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EXPEDITED REVIEWS

Prospective, Randomized Evaluation of Thrombectomy Prior to Percutaneous Intervention in Diseased Saphenous Vein Grafts and Thrombus-Containing Coronary Arteries

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OBJECTIVES We sought to determine whether routine thrombectomy prior to stent implantation in diseased saphenous vein grafts (SVGs) and thrombus-containing native coronary arteries would reduce peri-procedural myonecrosis and subsequently enhance event-free survival.

BACKGROUND Percutaneous coronary intervention in diseased SVGs and thrombotic native coronary arteries is complicated by a high rate of peri-procedural myocardial infarction (MI). Thrombectomy prior to intervention may enhance the safety of intervention and improve early and late outcomes in these high-risk patients.

METHODS At 60 centers in the U.S. and Canada, 797 patients with 839 diseased SVGs or thrombus-containing native coronary arteries were prospectively randomized to stent implantation with versus without prior thrombectomy with the X-SIZER device (ev3, Plymouth, Minnesota).

RESULTS Peri-procedural MI occurred in 15.8% of patients assigned to the X-SIZER device compared with 16.6% of control patients ($p = 0.77$), although the rate of large MI (pre-specified as the development of new pathologic Q waves or creatine phosphokinase-MB isoenzyme elevation $>8 \times$ upper limits of normal) was reduced with X-SIZER device use from 9.6% to 5.5% (multivariate risk ratio 0.35 [95% confidence interval 0.18 to 0.66], $p = 0.002$). Major adverse cardiac events (cardiac death, MI, or repeat target vessel revascularization) occurred in 16.8% of X-SIZER patients versus 17.1% of control patients at 30 days ($p = 0.92$), and in 31.3% of X-SIZER patients versus 28.2% of control patients at 1 year ($p = 0.35$).

CONCLUSIONS Thrombectomy with the X-SIZER device prior to stent implantation in high-risk diseased SVGs and thrombus-containing native coronary arteries may reduce the extent, but not the occurrence, of myonecrosis. Early and late event-free survival, however, were not improved by routine thrombectomy with this device. (J Am Coll Cardiol 2003;42:2007–13) © 2003 by the American College of Cardiology Foundation

The introduction of coronary stents and adjunctive pharmacologic agents including thienopyridines and glycoprotein (GP) IIb/IIIa receptor inhibitors have improved the safety profile of percutaneous coronary intervention (PCI) (1–5). Despite contemporary approaches, however, the rate of peri-procedural complications remains excessively high after PCI in friable lesions prone to embolization, including native coronary arteries with thrombus and diseased saphenous vein grafts (SVGs) (6–8). Mechanical extraction of soft atherothrombotic material prior to stent implantation may further enhance the safety and efficacy of PCI in high-risk lesions. Therefore, we performed a large-scale, multicenter, prospective, randomized trial to determine the utility of thrombectomy with the X-SIZER device (ev3, Plymouth, Minnesota) during PCI.

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METHODS

Study population and study protocol. Angiographic inclusion criteria required the presence of ≥1 lesion in a native coronary artery or SVG with a reference vessel diameter

Abbreviations and Acronyms

CPK = creatine phosphokinase
GP = glycoprotein
MACE = major adverse cardiac events
MI = myocardial infarction
PCI = percutaneous coronary intervention
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction
TVR = target vessel revascularization
ULN = upper limit of normal
X-TRACT = X-SIZER for Treatment of Thrombus and Atherosclerosis in Coronary Interventions Trial

≥3.0 mm and a diameter stenosis >50% but <100%; totally occluded SVG lesions could be enrolled if successfully crossed with a guidewire. The presence of angiographic thrombus as assessed by the investigator was also mandatory for inclusion of native coronary artery lesions, although *not* for SVGs. Patients with multiple lesions in the same or different vessels were eligible if all lesions met enrollment criteria. Clinical and angiographic exclusion criteria included: recent (<24 h) or acute myocardial infarction (MI) or elevated creatine phosphokinase (CPK)-MB isoenzyme on the day of the procedure; left ventricular ejection fraction <30% or cardiogenic shock; target lesion was either an isolated ostial lesion, at the distal SVG anastomosis, within a SVG <6 months old or an arterial bypass graft conduit, or within a previously stented segment; excessive vessel or lesion tortuosity or calcification; prior unsuccessful or complicated PCI within 6 months; and current participation in other investigational protocols. The study was approved by the institutional review board at each participating center, and consecutive, eligible patients signed informed, written consent.

Before the catheterization procedure, patients received chewable aspirin 325 mg and clopidogrel 300 mg. The decision to use procedural GP IIb/IIIa inhibitors was left to

Table 1. Baseline Clinical and Angiographic Characteristics

	X-SIZER Prior to Stent	Stent Alone	p Value
Demographic features			
Number of patients	400	397	
Age (yrs)	66.4 ± 10.3	65.4 ± 12.1	0.54
Range	31–88	30–88	–
Male gender (%)	78.5	79.1	0.86
Diabetes mellitus (%)	31.6	29.5	0.54
Hypertension (%)	68.9	67.5	0.70
Hyperlipidemia (%)	72.4	69.4	0.39
Current cigarette use (%)	19.6	22.6	0.33
Prior myocardial infarction (%)	66.2	62.4	0.29
Prior coronary bypass surgery (%)	77.0	73.6	0.29
Peripheral vascular disease (%)	16.8	17.0	0.99
Cerebrovascular disease (%)	8.6	11.4	0.19
Unstable angina (%)	85.5	88.9	0.17
Left ventricular ejection fraction (%)	49.4 ± 11.8	50.7 ± 11.1	0.15
Angiographic features			
Number of target vessels	420	419	
Single-vessel disease (%)	22.3	24.9	0.40
Double-vessel disease (%)	18.5	19.5	0.79
Triple-vessel disease (%)	59.1	55.6	0.32
Target lesion			
Left anterior descending artery (%)	6.1	9.6	0.07
Left circumflex artery (%)	3.5	3.0	0.69
Right coronary artery (%)	15.7	15.6	0.99
Saphenous vein graft (%)	74.7	71.9	0.38
Core laboratory analysis			
TIMI flow (%)			
0/1	12.9	10.5	0.46
2	13.4	10.9	0.33
3	73.7	78.6	0.11
Thrombus (%)	70.1	57.7	< 0.001
Eccentric lesion (%)	36.5	41.0	0.19
ACC/AHA lesion class B_2/C (%)	69.1	70.6	0.94
Reference vessel diameter (mm)	3.33 ± 0.74	3.30 ± 0.66	0.94
Minimal luminal diameter (mm)	1.01 ± 0.68	1.10 ± 0.69	0.07
Diameter stenosis (%)	69.9 ± 18.8	66.8 ± 19.2	0.01
Lesion length (mm)	15.1 ± 10.4	15.2 ± 10.0	0.88

ACC = American College of Cardiology; AHA = American Heart Association; TIMI = Thrombolysis In Myocardial Infarction.