

Efficacy of a New Angioplasty Catheter for Severely Narrowed Coronary Lesions

EDWARD S. THOMAS, MD,* DAVID O. WILLIAMS, MD, FACC,* ALAN L. NEIDERMAN, MD,†
JOHN S. DOUGLAS, MD, FACC,† SPENCER B. KING III, MD, FACC†

Providence, Rhode Island and Atlanta, Georgia

Conventional over the wire dilation catheters may be unsuccessful in crossing coronary lesions that are severely narrowed. Hence, a new, extremely low profile coronary angioplasty catheter specifically designed to dilate such lesions was investigated. The catheter features a 2.0, 2.5 or 3.0 mm (inflated diameter) balloon mounted on a guide wire. The deflated profile of the 2.0 mm balloon measures 0.020 ± 0.001 in. (0.51 ± 0.03 mm). The catheter can be used in conjunction with 7F angiographic or 8F guide catheters.

The catheter was used in 61 patients, aged 43 to 86 years, with predominantly Canadian Cardiovascular Society class III-IV angina. Dilation was attempted in 77 lesions. Lesion length averaged 5.7 ± 3.1 mm (mean \pm 1 SD), minimal diameter 0.51 ± 0.25 mm and internal vessel diameter 2.27 ± 0.43 mm. Sixty lesions (78%) were successfully dilated to $<50\%$ residual stenosis with this catheter alone; nine lesions were further dilated with a larger balloon catheter. The new catheter was unable to cross 13

lesions (17%); only 2 of these lesions were subsequently crossed with a conventional over the wire system. On the other hand, the catheter was used after failure of conventional dilating catheters in 21 lesions and was successful in 16. The new catheter was particularly valuable for distal lesions and those demonstrating 90 to 99% diameter reduction. For all lesions crossed, stenosis decreased from 76 ± 11 to $29 \pm 12\%$ after 2.9 ± 2.7 inflations and peak inflation pressure of 8.0 ± 2.9 bar. Complications were rare; coronary occlusion occurred in two lesions (3%) and dissection in three lesions (4%). There were no instances of death or emergency coronary artery bypass surgery.

Thus, this new angioplasty catheter was uniquely effective and safe in patients with severe coronary lesions. Importantly, success was often achieved after failure of conventional angioplasty catheters.

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Percutaneous transluminal coronary angioplasty has been performed in patients with symptomatic coronary artery disease for the past decade. The original catheter designed by Gruentzig featured a double lumen balloon catheter with a fixed wire guide (1). The catheter was modified to permit the utilization of a coaxial movable guide wire that facilitated access throughout the coronary artery tree (2). The major problem in using both of these catheter systems was lack of steerability (3). Improved steerable guide wires were introduced by Gruentzig in 1982. The development of lower

profile systems permitted crossing of severely stenotic lesions (4). However, despite these improvements, it is not unusual for balloon catheters to be unable to cross severely stenotic lesions. We report on our initial experience evaluating a newly developed balloon catheter especially designed for severely narrowed coronary lesions.

Methods

Dilation catheter. The design of the catheter (The Probe, USCI, C. R. Bard, Inc.) is shown in Figure 1. The proximal end consists of Teflon coated stainless steel tubing measuring 0.022 in. (0.56 mm) in diameter and 43.3 in. (110 cm) long. The midportion consists of an intermediate shaft of a smaller 0.013 in. (0.33 mm) tube. A polyethylene neck extends from the intermediate shaft to the balloon. A core wire is attached to the intermediate shaft and tapers over a 30 cm length ending 2 cm from the distal tip. The final 2 cm is free of core and is constructed similar to the USCI 0.014

From the *Division of Cardiology, Department of Medicine, Rhode Island Hospital, Brown University Program in Medicine, Providence, Rhode Island and †Andreas Gruentzig Cardiovascular Center, Division of Cardiology, Department of Medicine and Radiology, Emory University School of Medicine, Atlanta, Georgia. This study was presented in part at the 37th Annual Meeting of the American College of Cardiology, Atlanta, Georgia, March 27 to 31, 1988.

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Address for reprints: David O. Williams, MD, Division of Cardiology, Rhode Island Hospital, Providence, Rhode Island 02903.

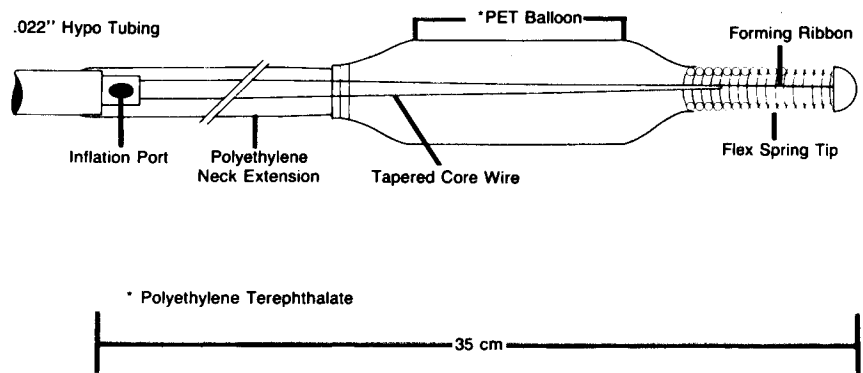


Figure 1. Schematic design of the study catheter. PET = polyethylene terephthalate.

in. (0.35 mm) flexible steerable guide wire (5). The distal 2 cm tip wire is radiopaque.

The balloon is constructed of polyethylene terephthalate and is located proximal to the 2.0 cm tip wire and is designed to be inflated up to 12 bar. Four balloon sizes were used in 77 lesions. A 2.0 × 15 mm balloon was used for 62 lesions (81%), 2.0 × 20 mm for 10 (13%), 2.5 × 20 mm for 1 (1%) and 3.0 × 20 mm for 4 (5%). In each instance, balloon size was chosen to best match the internal artery diameter or undersized to cross severely stenotic lesions. The 2.0 mm balloon has a deflated profile of 0.020 ± 0.001 in. (0.51 ± 0.03 mm). The proximal end of the balloon is marked by a discrete radiopaque platinum marker band. The catheter is used with a standard inflation device. There is no additional lumen to inject contrast or measure intracoronary pressures.

Study patients. The dilation catheter was used in 61 patients at either Emory University Hospital or Rhode Island Hospital between November 1986 and September 1987. The catheter was selected in 33 patients as the initial dilation catheter on the basis of circumstances that were considered unfavorable for successful dilation by conventional over the wire dilation catheters. These circumstances included lesions located within small (<2 mm) diameter vessels, lesions distal in the coronary artery and lesions severely narrowed. In an additional 20 patients, the catheter was employed after conventional catheters were unable to cross the lesion. For eight other patients the catheter was chosen electively in a circumstance in which a conventional over the wire system could have been selected.

Coronary angioplasty. Therapy with aspirin alone or with dipyridamole was begun the evening before the procedure and all patients were premedicated with diazepam and nifedipine and some with diphenhydramine. After femoral artery and vein sheaths were placed, heparin (8 to 10,000 U) was given intravenously. The dilation catheter was advanced to the coronary orifice by way of either a standard 8F guiding or 7F angiographic catheter. Once the guiding catheter was positioned within the coronary orifice, the dilation catheter was advanced into the coronary vessel. The wire was steered over the lesion and advanced beyond so that the

balloon was centered over the lesion, utilizing the proximal balloon marker and tip wire as reference guides. With use of an inflation device, the balloon was then inflated with gradually increasing pressures until it was fully inflated and no longer compressed by the stenosis. After a 10 to 120 s inflation, the balloon was deflated. Angiography was performed with the catheter positioned across the lesion. The small profile of this new catheter permitted enhanced delivery of contrast medium for improved angiographic assessment of the results of balloon inflation. If the stenosis appeared satisfactorily dilated after one or more inflations, the catheter was removed. In nine patients with a proximal lesion, a conventional over the wire dilation catheter with a larger balloon was subsequently used to increase the luminal size of the stenosis. After the procedure, the patients were maintained on a regimen of aspirin alone or in combination with dipyridamole. Some patients received heparin intravenously for 18 to 24 h.

In six patients the catheter and a conventional dilating catheter were used together with a kissing balloon technique (6). In these patients, a separate guide catheter was advanced from each femoral site with the study dilation catheter advanced down a small branch vessel. In another patient, two study catheters were inserted into a single guide catheter through a double Tuohy-Borst type adapter to perform kissing balloon dilation of a left anterior descending and diagonal coronary artery bifurcation lesion.

Angiographic analysis. The coronary angiograms obtained before balloon dilation were examined for 1) lesion location, and 2) lesion morphology, described as discrete, diffuse, mild tortuosity (>25°) or severe tortuosity (>45°), eccentric, calcific or containing thrombus. With the use of caliper techniques, lesion length and minimal diameter and diameter of adjacent normal vessel were measured. Percent luminal reduction by the stenosis before and after angioplasty was measured (in orthogonal views when possible) and the mean value reported. Additionally, postangioplasty coronary angiograms were reviewed for the presence of coronary occlusion, coronary branch occlusion, coronary

Table 1. Clinical Characteristics of 61 Patients

Age (yr)	63 ± 10*	
Men	41	(67)
Cardiac risk factors		
Diabetes mellitus	9	(15)
Hypertension	38	(62)
Elevated cholesterol	8	(13)
Smoker	34	(56)
Family history	28	(46)
Canadian Cardiovascular Society class		
I-II	16	(26)
III-IV	45	(74)
Left ventricular ejection fraction		
<30%	0	
30 to 49%	8	(13)
>50%	48	(79)
Not available	5	(8)
Prior CABG	15	(25)
Prior PTCA	15	(25)
Restenosis	5	(8)
Extent of coronary disease		
1 Vessel	36	(59)
2 Vessel	13	(21)
3 Vessel	12	(20)
Clinical status		
Unstable angina	41	(67)
Stable angina	13	(21)
Remote MI	19	(31)
Recent MI	10	(16)
Acute MI	1	(2)

*Mean ± 1 SD. Values in parentheses = percent of patients. CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

dissection or intimal tears. Successful dilation was defined as achieving a residual stenosis ≤50%.

Statistics. Unpaired Student's *t* tests were employed for analysis of continuous variables. For all tests, *p* < 0.05 was considered significant. Values are listed as mean ± 1 SD.

Results

Patient characteristics (Table 1). The catheter was used in 61 patients, predominantly male (41 patients, 67%) and aged 43 to 86 years. Single vessel disease was present in 36 patients (59%) and multivessel disease in 25. Global ejection fraction by left ventriculography exceeded 50% in 48 of 56 patients. Cardiac risk factors present included hypertension in 38 patients, diabetes mellitus in 9, smoking history in 34, hypercholesterolemia in 8 and a family history for premature coronary disease in 28. Twenty-nine patients had had a myocardial infarction, in 10 of whom it occurred within 3 months before the angioplasty. One patient underwent angioplasty during acute infarction. The majority of patients had a history of unstable angina (67%) and Canadian Cardiovascular Society class III or IV symptoms. Fifteen pa-

Table 2. Characteristics of 77 Lesions With Attempted Dilation

	Lesions With Attempted Dilation	Lesions With Successful Dilation (n = 60)
Discrete	47	41 (87)
Diffuse	30	19 (63)
Mild tortuosity	8	6 (75)
Severe tortuosity	10	5 (50)
Concentric	17	14 (82)
Eccentric	60	46 (77)
Calcific	19	13 (68)
Noncalcific	58	47 (81)
Thrombus	2	2 (100)
Total occlusions	4	2 (50)

Value in parentheses = percent of lesions with attempted dilation.

tients had had prior coronary artery bypass surgery. Previous angioplasty was performed in 15 patients, of whom 5 presented with restenosis. In general, the patient group is typical of those undergoing elective angioplasty at our institutions.

Lesion characteristics (Tables 2 and 3). The dilation catheter was used for 77 lesions in 61 patients. Forty-seven lesions were characterized as discrete, 30 were diffuse, 18 tortuous, 60 eccentric, 19 calcific and 2 contained thrombus. Sixty-seven lesions were present in native coronary arteries; 35 were located in the left anterior descending coronary artery distribution, 19 in the right coronary artery and 13 in the left circumflex artery. Twenty lesions were located in the

Table 3. Location of 77 Lesions With Attempted Dilation

	Lesions With Attempted Dilation	Lesions With Successful Dilation
Number	77	60 (78)
Proximal or mid LAD	11	11 (100)
Distal LAD	14	14 (100)
Diagonal	10	8 (80)
Proximal LCx	1	0 (0)
Distal LCx	3	2 (67)
Obtuse marginal	9	5 (56)
Proximal or mid RCA	8	4 (50)
Distal RCA	8	6 (75)
PDA	3	3 (100)
Bypass graft	10	7 (70)
Proximal	2	2 (100)
Body	1	0 (0)
Distal	7	5 (71)

Value in parentheses = percent of lesions with attempted dilation. LAD = left anterior descending artery; LCx = left circumflex artery; PDA = posterior descending artery; RCA = right coronary artery.

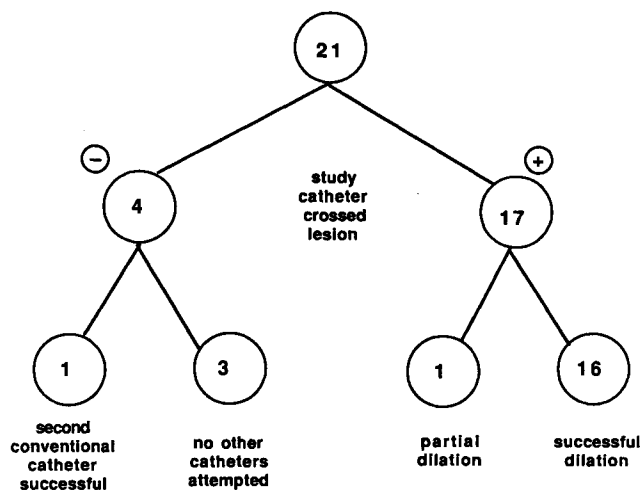


Figure 2. Flow diagram reflecting outcome of angioplasty in 21 lesions in which a conventional over the wire system was used unsuccessfully and the study catheter was subsequently employed.

proximal or mid portion of the major coronary arteries, 19 in major branch arteries and 28 distally within the three major coronary arteries or posterior descending artery. Of 10 lesions located in bypass grafts, 2 were proximal, 1 was within the body of the graft and 7 were distal. Of the 77 lesions with attempted dilation, lesion length measured 5.7 ± 3.1 mm, and minimal diameter measured 0.51 ± 0.25 mm. Vessel diameter (adjacent normal region) measured 2.27 ± 0.43 mm. Lesion stenosis severity ranged from 50 to 100%; the median stenosis was 78% and mean stenosis was $78 \pm 12\%$.

Outcome of attempted dilation (Fig. 2 and 3). In all 77 lesions in which angioplasty was attempted, the dilation catheter was able to be positioned proximal to the stenosis. In 11 lesions (14%) the wire tip could not be manipulated across the stenosis, and in an additional two lesions, the wire could not be advanced sufficiently distal to allow positioning of the balloon across the lesion. Thus, the balloon was able to cross the lesion in 64 instances (83%), which represented 97% of the instances in which the wire successfully passed the lesion. On one occasion, excessive rotation of the catheter to cross the lesion caused a twisting of the folded balloon, which could not inflate or deflate properly; it was removed without sequelae. Partial dilation occurred in another patient with a total occlusion, resulting in a decrease in the stenosis to 67% luminal reduction.

Among the 64 lesions that were crossed, dilation to a residual stenosis of <50% diameter reduction was accomplished in 62 (97%). Two lesions subsequently reclosed suddenly in the catheterization laboratory and could not be successfully redilated. In all nine lesions wherein a conventional catheter with a larger balloon was used for further dilation, a successful outcome was achieved.

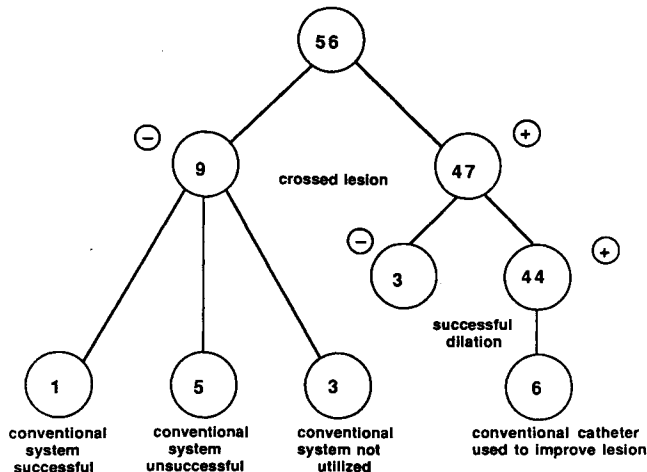


Figure 3. Flow diagram reflecting outcome of angioplasty in 56 lesions in which the study catheter was the initial catheter selected.

Of the 77 lesions in which angioplasty was attempted, the new catheter was used in 21 that could not be crossed with a conventional catheter system (Fig. 2). In these instances, a guide wire was able to reach and cross the lesions. Failure was due exclusively to the inability of the conventional balloon catheters to be advanced across the lesion because of the extreme severity of narrowing. These catheters included current generation low profile models such as Profile Plus and Lo Profile II dilation catheters (USCI, CR Bard, Inc.) and Hartzler Micro and Simpson Ultra Low-Profile catheters (Advanced Cardiovascular System, Inc.). The inflated balloon sizes of these catheters ranged from 2.0 to 3.0 mm, with the 2.0 mm size typically selected. The new catheter crossed 17 of these 21 lesions and achieved successful dilation in 16. Of four lesions in which the new catheter was also unable to cross, a second conventional catheter system was ultimately successful in dilating one stenosis.

The new catheter was chosen as the initial dilating system for 56 lesions (Fig. 3). In 47 stenoses (84%), the catheter was able to cross the lesion and successful dilation was performed in 44 lesions (79%). Three lesions could not be successfully dilated after crossing with the wire tip because of inability to advance the balloon portion of the catheter across the stenosis in two total coronary occlusions and to twisting of the balloon after rotation in the third case. Nine lesions (16%) could not be successfully crossed by the new catheter; for six of these lesions, a conventional dilating system was subsequently utilized but was successful in only one instance.

The catheter was generally successful regardless of the morphologic characteristics of the lesion (Table 2). The highest success rates were achieved with discrete (87%), concentric (82%) and noncalcific (81%) lesions. Slightly

lower success rates were seen with eccentric (77%), calcific (68%) and diffuse (63%) lesions.

Among lesions located within native coronary arteries, successful dilation was achieved in 33 (94%) of 35 lesions within the left anterior descending artery distribution, 13 (68%) of 19 within the right coronary artery distribution and 7 (54%) of 13 within the left circumflex artery system (Table 3). Of those lesions located in the proximal or mid portion of the three major coronary arteries, an 80% success rate was achieved. Thirteen (68%) of 19 lesions located in major branch arteries were successfully dilated. Distal lesions were successfully dilated in 25 attempts (89%). An example of a distal lesion before, during and after angioplasty is shown in Figure 4. Seven (70%) of 10 lesions located within bypass grafts underwent successful dilation.

Dilation data. The mean percent stenosis before angioplasty was significantly higher for lesions unsuccessfully dilated ($85.1 \pm 11.8\%$) than for those successfully dilated ($76.4 \pm 11.0\%$, $p = 0.01$). Similarly, the mean measured diameter of the coronary artery within the stenosis was smaller in lesions that could not (0.34 ± 0.23 mm) than in those that could (0.56 ± 0.23 mm; $p < 0.01$) be successfully dilated. The measured vessel diameter and lesion length did not significantly differ between lesions successfully and unsuccessfully dilated. After successful angioplasty, the mean postinflation stenosis diminished to $28.8 \pm 11.5\%$ (range 9 to 50%) in 60 patients. For those lesions successfully dilated, the number of inflations ranged up to 18 (mean 2.9 ± 2.7 inflations), the longest individual inflation times ranged from 10 to 120 s (mean 57 ± 24) and the total time of all inflations for the procedure ranged from 20 to 900 s (mean 126 ± 124). The maximal inflation pressure ranged from 4 to 18 bar (mean 8.0 ± 2.9).

Circumstances of catheter use (Table 4). We assessed outcome with respect to the circumstances for choosing this dilating catheter. The most common indication was a lesion in a small (<2 mm) diameter vessel. Of 37 lesions with attempted dilation, 28 (76%) were successfully dilated, 5 (14%) could not be crossed and 4 (11%) developed partial dilation or sustained reocclusion. Among 36 distally located lesions (including those in bypass grafts), dilation was successful in 31 stenoses (86%) and unsuccessful in 5 (14%) because of inability to cross the lesion. Other common circumstances included severe (90 to 99%) stenosis and tortuosity within the targeted artery, which were associated with 73 and 78% success rates, respectively. The catheter was successful in each of seven patients in whom the kissing balloon technique was utilized and in all eight patients for whom a conventional dilation catheter could have been selected. Of four vessels with a total occlusion, one procedure was unsuccessful because of inability to cross the lesion, one lesion was partially dilated to a residual 67% luminal reduction and two lesions were dilated to <50% residual stenosis.

Catheter-related problems. Problems related to the use of the dilation catheter included balloon rupture and balloon volvulus. The single episode of balloon volvulus occurred after excessive catheter rotation to manipulate over a lesion in a 2 mm diameter artery. Balloon rupture developed in four patients, with inflation pressures of 6, 11, 17 and 18 bar, respectively. There were no adverse sequelae to these events. In no instance did fragmentation of the catheter occur.

Angiographic complications. As already noted, coronary occlusion occurred in two patients. Additionally, coronary dissection exceeding the length of the lesion developed in three patients and an intimal tear within the lesion was seen in eight patients. There were no instances of coronary side branch occlusions.

Clinical complications. Clinical complications were observed in 5 of the 61 patients in whom the dilation catheter was used. Two patients had prolonged angina; one episode occurred during an unsuccessful attempt to cross a lesion with a 95% stenosis and the other episode was due to a side branch occlusion induced during angioplasty of another lesion with a conventional catheter. In one patient who developed reocclusion, a nonfatal myocardial infarction occurred. One patient developed ventricular fibrillation requiring electrical cardioversion. No patient developed systemic hypotension or required emergent intraaortic balloon insertion or coronary artery bypass surgery. No cerebrovascular accident or death occurred in the catheterization laboratory. Fifty-six patients (92%) were free of clinical complications during the procedure.

Discussion

Advantages of the new angioplasty catheter. As a result of improved technology, the primary success rate of angioplasty has increased despite a broadening of the indications to include patients with multivessel disease, distal coronary disease and total coronary occlusion. Hence, angioplasty was successful without adverse events in at least one or in all sites attempted in 88 and 78%, respectively, in the 1985 National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry (7). One common cause for failure is inability of the guide wire or balloon catheter to cross a highly stenotic lesion despite the new generation of low profile, steerable balloon catheters. The external dimension of the currently available low profile 2.0 mm balloon systems is approximately 0.032 in. (0.81 mm) (5). Because the dimension of our new catheter is only 0.020 in. (0.51 mm), it offers the potential for improved crossing rates, as is confirmed in this report. Thus, if a lesion could be crossed by the tip wire, the balloon was able to traverse the lesion to perform inflation in almost every instance (64 of 66). Of 21 lesions that could not be crossed initially by conventional low profile balloon catheters or guide wires, 16

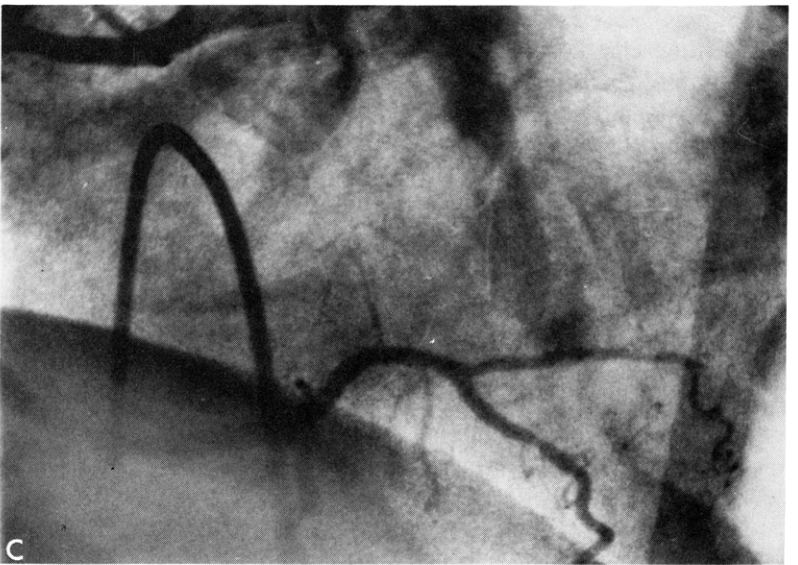
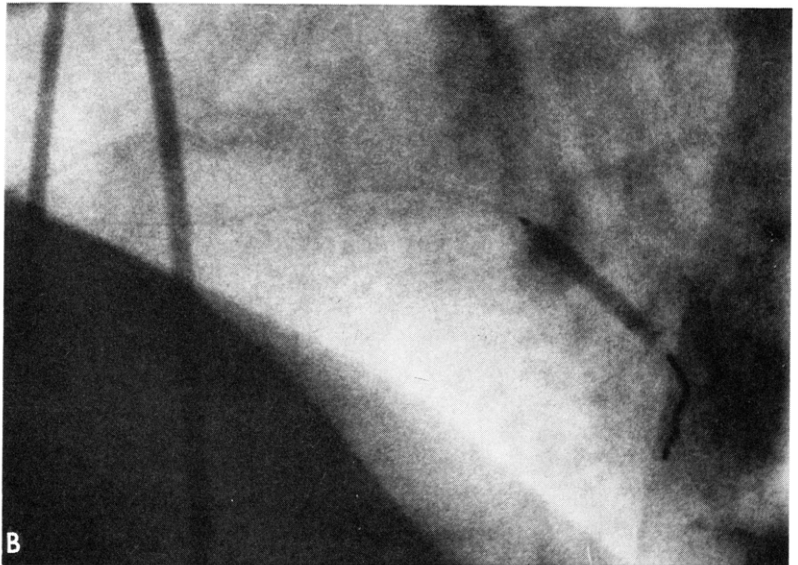
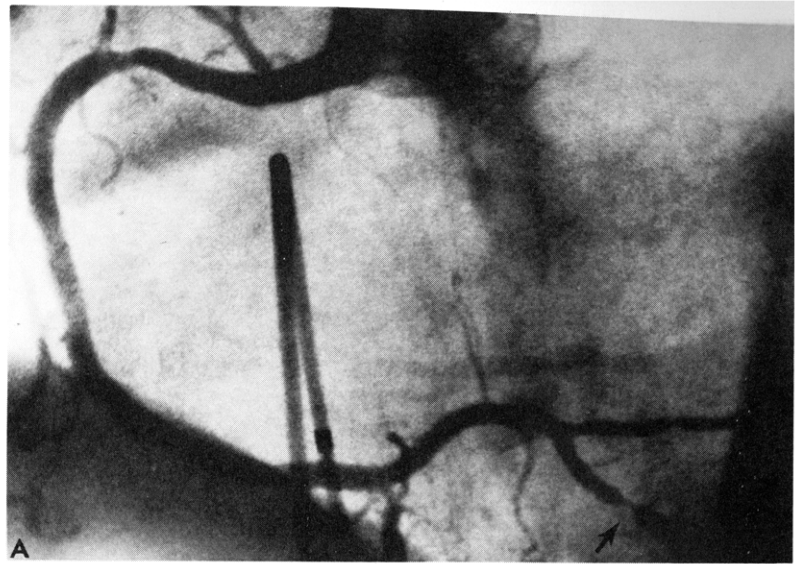


Figure 4. A, Coronary arteriogram of a patient with a significant distal stenosis in a postero-lateral branch of the right coronary artery (arrow). B, New catheter positioned across the distal stenosis during balloon inflation. C, Coronary arteriogram of the same patient after dilation.

Table 4. Factors Influencing Outcome in 77 Lesions With Attempted Dilation

Circumstance	Lesions With Attempted Dilation	Lesions With Successful Dilation	Unsuccessful Outcome	
			Unable to Cross	Unable to Dilate
Small (< 2 mm) diameter vessel	37	28	5	4
Tight (90 to 99%) stenosis	36	31	5	0
Distal location of stenosis	22	16	5	1
After failure of conventional system	21	16	4	1
Tortuous vessel	18	14	3	1
Elective use	8	8	0	0
Kissing balloon technique	7	7	0	0
Total occlusions	4	2	1	1
Total	77	60	13	4

Multiple circumstances may be present.

were successfully crossed and dilated by the new catheter. In the absence of the new catheter system, angioplasty would have failed in these patients. In addition to highly stenotic lesions, lesions that were distally located, or were in bypass grafts or in vessels that were <2 mm in diameter or tortuous were successfully dilated by the catheter. The catheter was also shown to be safe and free of significant morbidity in our study.

One important advantage of the new catheter system is that its small diameter allows use of a conventional 7F angiographic catheter as the guiding catheter. This permitted use of a diagnostic angiographic catheter as a guide for an internal mammary artery bypass graft in one patient and a venous saphenous bypass graft in another patient in whom cannulation by an 8F guiding catheter had been unsuccessful. The use of smaller diameter catheters as guiding catheters reduces coronary obstruction and enables enhanced guide catheter responsiveness.

Another important advantage of this catheter is that excellent opacification of the coronary artery results when contrast medium is injected through the guiding catheter. The low profile of the catheter throughout its entire length presents little obstruction for delivery of contrast medium. Therefore, accurate assessment of the results of the dilation can be made even with the deflated balloon positioned across the lesion. Contrarily, for the conventional over the wire system, the dilating catheter needs to be withdrawn into the guiding catheter or removed to permit adequate coronary visualization.

An exciting application of this new catheter is the insertion of two dilation balloon catheters through a single 8F guide catheter to perform kissing balloon angioplasty of a left anterior descending and diagonal coronary artery bifurcation lesion (Fig. 5). The procedure can be performed more expeditiously without sacrificing safety. Furthermore, the morbidity of the procedure is diminished because only one

arterial puncture and one guide catheter are needed to manipulate into the main coronary orifice.

Drawbacks and problems. There are potential drawbacks to the use of this new catheter system. The absence of a distal port does not allow for measurement of a translesional pressure gradient. Hodgson et al. (8) showed that the translesional pressure gradient is a powerful predictor of immediate angiographic and clinical results. Also, Redd et al. (9) identified a higher rate of acute postangioplasty complications in those patients having a rising transstenotic pressure gradient after balloon deflation. The design requirements to create an extremely low profile balloon catheter, forbid the presence of a distal port for pressure measurements; however, the added angiographic information that can be obtained with this system may offset this shortcoming.

Another problem is the absence of an independently movable guidewire that could allow the balloon catheter to be withdrawn into the guide catheter to perform coronary angiography after balloon inflations to assess residual stenosis. On the other hand, the new catheter system permits rapid delivery of contrast medium through the guide catheter such that the ability to judge success of angioplasty is actively enhanced even with the deflated balloon positioned across the lesion. Also, this system does not allow for the use of an exchange wire to permit a larger balloon catheter to be subsequently used without the need to recross the lesion. We have, however, on several occasions recrossed a dilated lesion with this system without difficulty.

Conclusions. We report our initial experience using a new, extremely low profile balloon catheter for performing percutaneous transluminal angioplasty. The catheter is safe and of particular value for dilating a high grade stenosis, especially in small or distal vessels. Because of the absence of a movable guide wire and possible need and risk of recrossing lesions. The catheter should not be used where conventional over the wire systems appear to be favorable.

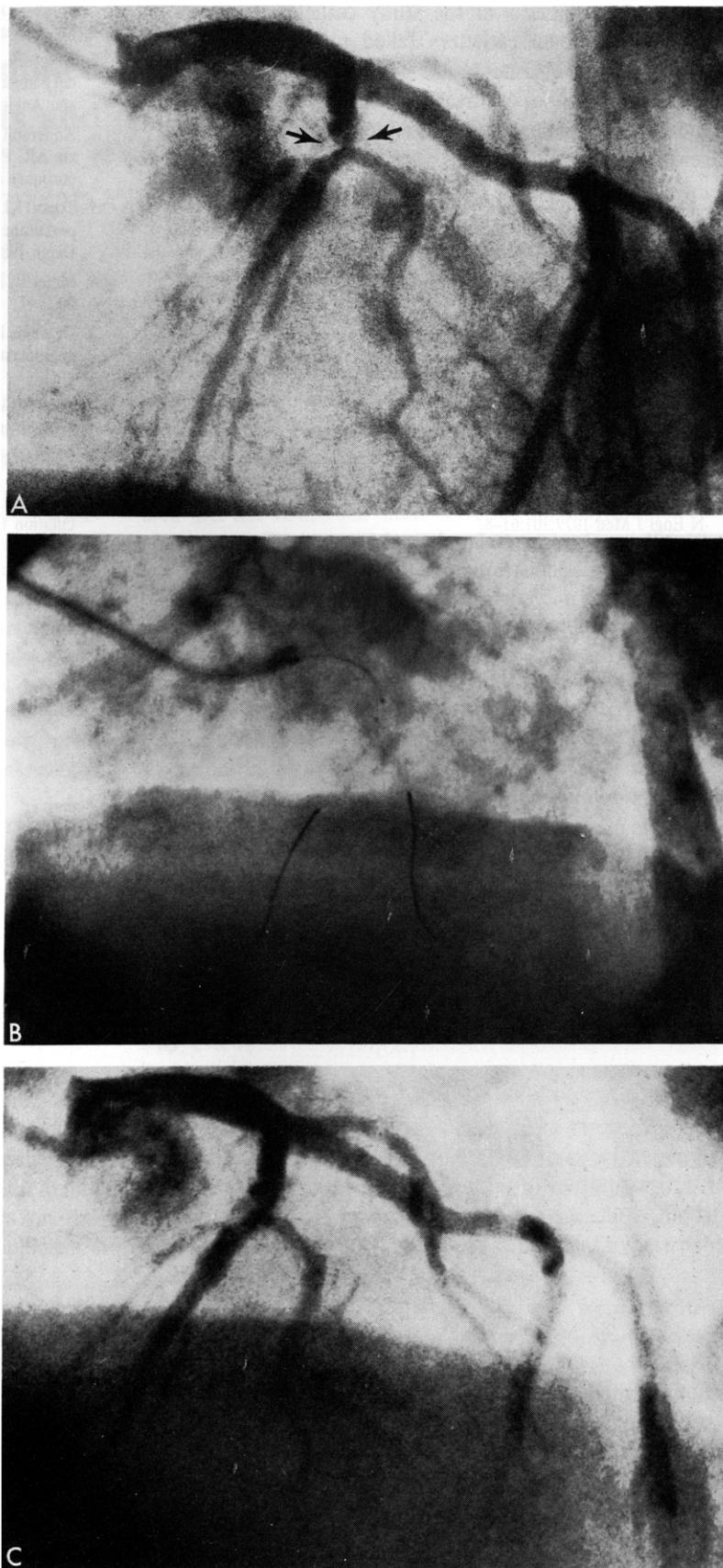


Figure 5. A. Coronary arteriogram of a patient with a significant bifurcation stenosis involving both the left anterior descending artery and diagonal branch (arrows). B. Two new catheters positioned in both vessels utilizing a single 8F guiding catheter. C. Coronary arteriogram of the same patient after kissing balloon inflation.

However, the success of the study catheter in situations where conventional catheters failed makes this a useful addition to our armamentarium for performing angioplasty and has the potential of further increasing the application of angioplasty to patients with symptomatic coronary artery disease.

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