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Coronary Angioplasty Using New 6 French Guiding Catheters

Robert Feldman MD, Eric Glemser BSN, Judy Kaizer RN, and Mary Standley BS

Coronary angioplasty (PTCA) was performed with specially constructed 6-French guiding catheters with an internal lumen of 0.051 inches. In 154 patients these guiding catheters were used in a variety of configurations in conjunction with miniature balloon-on-a-wire dilatation catheters in 1.5 to 3.5 mm sizes to perform PTCA.

Overall patient success was 94%. PTCA was attempted in 24 totally occluded arteries with a success rate of 83% and 174 stenoses with a success rate of 97%. 6 French guiding catheters can be used to successfully perform PTCA.

Key words: coronary artery disease, coronary revascularization, ischemic heart disease, coronary angioplasty

INTRODUCTION

One avenue in which percutaneous transluminal coronary angioplasty (PTCA) technology is rapidly advancing is in the miniaturization of equipment, particularly balloon-on-a-wire dilatation system catheters. These miniature PTCA balloons are currently available from 3 manufacturers (Cordis ORIONTM, Cordis Corp., Miami, FL; Sci-Med ACETM, Sci-Med Life Systems, Inc., Minneapolis, MN; and USCI PROBETM, C.R. Bard, Inc., USCI Division, Billerica, MA) in balloon sizes from 1.5 through 3.5 mm and have balloon profiles in the 0.020–0.036 inch range (Table I). The shaft size of these balloon-on-a-wire dilatation catheters is 1.7–2.4 French (approximately 0.6–0.8 mm or 0.023–0.032 inches). In addition, a 1.5 mm Dilating Guidewire (.018 inches, Sci-Med) which can be used alone or placed through some over-the-wire balloons is also available.

Because of their small catheter size these PTCA balloon dilatation systems can be used with smaller-sized guiding catheters than the larger conventional over-the-wire PTCA balloons. In fact, anecdotal and several case reports have documented use of the USCI PROBE balloon catheter with diagnostic catheters as small as 5 French [1–6]. The 2.0 mm balloon sizes (ACE or PROBE) can work reasonably well through uncoated, tapered diagnostic catheters if considerable catheter manipulation is not necessary in the target vessel. However, in our experience, balloons larger than the 2.0 mm size move poorly if at all through a diagnostic catheter. This poor movement becomes particularly apparent as the balloon exits or returns to the preformed curve of the diagnostic catheter turned “guide.” Any winging of the PTCA balloon after it has been inflated either during

preparation or during dilatation adds to the difficulty in movement through a diagnostic catheter [4]. This paper describes our present experience using 6 French custom-made guiding catheters and miniature PTCA balloons in a range of clinical circumstances.

MATERIALS AND METHODS

The guiding catheters were constructed in conjunction with Cordis Corporation. The catheters are similar to the 6 French Super TorqueTM diagnostic catheter, but differ in several important features. First, they are untapered in both their outer and internal diameter (.051 inches) from the hub to the tip. Second, attached to the distal end is a soft, radiopaque 2 mm extension, which is the Brite TipTM. Third, unlike conventional guiding catheters where to facilitate balloon movement Teflon^R comprises the inner layer, the internal lumen of this catheter is coated with silicone. An illustration showing relative guiding catheter-to-balloon shaft ratios, comparing an 8 French guiding catheter with an over-the-wire balloon and a 6 French guiding catheter with a balloon-on-a-wire is shown in Figure 1.

PTCA was otherwise performed in a standard fashion. A successful PTCA was defined as a residual stenosis

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TABLE I. Balloon-on-a-wire Dilatation Catheters: Summary of Currently Available Profiles (in inches)

	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm
ACE TM	.020	.022	.030	.032	.036
DGW TM	.018	—	—	—	—
ORION TM	—	.028	.028	.030	.032
PROBE ^{TMa}	—	.020	.025	.030	—

^aNot currently available but when released will be available in 1/4 sizings as well.

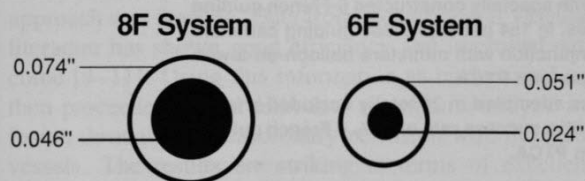


Fig. 1. Proportional comparison of a conventional 8 French guiding catheter with a 3.5 French over-the-wire balloon and the described 6 French guiding catheter with a 1.8 French shaft balloon-on-a-wire.

(<50%) and no in-hospital angina, myocardial infarction, bypass surgery, or death.

RESULTS

PTCA was performed using a 6 French guiding catheter in 154 patients. In 152 patients a 6 French guiding catheter was the initial guiding catheter chosen. In 2 patients an 8 French guiding catheter was tried first. In one of these patients, no conventional 8 French guiding catheter would seat in a small right ostium, but a 6 French JR 4 fit well. In the other patient, both an 8 French JL 4 and an 8 French AL 2, both without side holes, functionally occluded the left main artery; however, a 6 French AL 2 fit without pressure dampening. A femoral approach was used in 144 patients and a percutaneous right or left brachial approach in 10.

Patient diagnosis varied as expected, including silent ischemia in 3 patients, stable angina in 10, unstable angina in 95, evolving acute myocardial infarction in 16, and myocardial infarction within the past 2 weeks in 30. Patient weight averaged 76 kg (range 46 to 133 kg) and body surface area averaged 1.85 m² (range 1.45 to 2.45 m²). The average age was 66 years (range 38 to 85 years), 81 of the patients were male, 73 female.

Complications occurred in 5 patients, in hospital death occurred in 2 patients, myocardial infarction in 2, and coronary bypass surgery before discharge in 4 patients. 1) An 85-year-old woman with refractory unstable angina and severe peripheral vascular disease agreed to PTCA, but declined surgery under any circumstances. PTCA of a subtotal anterior descending using a 6F AL 1

TABLE II. Guiding Catheter Shapes Selected

Shape	LM	LAD	LCX	RCA	DIAG	GRAFT
JL 5	1	—	2	—	—	—
JL 4.5	—	—	5	—	—	—
JL 4	—	34	20	—	2	—
JL 3.5	—	9	—	—	1	—
JL 5	—	—	—	1	—	—
JR 4	—	—	—	36	—	1
JR 3.5	—	—	—	2	—	1
AL 2	—	—	3	—	—	1
AL 1	—	8	11	4	1	—
AR 2	—	—	—	4	—	2
LSVBG	—	—	—	19	—	5
RSVBG	—	—	2 ^a	1	—	4
IMA	—	—	—	2	—	2
Sones	—	1	—	1	—	—

^aCongenitally aberrant arising from right Sinus of Valsalva.

TABLE III. Balloon-on-a-Wire Catheters Used

	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm
ACE TM	1	3	2	3	1
ACS Gold ^{TMa}	N/A	—	1	1	N/A
PROBE TM	N/A	17	6	12	N/A
ORION TM	N/A	35	33	46	5

^aInvestigational devices.

— = Not used.

N/A = Not available.

and a 2.5 mm Cordis Orion by the percutaneous left brachial approach was initially technically successful (>90% to 30%). One hour later angina recurred and the anterior descending had occluded. Repeat PTCA was complicated by repeated reocclusion. She died 1 day later having sustained an anterior infarction. 2) A 64-year-old woman presented in cardiogenic shock secondary to an evolving inferior infarction. PTCA using a 6-French JR 4 and a 3.0 mm Cordis Orion was successful in opening the occluded right coronary artery (100% to 10%) and the patient stabilized. Because her left main was narrowed 90%, she underwent coronary bypass surgery 8 days later. Postoperatively she developed adult respiratory distress syndrome and died 11 days after PTCA. 3) A 65-year-old diabetic woman had multivessel PTCA. Her anterior descending (99% to 20%) occluded 24 hours after PTCA and was heralded by recurrent angina, new nonspecific ST-T wave changes; and minimal CPK elevation. Rather than repeat PTCA, she chose bypass surgery which was done 3 days after PTCA. 4) A 63-year-old woman with silent ischemia and restenosis (90%) of a right coronary required emergent bypass. Initial dilatation was through a 6-French left saphenous vein bypass graft guide and a 3.0 mm Orion was used. Because of residual stenosis of 40%, balloon size was increased to 3.5 mm (Orion). The final angiographic result

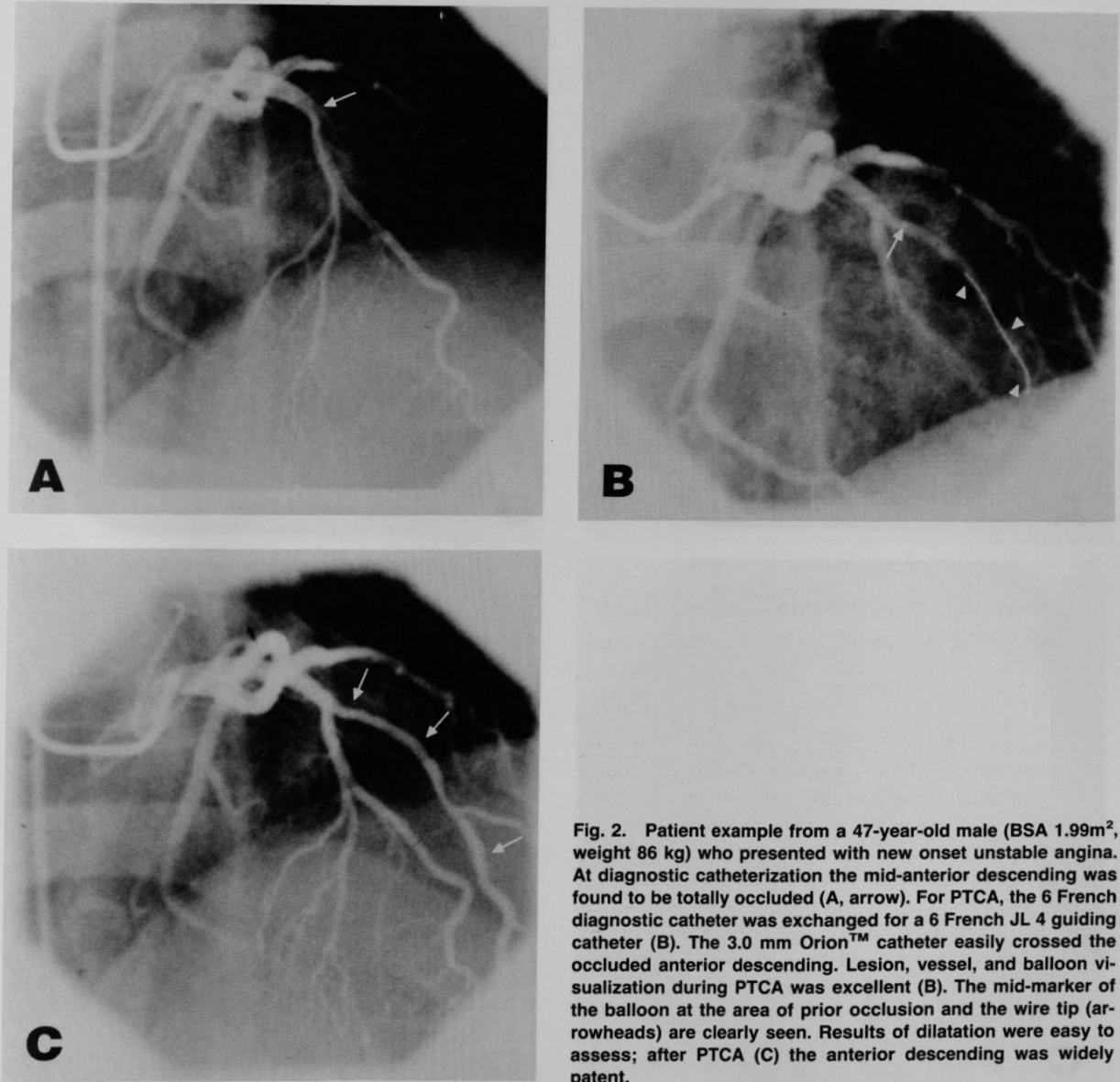


Fig. 2. Patient example from a 47-year-old male (BSA 1.99m², weight 86 kg) who presented with new onset unstable angina. At diagnostic catheterization the mid-anterior descending was found to be totally occluded (A, arrow). For PTCA, the 6 French diagnostic catheter was exchanged for a 6 French JL 4 guiding catheter (B). The 3.0 mm OrionTM catheter easily crossed the occluded anterior descending. Lesion, vessel, and balloon visualization during PTCA was excellent (B). The mid-marker of the balloon at the area of prior occlusion and the wire tip (arrowheads) are clearly seen. Results of dilatation were easy to assess; after PTCA (C) the anterior descending was widely patent.

was excellent (10%) without dissection; but 2 hours later chest pain with transient ST changes occurred. Repeat angiography showed a new extensive partially occlusive dissection. Repeat dilatation with a larger guiding catheter (7-French, Cordis) and use of an ACS Stack Perfusion balloon (ACS, Advanced Cardiovascular Systems Inc., Temecula, California) failed to yield an optimal result and emergency bypass surgery was done. 5) A 66-year-old woman with post-infarction angina was found to have 3-vessel disease including occlusion of the right. PTCA with a 6 French JR 4 guiding catheter and a 3.0 mm Orion resulted in an excellent angiographic re-

sult (< 30%). However repeated, symptomatic reocclusion led to urgent bypass surgery. None of the complications seemed related to choice of initial equipment. Although in each case the stenosis was initially technically successful crossed and dilated, none of these patients or these lesions were counted as successful. No peripheral vascular complications requiring surgery occurred. Two patients had hematomas at the femoral catheterization site which were managed conservatively.

PTCA was successful in 143 of the 152 patients in whom a 6 French guiding catheter was used initially and in both of those in whom an 8 French guiding catheter

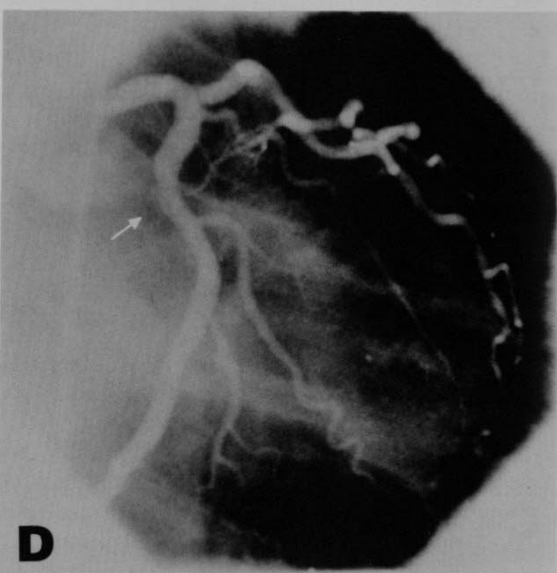
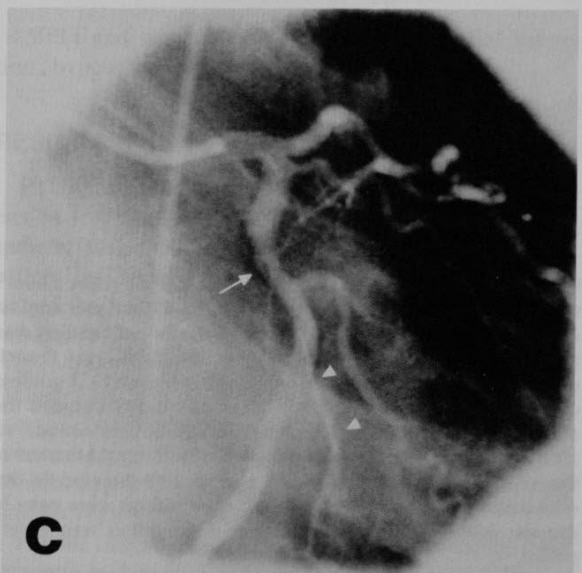
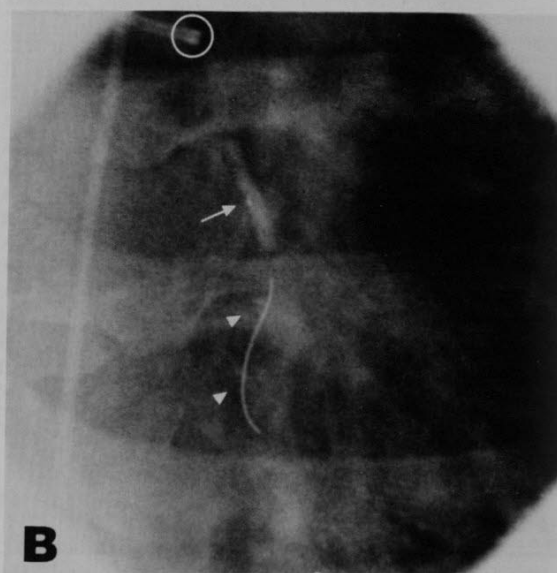
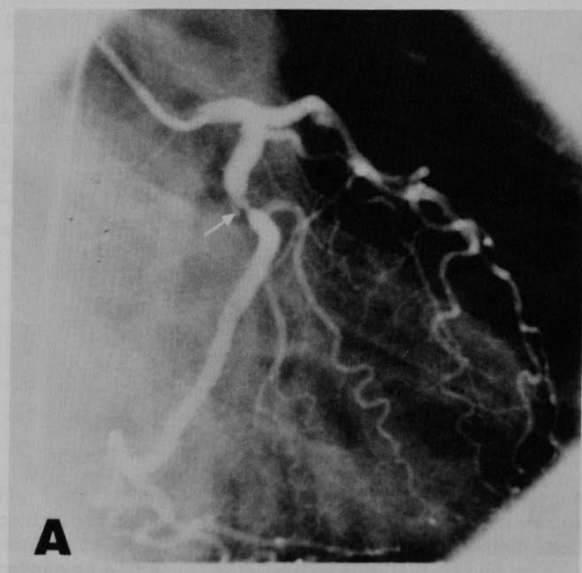


Fig. 3. Patient example from a 62-year-old male (BSA 1.93 m², weight 76 kg) who presented with recent onset unstable angina. The circumflex arises at a sharp angle and has a severe, complex stenosis (A, arrow). Dilatation was performed with a 6

French JL 4.5 guiding catheter and a 3.5-mm Orion catheter. The Brite Tip™ (O), the balloon marker (arrow), wire tip (arrow-head), and stenosis (arrow) were easily visualized during PTCA (B and C). After PTCA (D) the circumflex was widely patent.

had failed first. In order to achieve a successful dilatation a 6 French guiding catheter was changed to a 7 French guiding catheter in 4 patients. In each of these cases the initial 6 French shape chosen fit imperfectly or gave inadequate support. A 7 French guiding catheter of a different shape not available in 6 French was always used; and PTCA was uneventful. We suspect if the same

shape had been available in the 6 French guiding catheter, PTCA would have been successful as well. In 2 patients PTCA was unsuccessful because of inability to cross a recent (2-month-old) total occlusion and a long tortuous subtotal occlusion, both in the right coronary artery. Despite attempts with 8 French guides and a variety of fixed and over-the-wire balloon systems, neither

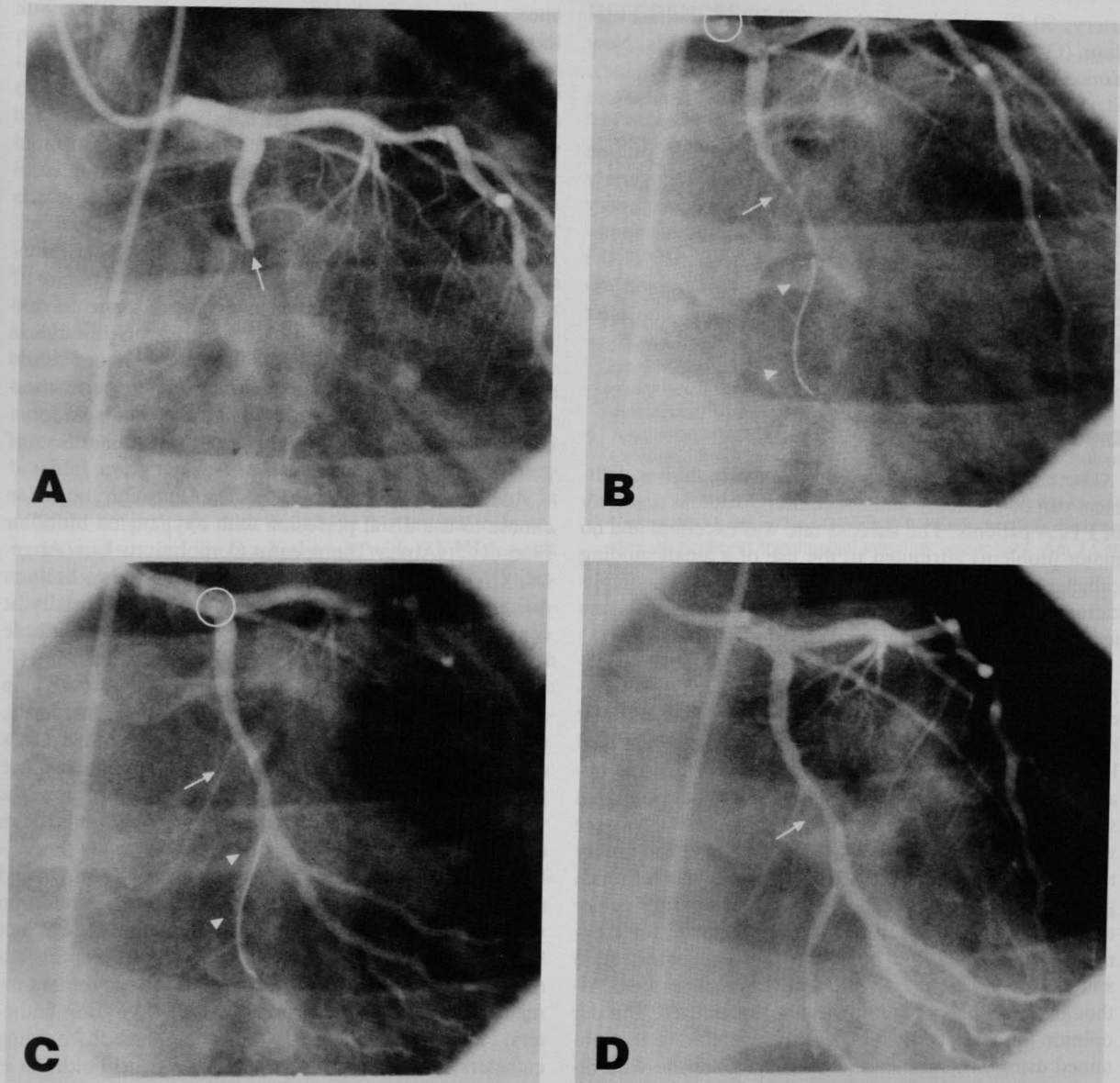


Fig. 4. Patient example from a 38-year-old male (BSA 2.23 m², weight 107 kg) who resented with a posterior infarction complicated by postinfarction angina. The circumflex was occluded (arrow) in its mid-portion (A). Dilatation was accomplished with a 6 French JL 4 guiding catheter and a 2.5-mm Orion catheter. To obtain extra support the guiding catheter was advanced over

the balloon-on-a-wire relatively far into the left main stem (B and C). The catheter tip marker (O) was easily seen. Visualization of the balloon (arrowhead), wire tip (arrows), and lesion during PTCA (B and C) was excellent. After PTCA (D) the result was acceptable.

the occlusion or the stenosis was crossed. Overall PTCA was successful in 145 of 154 patients, in 178 of 186 vessels, and in 189 of 198 lesions.

PTCA was attempted in 24 total occlusions and was successful in 21 (83%). These occlusions were usually in patients with a recent or evolving acute myocardial in-

farction. PTCA was attempted in 174 stenoses, <100% blocked, and was successful in 169 (97%). Visualization of the coronary anatomy when the balloon was in the guiding catheter or in the coronary arteries was adequate for diagnostic and technical purposes in each patient. When the balloon was in the guiding catheter or coronary

artery, 50:50 or higher mixtures (70:30) of contrast medium (Omnipaque 350, Winthrop Pharmaceuticals, New York, NY; or Optiray 320, Mallinckrodt Medical, Inc., St. Louis, MO) and heparinized normal saline were used.

The selected 6-French guiding catheters had routine diagnostic curves and were used successfully in a variety of circumstances including vein and internal mammary artery bypass grafts and coronary arteries with anomalous origins (Table II). The sizes and frequency of the balloons used are listed in Table III. Angiographic examples of lesion visualization before, during and after PTCA are shown in Figures 2–4.

DISCUSSION

Our experience documents that 6 French guiding catheters can be routinely and successfully used in a variety of PTCA patients. The success rate was excellent and no major problems attributed to the use of a small guiding catheter were identified. Specifically, no patient complication occurred by using these smaller guiding catheters instead of larger conventional guiding catheters.

Although there was no apparent learning curve or major difficulty encountered, these 6 French guiding catheter/balloon-on-a-wire dilatation systems have different handling characteristics when compared to conventional PTCA equipment. As discussed elsewhere, balloon-on-a-wire dilatation devices handle differently than standard shaft over-the-wire or larger fixed or partially moveable wire balloons [6]. The feel, control, stability, and ability to opacify the distal vessels differed with these 6 French guiding catheters as compared to larger guiding catheters. Distal vessel opacification was adequate for diagnostic images, but was obviously less than when these small balloons are used with 7 or 8 French guides. Although vessel opacification was not “quantified,” in our opinion vessel opacification was comparable to that obtained using of larger shaft 3.5 French over-the-wire dilatation balloons with standard 8 French guiding catheters. Opacification as expected was better in the right than the left coronary system. Suboptimal visualization was uncommon and did not necessitate changing to a larger guide. Although conceptually backup was expected to be only fair at best, the 6-French guiding catheters offered good backup. Once the balloon-on-a-wire was into the coronary artery, the guiding catheter could usually, if desired, be advanced easily over the balloon shaft and provided considerable support (Fig. 4). When this maneuver was used, the guiding catheter did not seem to obstruct the coronary artery as significant pressure dampening was uncommon and chest pain or electrocardiographic changes did not occur. Clinical experi-

ence remains limited, but no coronary dissections with these small guiding catheters occurred.

Certain limitations of small guiding catheters are obvious. These include the inability to use standard balloon-over-a-wire systems. Specially angled balloons and perfusion balloons (ACS) are useful in certain circumstances and cannot be used with 6 French guiding catheters. The ability to maintain access to the distal vessel is felt important by some Cardiologists. Control of the distal vessel can be maintained while using some balloon-on-a-wire dilatation systems if a Probing Catheter™ (USCI) is also used. However, this 4 French sheath cannot fit through a 6-French guiding catheter. Although in our opinion this is not a major limitation, others would disagree. Obviously capability of distal pressure measurement or distal dye injection is lost when balloon-on-a-wire systems are used. This is true regardless of guiding catheter size.

Additionally, some cardiologists may on occasion choose to use distal perfusion with oxygenated blood or Fluosol™ (Alpha Therapeutic Corporation, Los Angeles, CA) which can only be done when using balloon dilatation catheters with a large central lumen. Finally, it is not presently possible to simultaneously place multiple balloons through one 6-French guiding catheter.

In our initial endeavors (unreported cases) to develop a useable, small guiding catheter, a 6-French untapered, uncoated catheter was first tried. Although most cases could be successfully completed, considerable resistance in balloon catheter movements above the 2.0-mm size was encountered. Resistance was noted particularly in the preformed curves in the guiding catheter, as the balloon exited or after the dilatation as it was withdrawn and reentered the guiding catheter. A second generation which included an alternate lubricious coating was not helpful. The third generation, which this report addresses, is promising, but ease of balloon movement remains less facile than with larger lumen guiding catheters. Future developments in small French guiding catheters are in progress [unpublished data, Feldman et al.]. Larger lumen 6 French guiding catheters will soon be available from several companies. It will soon be possible to use over-the-wire balloons such as the new ACS Ten™ and monorail-type standard and perfusion balloons with small French shaft size in 6-French guiding catheters.

In our opinion, 6 and 7 French guiding catheters are particularly advantageous in patients with small proximal right or left coronary arteries. A small guiding catheter may obstruct the proximal coronary less or not at all as compared to 8 or 9 French guiding catheters. Additionally, in small vessels, as compared to larger guiding catheters, 6 French guiding catheters fit better, generally allow adequate perfusion, and are more stable. Although

8 French guiding catheters with side holes allow some perfusion, the 6 French guiding catheters may also be less traumatic by virtue of their smaller diameter and less tight fit. If necessary, 6 French guiding catheters could certainly have side holes as well. Several of our patients had ostial narrowing of the right coronary artery and a 6 French guiding catheter always fit, but at times did occlude.

Other reasons to develop a 6 French guiding catheter includes patients with severe peripheral vascular disease. In these patients PTCA has usually been performed by a brachial cutdown or percutaneously via the axillary or brachial approach. For years we had utilized a percutaneous brachial approach with 7 French guiding catheters, but were concerned, especially in smaller women, about catheter size. Our initial experience with 6-French guiding catheters placed percutaneously from the right or left brachial artery using Amplatz or Judkins shapes has been satisfying and no local complications have occurred. In addition to patients with occlusive bi-femoral disease, we have also used the brachial route with 6 French guiding catheters for patients with massive obesity. Additionally, there is a trend toward shorter post-PTCA hospitalization, earlier ambulation and patient discharge [7-8]. The use of smaller French guiding catheters for PTCA in this setting would be similar to the rationale for the use of small French diagnostic catheters, especially in patients undergoing outpatient diagnostic studies.

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