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Comparison of 6F with 7F and 8F guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter, randomized trial

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A group of 460 patients was considered in our prospective study of assessment of the efficiency and safety of 6F (internal diameter 0.062 inches) guiding catheters to perform elective percutaneous coronary angioplasty by the femoral approach by using conventional balloon systems. The patients were randomly assigned either a 6F guiding catheter (first group, n = 231; 247 coronary lesions), or a 7F or 8F guiding catheter (second group, n = 229; 252 coronary lesions). The exclusion criteria were the ongoing myocardial infarction, the marked reduction of left ventricular function, and the decision to treat the lesion with a device not fitting the 6F guiding catheter. The angioplasty success rates (87% in the 6F group vs 88% in the 7F or 8F group) and the stent implantation rates (21% vs 25%) were similar in both groups. The ischemic complication rates (death, 2 vs 1) were also similar. The incidence of the femoral complications was significantly less important in the 6F group than in the 7/8F group (13.8% vs 23.5%; $p < 0.01$). Significant differences also were noted for the procedural time (36 ± 22 vs 41 ± 28 min; $p < 0.01$), the fluoroscopy time (11 ± 10 vs 14 ± 4 min; $p < 0.05$), the volume of contrast injected (136 ± 68 ml vs 168 ± 95 ml; $p < 0.0001$), and the time of femoral compression after the introducer sheath removal (11.7 ± 9 vs 14.1 ± 12 min; $p < 0.01$). Our data suggest that 6F guiding catheters for elective coronary angioplasty are more effective than are the larger diameter catheters. Besides a significant decrease of vascular complications, angioplasty with a 6F guiding catheter reduces the procedural time and the amount of contrast. (Am Heart J 1997;134: 131-137.)

The guiding catheter choice is an important factor in coronary angioplasty success. It must offer a compromise between its back-up support allowing balloon catheters to reach and cross severe narrowing, its compatibility with bailout techniques in failed angioplasty, and its coronary ostia tolerance. Large guiding catheters are usually considered to fulfill these requirements, but they are associated with an increased risk of bleeding complications at the vascular access site, especially when a severe anticoagulation regimen is necessary (e.g., after stenting).[1, 2]

Recent reports show successful coronary angioplasty with 7F,[3] 6F[4-7] guiding catheters, and even with 6F and 4F diagnostic catheters.[8-10] The theoretic advantages of smaller catheters include reduced local vascular complications, less bleeding during percutaneous transluminal coronary angioplasty (PTCA), decreased coronary pressure damping, and therefore earlier hospital discharge and cost savings. On the other hand, in spite of an improved maneuverability, its potential disadvantages include an inadequate back-up support and a potential increased procedure failure. Furthermore, the lack of an angiographic quality control, in comparison with that obtained with larger guiding catheters, remains a controversial problem. However, preliminary studies suggest that 6F guiding catheters are not prejudicial to the success and safety of the procedure[6, 7] because of their ability to accommodate intracoronary unsheathed Palmaz-Schatz stents.[11, 12]

The aim of this prospective randomized multicenter trial was therefore the assessment of the technical performance and the possible clinical advantages of PTCA by using a 6F guiding catheter in comparison with usual PTCA with a 7F or 8F guiding catheter.

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Methods

Patient population and selection criteria

A multicenter cohort of 460 patients was prospectively randomized over a 7-month period between May 1994 and December 1994. The investigators were selected on the basis of their previous experience with 6F, 7F, or 8F guiding catheters (GCs). Only physicians having a prior personal experience of ≥100 6F PTCA procedures were considered for the trial.

Only patients with demonstrated ischemic heart disease with angiographic coronary artery disease or coronary artery bypass grafts deemed suitable for balloon angioplasty were considered for the trial. Candidates eligible for the study included successive patients, except those with the following criteria: ongoing acute myocardial infarction, 6F device not fitting the coronary anatomy (atherectomy), marked reduction of left ventricular ejection fraction (<30%), last remaining coronary vessel, the need for radial approach, and patients enrolled in another study. Previous coronary angioplasty was not a criterion of exclusion.

PTCA procedure

Angioplasty was performed by the percutaneous femoral approach according to current clinical practice and after the informed consent of the patient had been obtained. All patients received either long-term oral aspirin, 100 to 250 mg/day, or intravenous aspirin, 250 to 500 mg, before the PTCA procedure. Full heparinization was performed after arterial access by using an intravenous bolus of 10,000 to 15,000 U, with repeated bolus if needed. The GC was inserted through a catheter-sheath introducer of the same size as the GC used during the PTCA.

When the randomization assigned a 6F GC size for the PTCA procedure, a Cordis Petite Brite tip 6F guiding catheter (Cordis Corp., Miami, Fla.) was used with all the available configurations including Judkins left and right, Amplatz left and right, Extra backup,[13] multipurpose, El Gamal, Bypass left and right, and internal mammary. This GC has an inner diameter of 0.062 inches, allowing balloon shafts ≤3.5F and the use of most standard "rapid exchange" and "over the wire" balloon catheters commercially available. When 7F or 8F GCs were used, the size was decided by the operator's judgment about the coronary anatomy and the approach condition of the lesion. Guide wires and balloon catheters were chosen without restriction by the operator in the two groups. Contrast injections were manually performed with a standard coronary injection syringe by using either ionic or nonionic contrast dye.

If a stenting procedure was decided on, additional heparin was given if needed. When 6F GCs were used, only uncoated Palmaz-Schatz balloon expandable stents were available, generally manually crimped onto the previously used Monorail balloon.[11, 12] The Gianturco-Roubin stent was used only in the 8F group or after a crossing over. In these stented patients, adjunctive oral ticlopidine (250 or 500 mg/day) was administrated the day of stent implantation and given over a 6-week period without coumadin.[14]

Femoral sheaths were removed either 4 hours after the angioplasty or the day after, following the operator's decision. Heparin infusion was maintained in patients with unstable angina or in whom sheaths were left in place. Local hemostasis after sheath removal was achieved by either manual or mechanical (Femostop; Radi Medical System, Uppsala, Sweden) compression.

End points and data collection

The study purpose was to assess PTCA efficiency, tolerance of the procedure, and the peripheral vascular complication rate with 6F GCs.

The PTCA efficiency was judged by the PTCA success rate, the time required for fluoroscopy, the procedure time beginning with the introduction of the first GC through the aorta, the number of devices and amount of contrast used, and final PTCA results after stenting, if needed. The technical success of angioplasty, clinical or electrocardiographic evidence of ischemia after the procedure, and events like abrupt closure, myocardial infarction, need for emergency coronary surgery, and death were assessed.

An additional subjective operator evaluation of GC ability was noted from 1 to 4 (1, satisfactory; 2, acceptable; 3, moderate; and 4, unacceptable). It concerned the back-up support, the coronary ostia tolerance (either coronary artery "damping" and spasm, dissection, and coronary slow flow), the GC stability, the coronary dye injection, the balloon sliding, and the quality of the angiogram. The procedure tolerance was further estimated by the femoral bleeding (assessed subjectively by the operator during the procedure and determined by the decrease in hemoglobin concentration before and after the PTCA procedure), the renal function (serum creatinine levels), and the creatine kinase increase the day after the angioplasty.

The peripheral vascular complications like groin hematoma, false aneurysm, or ecchymosis were judged by a physician examination, other than the primary operator. Moreover, the time between PTCA and the sheath removal, the time necessary to achieve local hemostasis after sheath removal, duration of supine bed rest, and duration of hospitalization also were assessed.

Clinical, procedural, and postprocedural data were prospectively collected in a computerized database file. Qualitative analysis was performed with cineangiograms by two independent invasive cardiologists who were not informed about the clinical outcome, the GC size, or the stent used. Lesions before angioplasty and after PTCA dissection were classified by visual assessment by using two orthogonal projections.[15, 16] Thrombolysis in myocardial infarction (TIMI) flow grade after angioplasty was evaluated.

Table I. Clinical characteristics of patients

Size of the GC	7F/8F	6F	p Value
Number	229	231	–
Age (yr)	61 ± 11	62 ± 11	NS
Sex (% female)	6	4.8	NS
Stable angina	77 (33%)	83 (36%)	NS
Unstable angina	100 (44%)	86 (37%)	NS
Prior MI	52 (23%)	62 (27%)	NS
Prior PTCA	19 (8.3%)	23 (10%)	NS
Prior CABG	15 (6.6%)	14 (6.1%)	NS

CABG, Coronary artery bypass graft; MI, myocardial infarction.

Table II. Baseline angiographic characteristics of patients

Size of the GC	7F/8F	6F	p Value
No. of lesions	252	247	–
Lesions per patient	1.1	1.07	NS
Ejection fraction	0.65 ± 0.13	0.64 ± 0.14	NS
Multivessel disease	62 (27%)	64 (27%)	NS
Lesion location			
Left main	0	1	NS
Left anterior descending artery	105	103	NS
Right coronary artery	66	81	NS
Left circumflex artery	80	60	NS
Saphenous CABG	1	3	NS
Type of lesion			
Type A and B1	133 (53%)	141 (57%)	NS
Type B2	102 (40%)	93 (38%)	NS
Type C	17 (7%)	13 (5%)	NS
Mean stenosis (%)	85.4 ± 11	83.5 ± 12	NS
Restenosis	13 (5.7%)	17 (7.4%)	NS

An additional subjective semiquantitative analysis was performed in the selected view, where the final result was judged the most pejorative. A residual stenosis of <50% and a normal anterograde flow defined angiographic success, and a residual stenosis of <30% without dissection grade more than type B defined a "perfect" result.

A further quantitative coronary angiographic analysis was performed by a trained technician on previous selected end-diastolic cine frames from views showing the lesion clearly without overlap or foreshortening. Pre- and post-PTCA percentage stenosis at the lesion site was determined in the most suggestive frame and measured with digital electronic calipers and computer-assisted edge detection. Each narrowing of a lesioned coronary artery was compared with the normal adjacent arterial regions and expressed in percentiles.

Statistical analysis

All data are presented as mean ± SD. Differences in categoric variables were analyzed by chi-square tests, and differences in continuous variables were analyzed by unpaired Student's *t* tests. Tests of differences were two-sided and the limit of significance was set at $p = 0.05$.

Results

Clinical and angiographic characteristics of the 460 randomized patients are summarized in Tables I and II. Coronary angioplasty was attempted in 247 lesions of 231 patients by using a 6F GC and in 252 lesions of 229 patients by using a 7F (85%) or an 8F (15%) GC. There were no differences in gender, mean age, unstable exertional angina, location, or American Heart Association/American College of Cardiology class coronary lesions. Of the angioplasty procedures, 75% were performed immediately after the coronary angiography with the same rate in both groups (72% in the 6F group vs 77% in the 7F/8F group; p = NS). Overall angioplasty success rate was similar in both groups (87% in the 6F group vs 88% in the 7F/8F group; p = NS), with coronary stenting if needed (21% vs 25%; p = NS). The mean residual stenosis in the successfully dilated lesions was 34.4% ± 21% in the 6F group and 34.5% ± 21% in the 7F/8F group (p = NS). In-hospital outcome was similar in the two groups, with no significant difference in ischemic complication rates (non-Q wave myocardial infarctions, coronary bypass grafting, and deaths), and in duration of hospitalization (Table III). The amount of contrast agents (136 ± 75 vs 167 ± 90 ml; $p < 0.0001$), the procedure time (36 ± 22 minutes vs 41 ± 28 minutes; $p < 0.01$), and the fluoroscopy time (11 ± 9 minutes vs 14 ± 14 minutes; $p < 0.05$) were significantly less in the 6F group. Subjective assessment of GC efficacy by the PTCA primary operator is shown in Table IV. Vessel opacification at the lesion site after balloon inflation with the guide wire across the lesion and the balloon withdrawn was subjectively better appreciated in the 7F/8F group. Conversely, the back-up support, the maneuverability, the ostia tolerance, and the reduced procedural bleeding were significantly superior in the 6F GC group, with an overall reduction in procedure duration. In this group, a significant decrease of bleeding complications at the vascular access site was noted (13.8% vs 23.5%; $p < 0.01$) with a significant difference for the compression time after sheath removal (11.7 ± 9 minutes vs 14.1 ± 12 minutes; $p < 0.01$) and supine bed-rest duration (34 ± 12 hours vs 37 ± 13 hours; $p < 0.05$; Table V). One patient in the 6F group required a delayed surgical repair at the vascular access site after the ticlopidine regimen was stopped. Nevertheless, no significant differences appeared between both groups concerning changes in creatinine level, but there was a significant decrease in hemoglobin level in the 7F/8F

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