter stenosis calculations. When the lesions were total occlusions or at an ostial location, only one reference vessel measurement was possible on the baseline angiogram, and this measurement site was used for the index reference diameters. Lesion length was measured on the baseline angiogram as the distance from the proximal to distal lesion shoulder. Lesions were characterized according to the modified American College of Cardiology/American Heart Association (ACC/AHA) score (15). *Thrombus* was defined as a filling defect seen in multiple projections surrounded by contrast agent in the absence of calcification. TIMI flow grade was recorded at the time of the initial procedure to characterize the indication for stenting, as previously described (16).

**Study end points and events.** The study end points were angiographic and clinical events that occurred within the first month of a successful stent procedure. The short-term events were carefully assessed through regular and uniform telephone contact with all patients between 1 and 5 months after the stent procedure. Any stent thrombosis occurring within the first month of the stent procedure was considered an angiographic event. *Acute thrombotic events* were defined as angiographically documented occlusion with TIMI grade flow 0 at the stent site occurring within 24 h of the stent procedure. *Subacute thrombotic events* were angiographically documented occlusions with TIMI flow grade 0 at the stent site occurring beyond 24 h of the stent procedure. Major clinical events were considered death, aortocoronary bypass surgery, myocardial infarction (Q wave or non–Q wave) and emergency repeat intervention (bail-out stenting or repeat angioplasty). Specific major event definitions were as follows: *death*—any death irrespective of cause. A diagnosis of *myocardial infarction* was made when new pathologic Q waves were documented (≥0.14 s) on an ECG in conjunction with elevation of creatine kinase to greater than twice the upper limit of normal (Q wave myocardial infarction) or if there was elevation of the cardiac enzymes to greater than twice the upper limit of normal without the development of new pathologic Q waves (non–Q wave myocardial infarction). *Emergency coronary artery bypass graft surgery* involved immediate transfer of the patient from the catheterization laboratory to the operating room. *Nonemergent elective coronary bypass surgery* was performed more than 24 h after a stent procedure had failed in the absence of ischemia or evolving myocardial infarction. *Emergency intervention* was bail-out stent implantation or emergency angioplasty performed for ongoing acute ischemia or evolving myocardial infarction in the setting of an angiographically documented stent thrombosis event.

**Table 1.** Clinical Characteristics (n = 127)

| | No. (%) |
|---|---|
| Lesions | 137 |
| Age (yr)* | 58 ± 10 |
| Ejection fraction (%)* | 53 ± 11 |
| Male | 117 (82) |
| Previous myocardial infarction | 40 (62) |
| Previous PTCA | 27 (21) |
| Previous CABG | 10 (8) |
| Multivessel disease | 58 (45) |
| Unstable angina | 56 (44) |
| Smoking | 84 (66) |
| Hypercholesterolemia | 66 (52) |
| Hypertension | 54 (43) |
| Family history | 46 (36) |
| Diabetes | 21 (17) |

*Mean value ± SD. CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

**Statistics.** Continuous variables were expressed as mean value ± SD. Angiographic measurements of baseline and poststent implantation were compared using the paired two-tailed *t* test. Comparisons between the stent thrombosis and nonstent thrombosis groups were performed using the Fisher exact probability test and the Mann-Whitney U test. Differences were considered statistically significant at $p < 0.05$.

## Results

**Clinical, angiographic and procedural characteristics.** A total of 127 patients with 137 stented lesions were treated only with antiplatelet therapy after successful high pressure assisted coronary stent implantation. Intravascular ultrasound evaluation was not performed in any of the lesions. Baseline patient and angiographic characteristics are shown in Tables 1 and 2.

Procedural characteristics of stent implantations are presented in Table 3. Elective stent placement was performed in 108 lesions (79%). Emergency stent deployment was done in 29 lesions (21%). A total of 201 stents were implanted with five different types of stents being used. The average number of stents per lesion was 1.4 ± 0.8 (range 0.5 to 6.0). The average number of stents per patient was 1.6 ± 1.1 (range 0.5 to 6.0). The short Palmaz-Schatz stent and 1- or 2-unit Micro Stents (each unit is 4 mm) were considered half (0.5) stents for calculating the mean number of stents per lesion or patient.

**Table 2.** Baseline Angiographic Characteristics (n = 137)

| | No. (%) |
|---|---|
| Vessel distribution | |
| LAD | 75 (55) |
| RCA | 32 (23) |
| LCx | 19 (14) |
| SVG | 9 (7) |
| LMCA | 2 (1) |
| Lesion site | |
| Ostial | 7 (5) |
| Proximal | 78 (58) |
| Mid | 46 (33) |
| Distal | 6 (4) |
| Lesion type* | |
| A | 20 (15) |
| B1 | 47 (34) |
| B2 | 39 (28) |
| C | 31 (23) |
| Small vessels (<3.0 mm) | 47 (34) |
| Bifurcations | 24 (18) |
| Long lesions (>20 mm) | 21 (15) |
| Chronic occlusions | 16 (12) |
| Thrombus | 11 (8) |
| Bend lesions (>45) | 8 (6) |

*Modified American Heart Association/American College of Cardiology criteria. LCx = left circumflex coronary artery; LAD = left anterior descending coronary artery; LMCA = left main coronary artery; RCA = right coronary artery; SVG = saphenous vein graft.

More than one stent (multiple stents) were implanted in 34 lesions (25%) and 42 patients (33%).

Quantitative angiographic measurements and procedural data are presented in Table 4. The baseline minimal lumen diameter of 0.87 ± 0.50 mm was significantly improved to a final stent diameter of 2.94 ± 0.89 mm. The percent diameter stenosis was improved from 71 ± 18% to 8 ± 14%. The results were achieved using a final balloon size of 3.3 ± 0.4 mm (range 2.5 to 4.5). The maximal inflation pressure at final balloon dilation was 17.4 ± 2.4 atm (range 8 to 20). Pressure ≤10 atm was used for the final balloon dilation in four lesions (3%). In these lesions, final dilations were performed with an oversized balloon to further improve the angiographic result, and low pressure was used in an attempt to limit the risk of vessel rupture. In all of these lesions, high pressure dilations with a smaller, appropriately sized balloon by angiographic variables preceded the final low pressure inflation. The final balloon/artery ratio (proximal reference site) was 1.03 ± 0.14. At the time of postprocedure angiographic measurements, residual dissection was noted at the stent site in six lesions (4.4%). The dissection was proximal to the stent in two lesions (1.5%) and distal to the stent in four lesions (2.9%).

**Table 3.** Stent Implantation Procedure Characteristics (n = 137)

| | No. (%) |
|---|---|
| Emergency stent implantation | 29 (21) |
| Threatened closure | 23 (17) |
| Acute closure | 5 (4) |
| Acute myocardial infarction | 1 (1) |
| Nonemergent stent implantation | 108 (79) |
| Elective | 89 (65) |
| Suboptimal PTCA | 7 (5) |
| Chronic occlusion | 16 (12) |
| Total stents | 201 |
| Stent type and number | |
| Palmaz-Schatz (15 mm) | 126 (63) |
| Short Palmaz-Schatz (7 mm) | 24 (12) |
| Gianturco-Roubin | 29 (14) |
| Wiktor | 16 (8) |
| Micro | 4 (2) |
| Cordis | 2 (1) |
| Number of stents/lesion | |
| 1 stent/lesion | 103 (75) |
| 2 stents/lesion | 19 (14) |
| 3 stents or more/lesion | 15 (11) |
| Average number of stents/lesion* | 1.4 ± 0.8 |
| Average number of stents/patient* | 1.6 ± 1.1 |

*Mean value ± SD.

**Table 4.** Quantitative Angiographic Measurements (n =137)

| | Baseline | Final |
|---|---|---|
| Reference vessel (mm) | 3.12 ± 0.41 | 3.13 ± 0.40 |
| Minimal lumen diameter (mm) | 0.87 ± 0.50 | 2.94 ± 0.89* |
| Diameter stenosis (%) | 71 ± 18 | 8 ± 15* |
| Lesion length (mm) | 12.22 ± 7.72 | |
| Final balloon size (mm) | | 3.32 ± 0.38 |
| Balloon/artery ratio | | 1.03 ± 0.14 |
| Maximal inflation pressure (atm) | | 17.4 ± 2.4 |
| Residual dissection [no. (%)]† | | 6 (4.4%) |

*$p < 0.0001$ (comparison between baseline and post-stent implantation). †Dissection noted at the time of core laboratory angiographic measurements were performed. Data are presented as mean value ± SD, unless otherwise indicated.

**Short-term angiographic and clinical events.** The mean hospital stay after stent implantation was 2.1 ± 1.8 days. Follow-up was obtained in all patients between 1 and 5 months after the stent implantation procedure at a mean of 4.9 ± 2.3 months. There were four stent thrombosis events, giving a per lesion stent thrombosis event rate of 2.9% and a per patient event rate of 3.1%. Acute stent thrombosis occurred in one patient (0.8%) 3 h after the procedure. Subacute stent thrombosis occurred in three patients (2.4%) with one lesion each (2.2%) at 3 days (n = 1) and 5 days (n = 2) after the stent implantation procedure. The stent thrombosis events occurred during the hospital stay in three patients (2.4%) and after the hospital stay in one patient (0.8%). An emergency intervention was performed in all four patients, with additional rescue stent implantation being necessary in two of the patients (1.6%). One of these patients underwent emergency bypass surgery owing to extensive thrombus even after the intervention. One patient developed Q wave myocardial infarction and three patients had non–Q wave infarction.

No major clinical event occurred in the other patients within the 1-month follow-up period. There was no vascular or bleeding complications after the stent implantation procedure. Leukopenia was noted in one patient (1%) due to ticlopidine

**Table 5.** Factors Associated With Stent Thrombosis

| Factors | No Stent Thrombosis (n = 133) | Stent Thrombosis (n = 4) |
|---|---|---|
| Unstable angina | 58 (44) | 2 (50) |
| Prior myocardial infarction | 78 (59) | 4 (100) |
| Emergency indication | 28 (26) | 0 (0) |
| Occlusion on baseline angiogram | 18 (14) | 2 (50) |
| Mean reference vessel (mm) | 3.10 ± 0.40 | 3.55 ± 0.50 |
| Baseline MLD (mm) | 0.89 ± 0.49 | 0.28 ± 0.33* |
| Baseline diameter stenosis (%) | 70 ± 17 | 93 ± 8* |
| Final stent MLD (mm) | 2.96 ± 0.89 | 2.26 ± 0.29* |
| Final diameter stenosis (%) | 7 ± 15 | 34 ± 3* |
| Lesion length (mm) | 12.2 ± 7.7 | 12.4 ± 9.3 |
| Inflation pressure (atm) | 17.4 ± 2.4 | 18.0 ± 1.3 |
| Balloon/artery ratio | 1.04 ± 0.15 | 0.90 ± 0.06* |

*$p < 0.05$. Data are presented as mean value ± SD or number (%). MLD = Minimal lumen diameter.

within the first month of the stent procedure. This patient was observed in the hospital for 5 days and leukopenia resolved after discontinuation of ticlopidine.

**Comparison between the stent thrombosis and no stent thrombosis groups.** The clinical and procedural factors in the group with stent thrombosis (4 lesions) and the group with no stent thrombosis (133 lesions) were analyzed (Table 5), although statistical comparison between the two groups suffers from the low number of overall patients and the low number of stent thrombosis events. Stent thrombosis occurred more frequently in lesions with occlusions at baseline angiography. Dilation strategies also played a role in stent thrombosis. Stent thrombosis occurred more frequently with a low final balloon/artery (proximal reference) ratio and high residual stenosis (>30%), which may be a reflection of the low final balloon/artery ratio. The frequency distribution of the final percent diameter stenosis, the balloon/artery ratio and final stent minimal lumen diameter and the relation to stent thrombosis are shown in Figure 1. There was no difference at the maximal inflation pressure between two groups. None of the lesions with stent thrombosis had angiographically evident calcification or evidence of residual dissection at the time of the stent implantation or at the time the final angiographic measurements were performed.

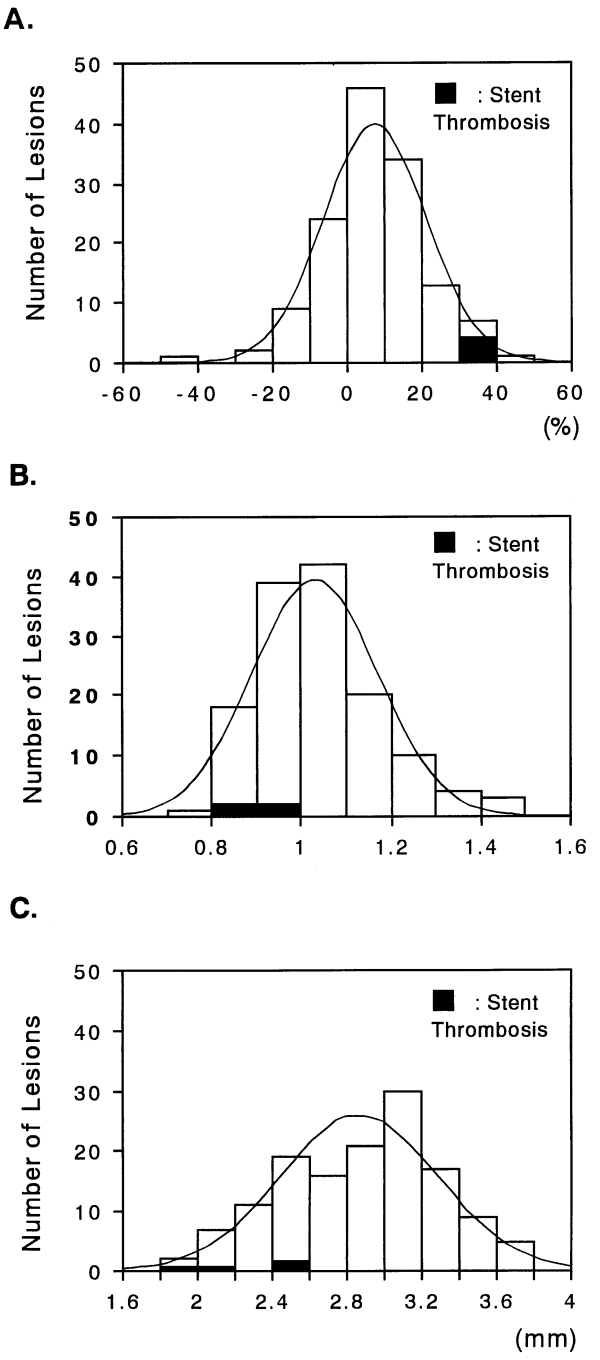


**Figure 1. A,** Frequency distribution of final percent diameter stenosis. **B,** Frequency distribution of balloon/artery (proximal reference) ratio. **C,** Frequency distribution of final stent minimal lumen diameter.

## Discussion

Previous IVUS-guided stent implantation studies demonstrated the benefit of final high pressure balloon dilations to appropriately and safely expand stents and emphasized the clinical importance of achieving good stent expansion in patients treated only with antiplatelet agents and no postprocedure anticoagulation (10–12). The present study evaluated a strategy of high pressure optimization without IVUS guidance or postprocedure anticoagulation. In a mixed population of 127 patients who underwent both elective and emergency stent implantation, there was a stent thrombosis event rate of 3.1% per patient and there were no vascular or bleeding complications due to the absence of postprocedure anticoagulation.

**Comparison with other studies.** The stent thrombosis rate in the present study was similar to the stent thrombosis rates of 3.5% for elective stent implantation in both the BENESTENT and the STRESS trials, and slightly less than the stent thrombosis rate of 4.7% for both elective and emergency stent implantation in the STRESS trial despite treatment without

anticoagulation (3,4). The absence of vascular or bleeding complications in the present study is in distinct contrast to the 7.1% and 13.5% vascular complication rates reported for these multicenter trials. More recently, other investigators have reported on the treatment with antiplatelet therapy and no Coumadin after stent implantation performed with angiographic evaluation only (17–21). Barragan et al. (17) reported a stent thrombosis rate of 4.2% and an incidence of vascular complications of 4.6% in 238 patients who were treated with ticlopidine (started 3 days before stent implantation) and a continuous heparin infusion for 24 h followed by low molecular weight heparin after the stent implantation procedure. The study was performed in an era when stent optimization with high pressure balloon inflation was not a standard practice. A strategy for treating only the ingress or the worst part of a dissection may also have partially contributed to the relatively high stent thrombosis rates. In contrast to the report of Barragan et al. (17), more recent reports on stent implantation performed without IVUS guidance and without anticoagulation appear to be more favorable (18–21). In these reports, poststent optimization was a standard practice, and patients received a combination of ticlopidine and aspirin (18–20). Morice, Cavalho and Jordan and their coauthors (18–20) separately report a stent thrombosis rate of 0% to 1.5% with a combination of ticlopidine (500 mg/day) and aspirin (325 mg/day) therapy for at least 1 month with low molecular weight heparin for 2 to 4 weeks. These studies were associated with vascular or bleeding complications up to 4.8%. Use of only ticlopidine and aspirin without low molecular weight heparin after a successful stent procedure reduces vascular complications without precipitating an increase in the incidence of stent thrombosis.

As reported by Lablanche et al. (21), combination therapy for 3 months with only ticlopidine (500 mg daily) and aspirin (200 mg daily) in 98 patients after stent implantation resulted in 0% stent thrombosis events, a 1.0% incidence of vascular complications and a 1% rate of bleeding complications. Differences in absolute stent thrombosis rates between the present study and the more recent reports on treatment with ticlopidine and aspirin after stent implantation may be the result of differences in patient selection or other technical or procedure-related factors.

**Technical factors associated with stent thrombosis.** The importance of technical factors during the stent implantation procedure in achieving both a high procedure success and low postprocedure stent thrombosis rates, irrespective of the poststent implantation medical regimen, cannot be underestimated. Although the use of large or angiographically oversized balloons can also improve stent expansion, the consistent use of this strategy is associated with increased procedural complications, including dissections and vessel rupture (10,12,22). A reduction in procedural complications during stent optimization was achieved when a strategy of using more appropriately sized balloons (balloon/artery ratio 1.0 to 1.1) for final stent optimization was used. In the present study, the importance of technical factors during the stent implantation procedure is revisited from a different perspective. Although the final stent percent diameter stenosis of 8 ± 14% is similar to or better than most studies that employed only angiographic evaluation during the stent implantation procedure, it is less than the negative final percent diameter stenosis that was obtained when stent implantation was performed with IVUS guidance, which may have an impact on late angiographic or clinical results (3,4,9,12). The analysis of the factors associated with stent thrombosis illustrates that high pressure balloon dilations are not a panacea, particularly when undersized balloons are used for final poststent deployment optimization as demonstrated by the frequency distribution histograms of the final stent percent diameter stenosis, the final stent minimal lumen diameter and the balloon/artery ratio (Fig. 1). The use of an undersized balloon for final poststent deployment optimization resulted in a high residual final stent percent diameter stenosis and a significantly higher incidence of stent thrombosis. An undersized balloon was used for final stent optimization in all lesions with stent thrombosis. The association between a high residual final stent diameter stenosis and subsequent stent thrombosis is also consistent with previously published reports on stent implantation (23,24).

**Implications.** It is important to put the results of the present study on stent implantation without IVUS guidance or subsequent anticoagulation therapy into a proper perspective in the present era of intracoronary stent implantation. Even with the reduction in vascular and bleeding complications, a stent thrombosis rate of 3.1% per patient remains relatively high, despite being comparable to the 3.5% incidence of stent thrombosis in several large multicenter trials on stent implantation (3,4). A decrease in the stent thrombosis rate will require more vigorous attention to optimizing stent expansion and covering flow-limiting dissections during the stent procedure. On-line quantitative coronary angiography may offer an improvement over visual angiographic estimation in the precise assessment of the final angiographic percent diameter stenosis and may provide one means to further reduce stent thrombosis. In an unselected cohort of patients, routine IVUS after stent implantation may also help to reduce the stent thrombosis rates to a more acceptable rate. Alternatively, the selected use of IVUS may also benefit the resistant or complex lesions, long lesions and multiple stents, cohorts that historically had a higher incidence of stent thrombosis. This strategy may be of help without prohibitively increasing procedural costs in all patients who undergo stent implantation. In addition to the use of good stent technique, preliminary reports with heparin-coated stents appear to offer promise to reduce stent thrombosis rates to below 1%, which should be considered the standard for an acceptable incidence of stent thrombosis (25).

**Limitations.** There are several limitations to the present study. The study represents a relatively small series of patients from two hospitals. The experience was a consecutive series at one center of 91 patients, whereas at the other center it was not a consecutive series because of the high percentage of patients who underwent stent implantation with IVUS guidance. Al-

though the standard period for assessing stent thrombosis is the first month after stent implantation, this may result in an underestimation of the incidence of stent thrombosis. This is particularly possible since 12% of the lesions were chronic occlusions, which may have a higher incidence of silent reocclusions. The restenotic process and severe flow-limiting intimal hyperplasia may have a role in precipitating late occlusions. A large multicenter trial may be necessary to confirm the results of this small study. An additional multicenter trial may be needed to evaluate the role that IVUS may have after stent implantation, particularly in patients at high risk of stent thrombosis.

**Conclusions.** This observational study demonstrated the feasibility of high pressure assisted stent implantation without IVUS guidance using the combination treatment of ticlopidine and aspirin after a successful procedure. This strategy of using intracoronary stents should provide the benefit of decreased restenosis while simultaneously reducing both the cost associated with routine IVUS guidance during stent insertion and the complications related to anticoagulation after stent implantation. Further reductions in stent thrombosis rates may be derived from more careful angiographic assessment during the stent implantation procedure, from the use of IVUS, particularly in the higher risk subgroups, from better selection of patients for stent implantation and possibly from heparin-coated stents.

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