

Comparative Results of Transluminal Extraction Coronary Atherectomy in Saphenous Vein Graft Lesions With and Without Thrombus

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Objectives. The purpose of this retrospective study was to compare the results of transluminal extraction coronary atherectomy in saphenous vein graft lesions with and without angiographic thrombus.

Background. Percutaneous interventions in lesions with thrombus are associated with reduced procedural success and increased risk of complications. Use of the transluminal extraction catheter, which cuts and aspirates atheroma and thrombus, has been advocated as a potential revascularization strategy for lesions with thrombus.

Methods. Baseline patient characteristics, lesion morphology, immediate angiographic results, in-hospital complications and follow-up were prospectively entered into an interventional cardiology data base. The results of transluminal extraction coronary atherectomy in saphenous vein bypass grafts with angiographic thrombus were compared with results in similar grafts without angiographic thrombus.

Results. Transluminal extraction coronary atherectomy was

performed in 175 patients with 183 vein graft lesions, including 59 lesions (32%) with thrombus (Group 1) and 124 (68%) without thrombus (Group 2). Compared with lesions in Group 2, lesions in Group 1 were associated with a higher incidence of baseline total occlusion, diffuse disease and abnormal Thrombolysis in Myocardial Infarction (TIMI) grade flow ($p < 0.05$); more severe diameter stenosis at baseline, after atherectomy and after final angiography ($p < 0.05$); a lower rate of clinical success (69% vs. 88%, $p < 0.01$); and more angiographic and clinical complications, including no reflow ($p < 0.05$), vascular repair ($p < 0.05$) and Q wave myocardial infarction ($p = 0.09$).

Conclusions. In transluminal extraction coronary atherectomy of saphenous vein bypass grafts, the presence of thrombus is associated with more baseline lesion complexity, reduced clinical success and increased risk of no reflow, Q wave myocardial infarction and vascular repair.

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Percutaneous coronary revascularization in the presence of thrombus or in clinical settings where thrombus is likely to be present is associated with increased risk of abrupt vessel closure, myocardial infarction, emergency coronary artery bypass surgery and death (1-3). The importance of angiographic thrombus was recognized in the American Heart Association/American College of Cardiology Guidelines for Percutaneous Transluminal Coronary Angioplasty (4).

Saphenous vein bypass grafts >4 years of age frequently contain thrombus (5-7). Percutaneous intervention in these lesions is associated with higher risks of distal embolization, no reflow and myocardial infarction than those associated with interventions in native coronary arteries (8,9). The translumi-

nal extraction catheter is a new percutaneous interventional device that may have a role in thrombotic lesions (10) by virtue of its ability to cut and aspirate atheroma and thrombus. The aim of this study was to determine the impact of thrombus on immediate results and complications for transluminal extraction coronary atherectomy of old saphenous vein bypass graft lesions.

Methods

Atherectomy procedure. Between 1989 and 1993, transluminal extraction coronary atherectomy of saphenous vein bypass grafts was performed in 183 lesions in 175 consecutive patients with a mean age of 65 ± 12 years. The immediate results, complications and follow-up of the first 146 patients were previously reported (11). All procedures were performed in accordance with a protocol approved by the Human Investigations Committee of William Beaumont Hospital, as previ-

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ously described (11). Device selection, use of intracoronary thrombolytic agents and adjunctive balloon angioplasty were used at the discretion of the operator. Since 1991, the results of percutaneous coronary interventions have been prospectively entered into the William Beaumont Hospital Interventional Cardiology Database with the use of a standard case report form. Interventions performed before 1991 were entered retrospectively into the data base.

Angiographic assessment. Assessment of baseline lesion characteristics and quantitative angiography using digital calipers was performed as previously described (11). Thrombus was defined as a definite circumscribed intraluminal filling defect on baseline angiography, whereas intraluminal haziness alone was not considered sufficient evidence for thrombus. Measurements were made of minimal lumen diameter, reference diameter and lesion length; percent diameter stenosis was calculated by using standard formulas.

Definitions. The following definitions were used: *Angiographic success* = final diameter stenosis <50%; *clinical success* = final diameter stenosis <50% in the absence of death, emergency bypass surgery or Q wave myocardial infarction; *distal embolization* = new appearance of circumscribed filling defects or abrupt cutoff of the vessel distal to the target lesion, or both; *no reflow* = poor anterograde flow (Thrombolysis in Myocardial Infarction [TIMI] grade ≤1) not explained by dissection or high grade residual stenosis at or adjacent to the target lesion; *abrupt closure* = poor anterograde flow (TIMI grade ≤1) due to acute occlusion of the target lesion; *non-Q wave myocardial infarction* = elevation of creatine kinase >3 times the upper limit of normal in the absence of pathologic Q waves; *sizing index* = the ratio of the final device diameter to the reference artery diameter (D/A ratio) or the ratio of the final balloon diameter to the reference artery diameter (B/A ratio), as previously described (12); *efficiency of transluminal extraction coronary atherectomy* or *balloon-mediated lumen enlargement* = the ratio of the residual lumen diameter after atherectomy to the final device diameter (RLD/D) or the ratio of the final lumen diameter after angioplasty to the final balloon diameter (FLD/B), as previously described (12).

End points. End points included procedural success, angiographic complications (abrupt closure, no reflow, distal embolization and perforation) and clinical complications (death, myocardial infarction, vascular repair, blood transfusion, stroke). Clinical follow-up was obtained for patients discharged from the hospital after successful revascularization. Late events included death, myocardial infarction and the need for target vessel revascularization (repeat percutaneous intervention or bypass surgery). Angiography was recommended to all patients with recurrent symptoms.

Statistical analyses. Data are reported as mean value ± SD. Comparisons were performed using the Student *t* test for continuous variables and the Fisher exact test for categorical variables with small observed frequencies (JMP software, SAS Institute).

Table 1. Baseline Characteristics of Patients Treated With Transluminal Extraction Coronary Atherectomy in Vein Grafts

| | Total (n = 183) | Group 1 (n = 59) | Group 2 (n = 124) |
|---------------------|--------------------|---------------------|----------------------|
| Age (yr) | 65 ± 9 | 64 ± 10 | 65 ± 9 |
| Male | 83% | 85% | 73% |
| CCS Angina class IV | 47% | 56% | 43% |
| Acute MI* | 3% | 8% | 0% |
| LVEF (%) | 47 ± 13% | 45 ± 12% | 48 ± 14% |
| SVG age (yr) | 8.2 ± 0.4 | 8.6 ± 0.5 | 8.0 ± 0.3 |

*p < 0.01, comparing Group 1 and Group 2. Data are expressed as mean value ± SD or percent of group. CCS = Canadian Cardiovascular Society; LVEF = left ventricular ejection fraction; MI = myocardial infarction; SVG = saphenous vein graft.

Results

Baseline characteristics. The 175 study patients were classified into two groups: Group 1 (n = 59 lesions, 32%) with thrombus and Group 2 (n = 124 lesions, 68%) without thrombus. The two groups were similar in age, gender distribution, Canadian Cardiovascular Society angina class, left ventricular ejection fraction and vein graft age (Table 1). The indication for percutaneous revascularization was acute myocardial infarction in five patients (8%) in Group 1 in contrast to no patients in Group 2 (p < 0.01).

Angiographic results. Baseline angiography revealed a significantly higher incidence of baseline total occlusion (17% vs. 6%, p < 0.05), diffuse disease (71% vs. 43%, p < 0.05) and delayed anterograde flow (53% vs. 16%, p < 0.05) in Group 1 than in Group 2 but a lower frequency of aortoostial lesions (7% vs. 23%, p < 0.05) (Table 2). Adjunctive percutaneous transluminal coronary angioplasty was used in 92% of lesions and was similar for both groups. Despite similar reference vessel diameters in the two groups of lesions, quantitative angiography revealed more severe diameter stenoses in Group 1 than in Group 2 (p < 0.05), including those at baseline, after extraction coronary atherectomy and after final angiography (with or without adjunctive angioplasty) (Table 3). These findings may be partially explained by the smaller D/A and B/A

Table 2. Qualitative Angiographic Characteristics of Vein Graft Lesions Treated With Transluminal Extraction Coronary Atherectomy

| | Group 1 (n = 59) | | Group 2 (n = 124) | |
|-----------------------------|---------------------|-----|----------------------|-----|
| | No. | % | No. | % |
| Multivessel disease | 59 | 100 | 124 | 100 |
| Aorto-ostial* | 4 | 7 | 29 | 23 |
| Total occlusion* | 10 | 17 | 7 | 6 |
| Eccentric | 32 | 54 | 80 | 64 |
| Ulceration | 6 | 10 | 20 | 16 |
| Diffuse disease* | 40 | 71 | 52 | 43 |
| Baseline TIMI flow grade 3* | 28 | 47 | 104 | 84 |
| Final TIMI flow grade 3* | 38 | 64 | 113 | 91 |

*p < 0.05, comparing Group 1 and Group 2. TIMI = Thrombolysis in Myocardial Infarction.

Table 3. Quantitative Angiographic Results of Vein Graft Lesions Treated With Transluminal Extraction Coronary Atherectomy

| | Group 1 (n = 59) | Group 2 (n = 124) |
|-------------------------------|---------------------|----------------------|
| Reference diameter (mm) | 3.91 ± 0.1 | 3.68 ± 0.1 |
| Lumen diameter (mm) | | |
| Baseline* | 0.72 ± 0.1 | 0.94 ± 0.1 |
| Residual (after atherectomy) | 1.38 ± 0.1 | 1.54 ± 0.1 |
| Final | 2.27 ± 0.1 | 2.44 ± 0.1 |
| Diameter stenosis (%) | | |
| Baseline* | 82 ± 2 | 74 ± 1 |
| Residual (after atherectomy)* | 64 ± 3 | 57 ± 2 |
| Final* | 40 ± 3 | 32 ± 2 |
| Final device diameter (mm) | 2.2 ± 0.1 | 2.2 ± 0.1 |
| D/A* | 0.59 ± 0.02 | 0.65 ± 0.01 |
| RLD/D† | 0.61 ± 0.04 | 0.70 ± 0.03 |
| Final balloon diameter (mm) | 3.60 ± 0.1 | 3.70 ± 0.1 |
| B/A | 0.99 ± 0.1 | 1.02 ± 0.1 |
| FLD/B* | 0.60 ± 0.25 | 0.68 ± 0.24 |

*p < 0.05, †p = 0.08, comparing Group 1 and Group 2. Data are expressed as mean value ± SD. B/A = ratio of final balloon diameter to reference diameter (balloon sizing index); D/A = ratio of final device diameter to reference diameter (device sizing index); FLD/B = ratio of final lumen diameter to final balloon diameter (balloon efficiency ratio); RLD/D = ratio of residual lumen diameter (after transluminal extraction coronary atherectomy) to final device diameter (transluminal extraction coronary atherectomy efficiency index).

ratios (sizing indexes) and lower efficiency of lumen enlargement (RLD/D) in Group 1. Final angiographic success was achieved in 84% of the lesions and clinical success in 81%. However, the rates of angiographic success (75% vs. 89%, p = 0.03) and clinical success (69% vs. 88%, p < 0.01) were lower in Group 1 than in Group 2, indicating a less favorable outcome in lesions with thrombus.

Angiographic assessment of thrombus extraction. By definition, baseline angiography revealed intraluminal filling defects consistent with thrombus in all lesions in Group 1. In these lesions, angiography revealed persistent filling defects consistent with residual thrombus or dissection, or both, in 26% of lesions after extraction coronary atherectomy and 12% of lesions after adjunctive coronary angioplasty. In contrast, new intraluminal filling defects were observed in 3% of Group 2 lesions after atherectomy and 0.8% after adjunctive angioplasty. The incidence of new or persistent filling defects was significantly higher after atherectomy and after angioplasty for Group 1 lesions (p < 0.001). Adjunctive intracoronary thrombolytic therapy (urinkase, 250,000 to 1 million U) was administered in 39% of Group 1 lesions and in 6% of Group 2 lesions (p < 0.0001), but the use of oral sodium warfarin (Coumadin) at the time of discharge was similar (66% of Group 1 and 50% of Group 2).

Angiographic complications (Table 4). Abrupt closure and distal embolization occurred in 4% and 7% of lesions respectively, but there were no differences between the two groups. Coronary perforation was not observed in any vein graft lesions. Overall, no reflow was observed in 17 lesions (9%) but its frequency was significantly higher in Group 1 than in Group

Table 4. Angiographic and Clinical Complications of Transluminal Extraction Coronary Atherectomy in Vein Graft Lesions

| | Total (n = 183) | | Group 1 (n = 59) | | Group 2 (n = 124) | |
|-----------------------------------|--------------------|-----|---------------------|----|----------------------|---|
| | No. | % | No. | % | No. | % |
| Angiographic complications | | | | | | |
| Abrupt closure | 7 | 4 | 3 | 5 | 4 | 3 |
| Distal embolization | 12 | 7 | 5 | 8 | 7 | 6 |
| No reflow* | 17 | 9 | 11 | 19 | 6 | 5 |
| Perforation | 0 | 0 | 0 | 0 | 0 | 0 |
| Clinical complications | | | | | | |
| Death | 3 | 2 | 1 | 2 | 2 | 2 |
| CABG | 1 | 0.5 | 1 | 2 | 0 | 0 |
| Q wave MI† | 4 | 2 | 4 | 6 | 1 | 1 |
| Non-Q wave MI | 4 | 2 | 2 | 4 | 2 | 2 |
| IABP | 9 | 5 | 4 | 7 | 5 | 4 |
| Vascular repair* | 2 | 1 | 2 | 4 | 0 | 0 |
| Transfusion | 9 | 5 | 4 | 6 | 5 | 4 |
| CNS event | 4 | 2 | 2 | 4 | 2 | 2 |

*p < 0.05; †p = 0.09 if patients presenting with acute myocardial infarction are excluded, comparing Group 1 and Group 2. CABG = coronary artery bypass grafting; CNS event = stroke or transient ischemic attack; IABP = intraaortic balloon pump; MI = myocardial infarction.

2 (19% vs. 5%, p < 0.05). Furthermore, the frequency of no reflow was still higher in Group 1 even when patients who presented with acute myocardial infarction were excluded from analysis (16% vs. 5%, p < 0.05).

Clinical complications (Table 4). Overall, the composite end point of death, coronary bypass grafting and Q wave myocardial infarction occurred in 11 patients (6%). However, the composite end point was more frequent in Group 1 than in Group 2 patients (13.3% vs. 2.4%, p < 0.01). After exclusion of patients who presented with acute myocardial infarction, there was a trend toward a higher frequency of Q wave myocardial infarction in Group 1 than in Group 2 patients (6% vs. 1%, p = 0.09). Although the need for vascular repair was more frequent in Group 1 patients (4% vs. 0%, p < 0.05), this need may have been associated with the use of adjunctive thrombolytic therapy (39% vs. 6%, p < 0.0001).

Follow-up. Complete clinical follow-up was available in 130 (92%) of 141 patients discharged from the hospital after successful atherectomy. Group 1 and 2 patients were similar with respect to angina class (class 0 in 45% and 34%, class 1 to 2 in 13% and 27%, class 3 in 23% and 20% and class 4 in 19% and 18%, respectively; p = NS) at an average follow-up interval of 6.0 ± 2.1 months after discharge. The hierarchical incidence of late cardiac events was similar for both groups, including recurrent angina treated medically in 16% and 23%, repeat percutaneous intervention on the original target lesion in 26% and 27%, percutaneous intervention on a new lesion in 4% and 3%, coronary bypass surgery in 3% and 9%, Q wave infarction in 6% and 3% and late death in 0% and 1.5%, respectively. Clinical restenosis, defined as repeat intervention (percutaneous procedure or coronary artery bypass grafting) on the original target lesion, Q wave infarction or death,

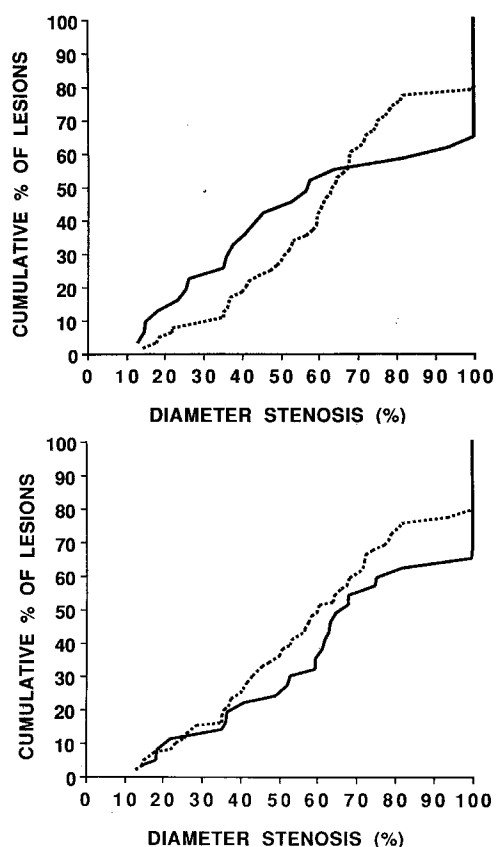


Figure 1. Cumulative frequency distribution of the follow-up diameter stenoses after transluminal extraction coronary atherectomy. **Top panel,** comparison of Group 1 (lesions with thrombus [solid line]) and Group 2 (lesions without thrombus [dashed line]). **Bottom panel,** comparison of patients discharged without [solid line] and with [dashed line] sodium warfarin therapy.

occurred in 35% of Group 1 patients and 40.5% of Group 2 patients ($p = \text{NS}$).

Angiographic follow-up was available on 110 (74%) of 148 eligible lesions. As assessed by a dichotomous angiographic definition of restenosis (follow-up diameter stenosis $>50\%$), the restenosis rate was 58% in Group 1 and 74% in Group 2 ($p = 0.11$). The cumulative frequency distribution of follow-up diameter stenosis was similar for both groups (Fig. 1, top), and the incidence of late total vessel occlusion was similar for both groups (35% and 22%, $p = \text{NS}$). The cumulative frequency distribution of follow-up diameter stenosis was also similar for patients discharged with or without sodium warfarin (Fig. 1, bottom).

Discussion

Interventional approaches to thrombotic vein grafts. The optimal interventional strategies for stenotic saphenous vein bypass graft lesions are unknown. Coronary angioplasty of vein graft lesions is associated with reduced procedural success, increased complications and high rates of recurrence (13), and these unsatisfactory results are frequently associated with older

(>4 to 6 years) degenerated grafts and intragraft thrombus (8,14). Chronically occluded vein grafts appear to have the highest rates of complications, reocclusion and restenosis (9), and although adjunctive thrombolytic therapy may be useful for immediate revascularization, there is still a high incidence of bleeding, myocardial infarction and reocclusion (14).

Thrombus in native vessels and vein grafts is also associated with an increased risk of major complications after interventions with new devices (15). Although the presence of intraluminal thrombus has generally been a contraindication to the use of metallic stents, some stents have been implanted in old degenerated grafts with a high angiographic success rate and low rate of in-hospital complications (16). Directional coronary atherectomy has also been used in saphenous vein graft lesions with high procedural success rates, but complications include myocardial infarction in 4.4% to 9.7% and distal embolization in up to 11% of lesions (17-19). The excimer laser has been used with high angiographic success rates, but distal embolization and myocardial infarction occurred in 4.4% of patients (13,20). These data suggest that the use of new devices in vein grafts is also associated with significant angiographic and clinical complications, possibly because of the frequency of thrombus in such lesions.

Use of transluminal extraction coronary atherectomy. The most important finding of this study is that vein graft lesions with thrombus are at higher risk after transluminal extraction coronary atherectomy than are vein grafts without thrombus. Although extraction coronary atherectomy has been advocated for treatment of saphenous vein graft lesions (10), its relative efficacy compared with that of coronary angioplasty or other procedures is unknown. By angiography, filling defects consistent with thrombus were removed in 74% of lesions immediately after extraction coronary atherectomy, which is similar to angioscopic studies that demonstrated thrombus extraction in 75% of lesions after the procedure (21). The failure of extraction coronary atherectomy to achieve 100% efficacy of thrombus removal is probably related to several factors, including the size mismatch between the largest transluminal extraction catheter cutter (2.5 mm) and the diameter of most saphenous vein grafts; differential effects on fresh globular thrombus compared with old laminated thrombus; and the forward cutting mechanism of action, which may limit effectiveness. Despite its demonstrated ability to remove thrombus, extraction coronary atherectomy did not eliminate angiographic and clinical complications in these high risk lesions. However, the degenerated vein graft lesions treated with this procedure were more complex than vein graft lesions treated with balloon angioplasty or other new devices.

These findings are similar to those of the New Approaches to Coronary Intervention (NACI) Registry, which reported similar angiographic (83%) and clinical success rates (71%) and major complication rates (9%) for extraction coronary atherectomy in vein grafts, in which 51% of lesions had angiographic evidence for thrombus (20). In another preliminary study of extraction coronary atherectomy from the NACI Registry, distal embolization occurred in 8.7% of vein graft

lesions and was associated with presence of thrombus and baseline total occlusion (22).

In the present study, angiographic thrombus was also associated with reduced angiographic success. In another study of extraction coronary atherectomy in 51 lesions in native vessels and bypass grafts, the presence of thrombus was associated with a procedural success rate of only 63% (23). These results may be partially explained by use of undersized devices and less aggressive atherectomy. However, even after correcting for differences in device size, the efficiency of transluminal extraction catheter atherectomy-mediated lumen enlargement (RLD/D) was lower in the thrombus group. The presence of thrombus was associated with more Q wave myocardial infarction even after excluding patients who presented with acute myocardial infarction.

Late outcome. As previously reported (11), extraction coronary atherectomy in vein grafts was associated with a high incidence of angiographic and clinical restenosis, late vessel occlusion and need for late revascularization. The presence of thrombus at the time of the original procedure or the use of oral Coumadin did not appear to have any impact on late angiographic results. Because of the unsatisfactory immediate and long-term results of percutaneous intervention in degenerated vein grafts, repeat coronary bypass surgery is a frequent consideration. However, perioperative mortality rates are two- to fourfold higher for a repeat procedure than for initial elective bypass surgery (24-31), and although total survival at 5 years is 84% to 94%, the event-free survival rate is only 50% (25,28).

Limitations of study. This study has several limitations. 1) It is a retrospective study and as such is subject to the same limitations of all retrospective studies. 2) There was no control group treated with coronary angioplasty to allow direct comparison of efficacy and safety. However, many of these lesions were considered unsuitable for angioplasty or other procedures because of severe graft degeneration. 3) Angiography is a relatively inaccurate method for detecting thrombus, particularly in old degenerated vein grafts with friable atherothrombotic material. The strict definition of thrombus in this study may have underestimated its true incidence. 4) The assessment of lumen enlargement itself may be less important than the degree of thrombus removal for lesions with thrombus. Unfortunately, the angiographic assessment of thrombus removal is unreliable. 5) The study size and low incidence of angiographic and clinical complications limit the interpretation of comparisons that are not statistically significant (beta error).

Conclusions. In patients undergoing transluminal extraction coronary atherectomy of stenoses in saphenous vein grafts, angiographic evidence of thrombus was associated with the clinical presentation of acute myocardial infarction and angiographic evidence of total occlusions and diffuse disease. Compared with results in lesions without thrombus, results of extraction coronary atherectomy of vein graft lesions with thrombus were characterized by reduced procedural success and increased risk of no reflow, Q wave myocardial infarction,

vascular surgical repair and the need for adjunctive intracoronary thrombolytic therapy.

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