

Prevention of Distal Embolization During Saphenous Vein Graft Lesion Angioplasty

Experience With a New Temporary Occlusion and Aspiration System

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Background—Repeat coronary artery bypass graft surgery (CABG) is associated with a high morbidity and mortality, rendering percutaneous treatment of saphenous vein graft (SVG) lesions an attractive alternative. However, percutaneous interventions of degenerated SVGs carries high risk of distal embolization.

Methods and Results—This study reports our initial experience with the PercuSurge GuardWire, a new device developed to prevent embolization during treatment of degenerated SVG. This device consists of a 190-cm-long, hollow 0.014-in guidewire with a central lumen connected to a distal occlusion balloon. A dedicated inflation device (the MicroSeal Adapter) was used to inflate the distal balloon and maintain complete lumen occlusion during balloon dilatation and stent implantation. A monorail aspiration catheter, connected to a vacuum syringe, was used to evacuate atherosclerotic and thrombotic debris. Angioplasty with stent implantation was performed in 15 degenerated SVGs (18 lesions). Procedural success was achieved in all patients with normal postprocedure flow (Thrombolysis in Myocardial Infarction grade 3). No distal embolization was observed. There were no major in-hospital adverse clinical events, including Q-wave or non-Q-wave myocardial infarction, emergency CABG, or death. All patients were asymptomatic at discharge.

Conclusions—This preliminary series supports the feasible use of the PercuSurge GuardWire for retrieval of plaque debris and prevention of embolization in degenerated SVGs. The good tolerance of temporary occlusions without angiographic or clinical evidence of distal embolization represents encouraging early findings. (*Circulation*. 1999;99:3221-3223.)

Key Words: angioplasty ■ veins ■ grafting ■ embolism

Approximately 33% of saphenous vein grafts (SVGs) become occluded by 10 years after bypass, and another 33% demonstrate significant atherosclerosis.¹ Repeat bypass surgery has a higher risk than the initial bypass operation.² Alternatively, percutaneous revascularization of degenerated SVGs remains a procedure with a risk of distal embolization. To overcome this problem, we evaluated a new device, the PercuSurge GuardWire temporary occlusion system (PercuSurge Inc), that provides temporary vascular occlusion during intervention of SVGs, preventing distal embolization of luminal material.

Methods

This study reports the initial experience at the San Raffaele Hospital and Columbus Hospital, Milan, Italy, in the use of a new technique for the treatment of SVGs. Fifteen consecutive patients, 13 male (87%), mean age 59 ± 9 years, with stenotic SVGs (18 lesions) were treated because of effort (8 patients, 53%) or unstable angina (7 patients, 47%). Mean ejection fraction was $42 \pm 17\%$. All patients

were pretreated with aspirin (100 mg/d) and ticlopidine (250 mg BID). Three patients received abciximab before the procedure. Serial creatine kinase levels were measured every 8 hours for the first 24 hours after the procedure (upper limit of normal value in our laboratory is 190 U/L).

The diagnosis of distal embolization was based on the following criteria: (1) cutoff of a distal branch or vessel at any point during the procedure; (2) decreased flow in a distal vessel in the absence of an occlusion at the site of the target lesion; or (3) myocardial infarction, death, or emergency CABG.

Description of the PercuSurge System

The PercuSurge GuardWire temporary occlusion and aspiration system (Figure) consists of 3 components: (1) a 190-cm-long, 0.014-in-OD hollow guidewire with a central lumen connected to a compliant distal occlusion balloon available in sizes from 3 to 6 mm in diameter (nominal size is reached at an inflation pressure of <2 atm). This guidewire balloon catheter has a distal shapable radiopaque tip to facilitate lesion crossing. Regular balloon catheters and stent delivery systems can be advanced over this wire to perform percutaneous interventions. A proprietary valve sealing system at the proximal end of

Received March 16, 1999; revision received April 19, 1999; accepted April 30, 1999.

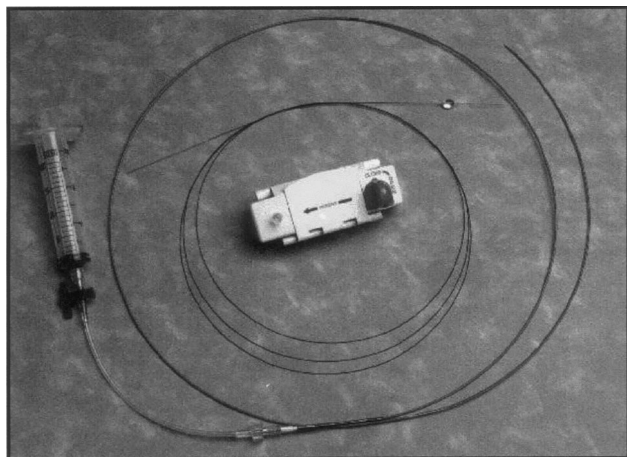
From the Istituto Scientifico San Raffaele (M.C., C.D., A.A., F.A., C.B., A.D., I.S., A.C.) and Centro Cuore Columbus (J.D., C.D., R.A., A.C.), Milan, Italy.

Dr Colombo has a small number of shares (equities) in the company PercuSurge.

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PercuSurge GuardWire temporary occlusion and aspiration system.

the guidewire maintains distal balloon inflation despite disconnection of the inflation device; (2) the MicroSeal Adapter, a device that controls the opening and closure of the proximal valve, allowing inflation and

deflation of the distal balloon; and (3) the Export Aspiration Catheter, a 5F monorail catheter connected to a 20-mL syringe providing a low-pressure vacuum to remove debris and thrombus from the graft.

Procedure

An 8F guiding catheter was used to cannulate the SVG. The PercuSurge GuardWire was prepped and advanced distal to the target lesion. The occlusive balloon was positioned 2 to 10 cm distal to the stenosis. The proximal end of the GuardWire was placed into the MicroSeal Adapter. By use of the Micro-Inflation Syringe and diluted contrast (1/3 dye and 2/3 saline), the occluding balloon was inflated and deflated in <10 seconds. The MicroSeal Adapter was removed, leaving the distal occlusion balloon inflated. A balloon catheter was then loaded over the proximal end of the GuardWire, advanced to the lesion, inflated for 10 to 20 seconds, and removed after deflation. The aspiration catheter (Export Aspiration Catheter) was then loaded over the proximal end of the GuardWire and advanced to the occlusion balloon. The plunger of the aspiration syringe was slowly retracted, and suction was applied to aspirate particulate debris. The maximal ID of the lumen at the distal tip is 1 mm, which limits material that can be extracted to ≤ 1 mm. If the material is conformable, the size of the extractable debris can be larger.

Vessel and Procedure Characteristics

	Graft																		Mean±SD
	1	2	3	4	5	6	7	8A	8B	9A	9B	10	11	12	13	14A	14B	15	
Graft																			
Age, y	6	6	13	15	8	10	1	6	6	14	14	11	1	13	9	15	15	11	9.2±4.5
Appearance*	DLI	DLI	SA	SA	DLI	DLI	SA	DLI	DLI	DLI	DLI	DLI	DLI	DLI	SA	DLI	DLI	SA	
Vessel supplied	OM	RCA	RCA	OM	OM	LAD	RCA	Diag	Diag	OM	OM	OM	OM	LCx	RCA	RCA	RCA	LAD	
Lesion																			
Appearance†	T	EP	T/U	EP/U	EP	T	T	EP	T/EP	T/EP	T	T	T	T	T	U	FD/U	CP	
Location	Prox	Distal	Prox	Mid	Mid	Prox	Ostial	Prox	Mild	Prox	Distal	Mid	Prox	Prox	Prox	Prox	Distal	Prox	
Length, mm	45.8	55.0	10.9	29.4	53.9	8.8	4.3	10.1	9.6	35.4	42.5	16.0	38.5	51.2	29.3	9.0	27.1	8.8	27.0±17.0
Balloon																			
Inflations‡	6	5	3	5	5	4	3	3	4	4	3	5	5	5	3	3	4	3	4.0±1.0
Size, mm	4.0	4.0	4.0	4.0	4.0	5.0	3.5	4.5	3.5	3.5	4.0	4.5	3.5	4.0	3.5	3.5	3.5	4.0	3.9±0.4
Length, mm	35	25	20	20	35	20	15	25	20	25	30	30	30	40	36	20	36	40	27.9±7.8
Pressure, atm	14	14	14	14	12	14	12	11	18	14	10	12	16	12	12	18	18	14	13.8±2.3
Distal balloon occlusion, min	5.5	6	3	7	6	4	5	4	3.5	4	4	7	6	5	4	5	5	3.5	4.8±1.2
Blood w/d, mL	40	40	20	40	40	20	20	20	20	20	20	40	40	40	20	20	20	20	27.8±10.0
Debris	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	Yes	Yes	No	No	No	No	Yes	
Peak creatine kinase, U/L	27	51	98	43	114	67	115	312	312	182	182	61	34	283	239	71	71	70	
RD, mm																			
Pre	4.05	4.79	4.01	4.52	3.89	4.58	3.69	3.74	3.43	3.52	3.80	4.31	4.02	4.20	3.45	4.40	4.40	4.45	4.01±0.50
Post	4.35	4.75	4.21	4.54	4.01	4.71	3.70	4.68	4.01	3.73	4.09	4.29	4.10	4.42	3.60	4.38	4.42	4.40	4.24±0.30
MLD, mm																			
Pre	1.33	0.75	1.36	1.78	1.00	0.90	1.10	0.36	1.63	0.54	0.65	0.46	0.90	0.50	0.67	2.01	1.10	1.41	1.02±0.48
Post	3.62	4.01	3.87	3.70	3.50	3.77	3.70	3.87	4.04	2.79	3.43	4.18	3.90	3.81	3.52	3.80	3.50	4.39	3.74±0.34§
TIMI grade																			
Pre	2	1	3	3	2	1	3	2	2	1	1	3	3	2	3	2	2	1	2.0±0.8
Post	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3±0

DLI indicates diffuse lumen irregularities; SA, smooth appearance; OM, obtuse marginal; RCA, right coronary artery; LAD, left anterior descending coronary artery; Diag, diagonal branch; LCx, left circumflex; T, thrombus; EP, eccentric plaque; U, ulceration; FD, filling defect; CP, concentric plaque; Prox, proximal; w/d, withdrawn; RD, reference diameter; and MLD, minimum lumen diameter.

*Refers to the appearance of the graft except for the culprit lesion.

†Refers to the appearance of the lesion.

‡Refers to the total number of balloon inflations (predilatation, stent placement, and postdilatation).

§ $P < 0.0001$ for comparison with pre-PTCA values (paired t test).

The occlusive balloon was then deflated to relieve ischemia. If the patient tolerated the occlusion of the graft (no major pain, ST-segment changes, pressure drop, or significant arrhythmias), this intermediate-phase aspiration and occlusion relief were skipped and we proceeded directly to stenting. After the stenting procedure, a final aspiration of blood and debris was performed. The occlusion balloon was then deflated, allowing flow to resume.

The efficacy and safety of the catheter system was evaluated, assessing the in-hospital end points of death, myocardial infarction, emergency CABG, occurrence of no-reflow, or deterioration in the initial TIMI grade of flow.

Results

Procedural characteristics and quantitative angiographic results are shown in the Table. The mean duration of graft occlusion was 4.8 ± 1.2 minutes, decreasing as experience was gained. Clinical and angiographic success was obtained in all patients. During balloon inflation, 9 of 15 patients developed angina, but in no instance was angina or arrhythmia so severe as to require premature deflation of the occlusion balloon. One patient with a left ventricular ejection fraction of 25% had the entire procedure performed with elective intra-aortic balloon counterpulsation. TIMI flow after the procedure was normal in all these patients and without angiographic evidence of distal embolization. No elevation of creatine kinase to greater than twice the upper limit was observed. No major adverse events occurred during the hospital stay, and all patients were discharged without symptoms the day after the treatment.

In 7 of 15 patients (47%), gross red-yellow debris in the extracted blood was macroscopically visible. In 3 other patients, histological examination of the extracted blood showed evidence of cholesterol clefts, lipid-rich macrophages, amorphous lipids, and fibrin.

Discussion

Intracoronary administration of urokinase,³ extraction coronary atherectomy,⁴ directional coronary atherectomy,⁵ laser angioplasty,⁶ and more recently ultrasound thrombolysis⁷ have been advocated to prevent or reduce embolization during treatment of SVGs. The initial expectations, however, were not fulfilled. The use of stents in the treatment of SVG lesions has shown improved outcome compared with conventional balloon angioplasty,⁸ without solving the problem of distal embolization. New techniques to reduce distal embolization include direct stenting and use of covered stents to segregate the friable plaque,^{9,10} but the covered stents are still investigational and are associated with a delayed endothelialization potentially worrisome during treatment of long lesions. The system studied in this trial can be used in conjunction with any other interventional device that can be advanced over the main shaft of the 0.014-in GuardWire.

In this preliminary cohort of consecutive patients, a favorable procedural outcome was obtained, because distal embolization was not observed in any patient despite the high incidence of lesions with thrombus, ulceration, or diffuse luminal irregularities. The fear that the period of occlusion (maximum 7 minutes in our series) was too long to be tolerated because of symptoms or hemodynamic or arrhythmic complications was not substantiated in this study.

Conclusions

The initial experience with the PercuSurge GuardWire temporary occlusion system demonstrates that it is feasible to use this device during percutaneous intervention of SVG lesions with a sufficient tolerance of temporary occlusions and absence of angiographic or clinical signs of distal embolization.

References

1. Bourassa MG, Fischer LD, Campeau L, Gillespie MJ, McConney M, Lesperance J. Long-term fate of bypass grafts: the Coronary Artery Surgery Study (CASS) and Montreal Heart Institute experiences. *Circulation*. 1985;72(suppl V):V-71-V-78.
2. Cameron A, Kemp HG Jr, Green GE. Reoperation for coronary artery disease: 18 years of clinical follow-up. *Circulation*. 1988;78(suppl I):I-158-I-162.
3. Hartmann J, McKeever L, Teran J. Prolonged infusion of urokinase for recanalization of chronically occluded aortocoronary bypass graft. *Am J Cardiol*. 1988;61:189-191.
4. Safian RD, Grines CL, May MA, Lichtenberg A, Juran N, Schreiber TL, Pavlides G, Meany TB, Savas V, O'Neil WW. Clinical and angiographic results of transluminal extraction coronary atherectomy in saphenous vein bypass grafts. *Circulation*. 1994;89:302-312.
5. Holmes DR Jr, Topol EJ, Califf RM, Berdan LG, Leya F, Berger PB, Whitlow PL, Safian RD, Adelman AG, Kellet MA Jr, Talley D III, Shani J, Gottlieb RS, Pinkerton CA, Lee KL, Keeler GP, Ellis SG, the CAVEAT-II Investigators. A multicenter, randomized trial of coronary angioplasty versus directional atherectomy for patients with saphenous vein bypass graft lesions. *Circulation*. 1995;91:1966-1974.
6. Bittl JA, Sanborn TA, Yardley DE, Tcheng JE, Isner JM, Chokshi SK, Strauss BH, Abela GS, Walter PD, Schmidhofer M, Power JA, for the Percutaneous Excimer Laser Coronary Angioplasty Registry. Predictors of outcome of percutaneous excimer laser coronary angioplasty of saphenous vein bypass graft lesions. *Am J Cardiol*. 1994;74:144-148.
7. Rosenschein U, Gaul G, Erbel R, Amann F, Velasquez D, Stoerger H, Reudiger S, Gomez G, Troster J, Bartorelli A, Peper M, Kyriakides Z, Laniado S, Miller HI, Cribier A, Fajadet J. Percutaneous transluminal therapy of occluded saphenous vein grafts: can the challenge be met with ultrasound thrombolysis? *Circulation*. 1999;99:26-29.
8. Savage MP, Douglas JS Jr, Fischman DL, Pepine CJ, King SB, Werner JA, Bailey SR, Overlie PA, Fenton SH, Brinker JA, Leon MB, Goldberg S, Saphenous Vein De Novo Trial Investigators. Stent placement compared with balloon angioplasty for obstructed coronary bypass grafts. *N Engl J Med*. 1997;337:740-747.
9. Greckens U, Muller R, Cattelaens N, Herchenbach, Grube E. The new coronary stent graft JoStent: first clinical experience. *J Am Coll Cardiol*. 1998;31:414A. Abstract.