
Current Management Of Saphenous Vein Graft Disease

S Sharma

Citation

S Sharma. *Current Management Of Saphenous Vein Graft Disease*. The Internet Journal of Cardiology. 2003 Volume 2 Number 2.

Abstract

The percutaneous management of saphenous vein graft disease is rapidly changing and continues to be an ongoing challenge for the interventional cardiologist. As compared to percutaneous coronary intervention in native vessels, graft vessel interventions are associated with sub-optimal results, increased major adverse cardiac events and less favorable long-term results. The arrival of stents, better antithrombotic medication, distal protection and thrombectomy devices have made it possible to attempt interventions in larger number of patients and obtain favorable results. The results vary according to age of the graft, clinical presentation and thrombus load. Chronically occluded vein grafts still pose the biggest challenge.

While treating a patient with saphenous vein graft disease, a choice should be made between treatment of native vessels, repeat bypass surgery and a vein graft intervention. The first choice should be an intervention of the native vessel if feasible. Repeat coronary artery bypass surgery should be seriously considered particularly if arterial grafts can be implanted. The last choice should be intervention on saphenous venous grafts and should include implantation of a stent along with use of a distal protection device. Drug coated stents may change the scenario and future data in this field is eagerly awaited. Aggressive atherosclerosis modification and intensive medication should continue in all these patients to improve the long-term survival.

INTRODUCTION

As surgical coronary revascularization enters its fifth decade, a growing patient population faces the need for repeat revascularization. Recurrent myocardial ischemia can be related to immediate post-surgical complications related to inadequate graft placement, poor distal circulation, unbypassed coronary vessels or more importantly, the relentless progression of coronary artery disease (CAD) in the native circulation or deterioration of venous conduits. It is estimated from longitudinal follow-up studies that up to 10% of saphenous vein grafts (SVG) become occluded by the end of 1 year, followed by an additional attrition rate of 3% to 5% per year. Thus, at 10 years after operation, only 40% to 60% of bypass grafts are functional (1,2). This significant erosion of the initial benefit of surgical revascularization translates into a 4% to 8% yearly incidence of acute ischemic events in survivors of a first bypass operation. These patients mostly have multivessel disease and they are usually receiving aggressive medical treatment when they develop new ischemic symptoms. As the drug therapy is often optimal, the crucial therapeutic decision is whether to submit the patient to repeat coronary artery bypass graft surgery (CABGS) or attempt a catheter based percutaneous coronary intervention (PCI). In the absence of

randomized trials of repeat revascularization, the cardiologist often encounters a difficult clinical dilemma with respect to the optimal strategy of treatment in such patients.

PATHOLOGICAL CHARACTERISTICS OF VEIN GRAFT DISEASE

It is important to understand the pathology of vein graft disease as the success and complications observed with repeat CABGS or with catheter based therapies are related to the same. Although the graft stenosis pathology varies according to the age of the graft, acute and chronic thrombus play a significant role in its causation. In the first few weeks after CABGS, obstructive lesions are always related to thrombus formation. Early thrombus may organize partially to form a coagulum peel within the graft. The process may be localized or diffuse and can obliterate the graft lumen. Technical factors such as the quality of vein graft material or suture placement, contribute to the process. Lesions developing between one month and three years after CABGS are usually due to diffuse neointimal hyperplasia which may arise in part in response to earlier thrombus formation. The histopathology of neointima at this stage resembles that of restenotic lesions developing after balloon angioplasty. Beyond 1 to 3 years, an accelerated form of atherosclerosis

predominates. Acute plaque haemorrhage and obstructive thrombosis overlay a chronic process of fibrin and platelet deposition within these diseased grafts. Calcification occurs but is less common than in native coronary arteries. In the older grafts (more than 8 years), ulcerated plaque, voluminous friable material and thrombus are responsible for higher complication and higher restenosis rate associated with catheter based techniques.

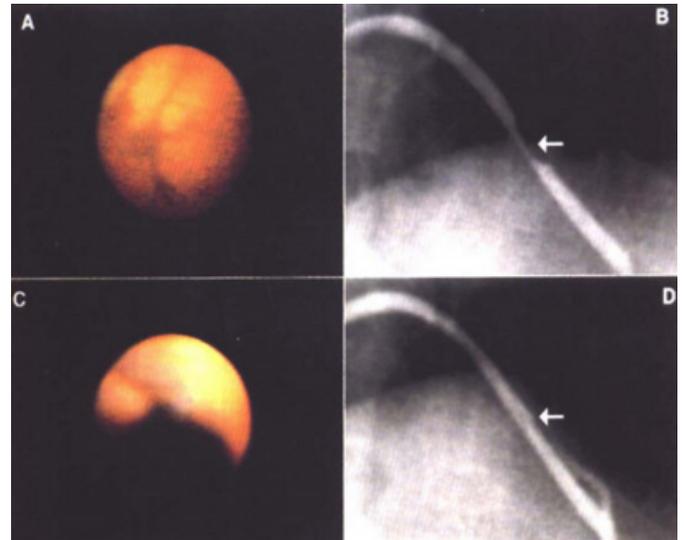
The mechanism of angioplasty also varies according to the underlying pathological substrate. Angioplasty of a fibroproliferative lesion causes graft stretching and intimal fissuring, but in an atherosclerotic lesion plaque fracture and intimal or medial dissection occurs.

PERCUTANEOUS ANGIOSCOPY OF SAPHENOUS VEIN CORONARY BYPASS GRAFTS

Angiography remains the reference standard for the diagnosis and treatment of intravascular pathology associated with atherosclerotic coronary artery disease (CAD). White CJ and colleagues (3) performed angioscopy in 21 patients undergoing angiography and concluded that angioscopy is superior to angiography for detecting complex lesion morphology. The authors demonstrated that the incidence of intravascular thrombi, dissection and plaque friability are underestimated by angiography in SVG grafts (Figure 1). It was also shown that the angioscopic identification of friable plaque does not preclude an uncomplicated procedure. In older grafts, no correlation was found between the absolute age and presence of friable plaques. Coronary angioscopy is an excellent research tool, however, its role in day-to-day management is not defined.

Figure 1

Figure 1 : A, Angioscopy view before coronary angioplasty showing loosely arranged friable yellow plaque. B, Angiogram before angioplasty does not show friability of the lesion. C, Angioscopy view after angioplasty revealing an improved lumen diameter and displacement of the friable plaque. D, Angiogram after angioplasty shows an excellent result and no evidence of plaque disruption or embolization.



PERCUTANEOUS CORONARY INTERVENTION (PCI) OR REOPERATION ?

The decision of whether and how to perform repeat revascularization depends on several factors discussed by Brener SJ and Ellis SG (4):

1. Procedural risk. Needs to be balanced against the severity of the symptoms and the limitations they impose on the patient.
2. Coronary artery anatomy and myocardium in jeopardy. Is the patient an appropriate candidate for surgery and/or PCI from the angiographic standpoint? What proportion of the viable myocardial mass is rendered ischemic and what are the chances for complete, or near complete revascularization ?
3. Clinical and demographic characteristics. Age, gender, body size, diabetes, left ventricular ejection fraction (LVEF), etc.
4. Concurrent illness. These may affect the outcome of the procedure or limit its usefulness
5. Concurrent cardiac abnormalities. Associated valvular or other cardiac disorder may affect the choice of revascularization strategy.

MANAGEMENT OF SVG DISEASE

The management of patients with SVG disease will be discussed under the following subheadings

1. Percutaneous Interventions
2. Native Vessel Intervention
3. Saphenous Vein Graft (SVG) Interventions
4. Newer Advances in SVG Interventions
5. Repeat CABGS
6. Other Measures

1. PERCUTANEOUS INTERVENTIONS

In general, the patients with prior CABGS are handled in the standard fashion. Clopidogrel is added to aspirin preferably 3 to 4 days prior to the procedure. The strategy for intervention should be clear to the patient and relatives before the procedure and the case should be discussed with surgical colleagues and therapeutic options agreed upon. Emergency surgery in these patients is possible but is more difficult and time to revascularisation is usually significantly longer. Higher risk patients who are thought to be ineligible for further CABGS should be considered for IABP or other hemodynamic support prior to PCI. Such high risk group includes those with compromised LV function (LVEF <30%), last remaining graft vessel supplying viable myocardium or unstable angina associated with thrombotic occlusion of a graft. Staging of the procedure may be needed if multiple grafts and native vessels need to be dilated

CONTRAINDICATIONS TO PCI

Due to technical advances the list of contraindications has changed and all the contraindications in today's date are relative.

1. Unprotected Left main coronary artery stenosis (LMCA)
2. Long eccentric tortuous grafts with intraluminal material and thrombus
3. Chronically occluded grafts
4. Heavy calcification of stenosis
5. Grafts with poor distal run off into the native circulation

6. Long diffuse disease

2. NATIVE VESSEL INTERVENTION

If the myocardium is supplied by stenotic SVG and stenosed native vessel, PCI to both can be considered, but if a choice has to be made, PTCA to native vessel should be preferred because of the lower complication and restenosis rate.

PCI of native vessel lesion in post CABGS patients may present unique challenges. The challenges may include interventions in protected or unprotected LMCA stenosis, ostial stenosis, chronically occluded native arteries, lesions in distal coronary vessels beyond the long, tortuous grafts or diffuse disease. In approaching the protected LMCA lesions or ostial right coronary stenosis, the interventional operator frequently encounters a rigid lesion that responds poorly to balloon angioplasty, and in addition, elastic recoil may be a significant factor. Debulking by rotational atherectomy is particularly helpful at these sites as an initial strategy to be followed by PTCA and stenting. Stenting of LMCA stenosis has been reported to be life saving in the perioperative graft closure and cardiogenic shock. Recanalization of chronic occlusion in the native coronary may be required when grafts are occluded or too diffusely diseased for intervention. In the presence of chronic occlusion with bridging collaterals fine recanalised tracts may be present. In such a case, a thinner (0.010" diameter) steerable wire has been found to be particularly effective in crossing the lesion. Where bridging collaterals are present with no evidence of a recanalised tract, more aggressive strategies with stiffer wires or hydrophilic wires or new devices are usually required. When very long venous grafts have been implanted that wrap the heart (snake grafts), an extra long balloon catheter shaft (or shortened guide catheter) may be required to reach the lesion. If retrograde passage is required from graft insertion into more proximal segments of native coronary arteries, special guide wire strategies may be necessary.

3. SAPHENOUS VEIN GRAFT (SVG) INTERVENTIONS :

Percutaneous treatment of SVG obstructions is notoriously difficult because it often results in inadequate dilatation, significant ($\approx 20\%$) risk of a major adverse clinical event (MACE) predominantly myocardial infarction (MI), high likelihood of distal embolisation and a high restenosis rate ($\approx 30\%$). The difficulties in the percutaneous treatment of SVG lesions are largely related to the extent and severity of vein graft atherosclerotic disease. The reduced antegrade flow

during the procedure can lead to slow or no reflow phenomenon (SNR).

RISK ASSESSMENT OF SLOW OR NO-REFLOW PHENOMENON IN SVG INTERVENTION

The mechanism of slow or no-reflow phenomenon (SNR) is not completely understood and many theories have been proposed. This phenomenon is probably due to a combination of multiple pathophysiological mechanisms which may have a different role in different clinical and procedural settings. The postulates include : spasm of the distal microcirculation, platelet clumping, and most recently the distal embolisation of pieces of lipid rich plaque. It is possible that macro debris/ thrombus distal embolisation plays a primary role and may initiate a cascade of events, leading to microvascular obstruction and antegrade flow impairment. Recent studies show that embolic material is present far more than was previously suspected. This particulates matter may play a role in the pathogenesis of distal embolisation, SNR and MI. The degree of flow impairment and /or myocardial hypoperfusion may be proportional to the material embolised distally and the quality of distal runoff. Therefore, prevention of distal embolisation may be the most effective measure to prevent SNR phenomenon.

SNR complicates 10-15% of PCI in SVG. At present, there are no uniform, effective strategies to predict or prevent this common and potentially serious complication. A recent study (6) correlated variables with the risk of SNR in SVG PCI in current era of stents and GP IIb / IIIa inhibitor. The clinical and angiographic characteristics of patients who developed SNR (n = 23) were compared with those who did not (n = 140). Four independent predictors for SNR were detected : (ADULT = acute coronary syndrome, degenerated graft, ulcer, thrombus)

- Probable thrombus (OR 6.9, 95% CI, 2.1-23.9 ; p = 0.001)
- Acute coronary syndromes (OR 6.9, 95% CI, 2.1-23.9; p = 0.001)
- Degenerated SVG (OR 5.2; 95% CI, 1.7-16.6% p = 0.003)
- Ulcer – (OR 3.4; 95% CI, 0.99-11.6; p = 0.04)

The risk of developing SNR could be estimated according to the number of predictors found :

- Low grade risk (1% - 10%) if \leq one variable was present
- Moderate risk (20%-40%) if two variables were present
- High risk (60%-90%) if three or more variables were present

The information from this study can be useful in deciding risk (high or low) of PCI against effective alternate strategies such as medical therapy or redo bypass surgery or in the selection of patients who will most benefit from the use of protection devices during PCI. Interestingly, this study could also identify low-risk lesions or negative predictors of SNR during PCI. These include SVG age < 3 years, ostial SVG intervention, and intervention in in-stent restenotic lesions. In all of the above three circumstances, the low incidence of SNR can also be explained by the underlying peculiar histologic characteristics of the lesions.

During the recent years there have been impressive advances in the management of SVG stenosis attributable to arrival of stents, distal protection devices and better antithrombotic medication. The results of treatment in SVG obstruction usually depend on clinical picture, age of graft, angiographic features and will be discussed under the following subheads :

1. Management of nonocclusive SVG obstruction
2. Management of acute / subacute graft occlusion in patients with acute coronary syndrome.
3. Treatment of chronically occluded vein grafts.

MANAGEMENT OF NONOCCLUSIVE SVG OBSTRUCTION

Balloon intervention in stenosed grafts is often challenging. Andreas Gruentzig (7) clearly recognized the value of PTCA in post CABGS patient which accounted for 16% in his initial series. In selected patients with focal lesions, the peri-procedural death rate was < 1% and the myocardial infarction (MI) rate < 4%, predominantly caused by distal embolization of friable material. The overall restenosis rate was approximately 40% but may have been as high as 60% when the lesion was located at the aorta-bypass anastomosis site (8). The 5-year follow-up was poor, and although 74% of the patients were still alive, only 26% were alive and event free with no MI or repeat revascularization (8). Other

devices, including directional atherectomy, transluminal extraction, and laser angioplasty, offered no better results.

INTRACORONARY STENTS

There has been substantial progress in percutaneous treatment of SVG stenosis with the arrival of intracoronary stents (Figure 2). Hong MK et al (9) compared earlier experience (1990 to 1994) of 1,055 patients with 1,412 SVG lesions with 964 patients (1,315 lesions) treated between 1995 to 1998. Baseline characteristics were similar between the two groups. However, there were significantly more unfavorable lesion characteristics (older, longer and more degenerated SVG) in the recent series. Between the two periods, there was decreased use of atheroablative devices, whereas stents use increased. The procedural success rates (96.6% vs 96.1%) were similar. However, one year outcome (event free survival) was significantly improved in the more recent experience (70.7% vs 59.1%), $p < 0.0001$ especially late mortality (6.1% vs 11.3%, $p < 0.0001$). Multivariate analysis showed stent use to be the only protective variable for both periods. This analysis shows that despite higher risk lesions, strategies to reduce distal embolisation have maintained high procedural success. Late cardiac events, including mortality have also been substantially reduced.

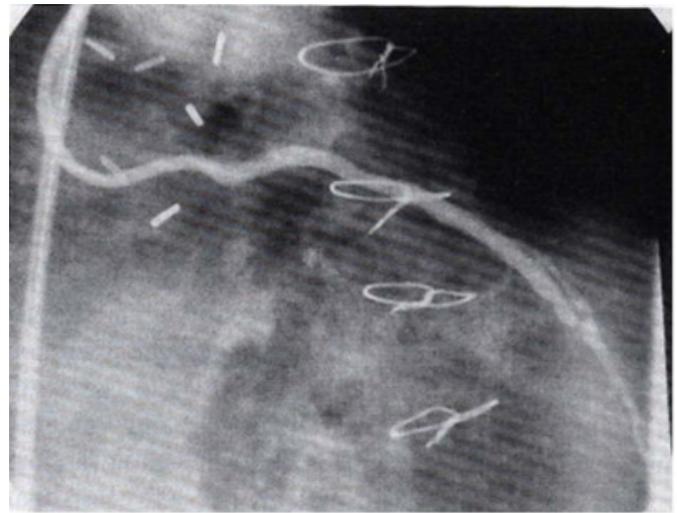
Figure 2

Figure 2 a: Top, base line right anterior oblique projection of a saphenous vein graft (SVG) angiogram showing 90% eccentric aorto-ostial lesion.



Figure 3

Figure 2 b: Bottom, angiogram after deployment of a single Pamaz-Schatz coronary stent shows a widely patent SVG to the left anterior descending (LAD) coronary artery.



In a randomized study (10), stenting for local SVBG lesions was shown to be superior to balloon angioplasty, with increased procedural success (97% versus 86%; $p < 0.01$), reduced major in-hospital complications (6% versus 11%; $p = 0.163$), reduced restenosis rate (37% versus 46%; $p = 0.24$), and better 1-year event-free survival (73% versus 58%; $p = 0.03$).

Recently published (The Venestent Study) (11), further substantiated the superiority of stenting using Wiktor I stent over balloon angioplasty in 150 patients with de novo lesions in body of a SVG. The angiographic restenosis rate at 6-month follow up was 32.8% in the balloon group and 19.1% in the stent group ($p = 0.069$). At 1 year follow-up, target vessel revascularization rate was 31.4% vs. 14.5% ($p < 0.05$), and event-free survival was 60.0% vs. 76.3% ($p < 0.05$) for the balloon and stent group, respectively.

However, despite the use of stenting, SVBG interventions continue to be associated with a significant morbidity and mortality during follow-up. de Jaegere et al (12) reported a 5-year survival rate of $83 \pm 5\%$ and a major event-free survival rate (free from infarction or repeat revascularization) of $30 \pm 7\%$. Keeley et al (13) reported the results of a single-center experience with treatment of 1142 SVBG lesions in 1062 patients. Interventional devices included balloon angioplasty (42%), atherectomy devices and excimer laser (16%), and stenting (42%). In hospital death occurred in 8%, Q-wave MI in 2% and CABG in 3% of the cases. After 3 ± 1 years of follow-up, the event-free survival rate was 46%, and death occurred in 9%, Q-wave MI in 9%, and target vessel

revascularization in 36%.

MEMBRANE COVERED STENTS: ARE THEY BETTER ?

The use of stents improved results of percutaneous revascularisation of obstructed vein grafts, but did not demonstrate the reduced elevated restenosis rate. In addition, long-term clinical event rate is still high compared with intervention in native vessels. Membrane covered grafts are a new advance designed to trap friable plaque against the graft wall and reduce the degree of subsequent neointimal proliferation inside the stent. Earlier data⁽¹⁴⁾ suggested that stents covered with a PTFE membrane might be associated with a low complication and restenosis rate in venous bypass grafts. Schachinger V, et al⁽¹⁵⁾ for the STING (Stents IN Grafts) Investigators conducted a prospective multicentric study in 211 patients who were randomly assigned to receive either a Flex stent or Stent graft. Acute success and procedural events were comparable between the two groups. Restenosis rate was not significantly different between the Flex (20%) and the Stentgraft (29%) groups ($p = 0.15$), although there was a nonsignificant trend toward a higher late occlusion rate in the Stentgraft group (7% vs 16%, $p = 0.069$) at follow-up. Likewise, after a mean observation period of 14 months, cumulative event rates (death, myocardial infarction, or target lesion revascularisation) were comparable in the two groups (31% vs 31%, $p = 0.93$). This controlled trial does not indicate a superiority of the PTFE-membrane-covered Stentgraft compared with a conventional stent with respect to acute results, restenosis, or clinical event rates. The preliminary data from Italian trial RECOVERS⁽¹⁶⁾ involving 301 patient showed significantly more peri-procedural MIs and six-month cumulative major adverse clinical events with the covered as opposed to bare metal stent. This likely reflects dislodgement of emboli during advancement of relatively rigid device. Based on the data from STING and RECOVERS, the Jomed Stent Graft provides no additional benefit against distal embolisation or restenosis. The final word on the use of covered stents will come from ongoing US BARRICADE trial using Jomed stent and Boston Scientific self-expanding Symbiot covered stent trials.

MANAGEMENT OF ACUTE / SUBACUTE GRAFT OCCLUSION IN PATIENTS WITH ACUTE CORONARY SYNDROME (ACS).

Each year, 3% of patients with a previous CABG develop an acute MI, of which about 30% to 50% are due to an acute occlusion of a vein graft. Thrombolysis of the infarct-related

vein graft has resulted in a low success rate.

The Global Use of Strategies to Open occluded coronary arteries I (GUSTO-I) trial⁽¹⁷⁾ has demonstrated that in patients with an acute infarction, thrombolysis of culprit occluded vein grafts resulted in TIMI-3 flow of only 31.7%. The outcomes of primary balloon angioplasty, too, were disappointing. Kahn et al⁽¹⁸⁾ reported a success rate of 85% (41 of 48 patients) with a mortality rate of 10%. The Second Primary Angioplasty in Myocardial Infarction Trial (PAMI-2) identified 32 patients with an infarct-related bypass graft treated with primary balloon angioplasty. The TIMI-3 flow achieved was 70%, and the in-hospital mortality, re-MI, and repeat revascularization rates were 9.4%, 3.1% and 13%, respectively. The 6-month mortality rate was 22.6%, and repeat MI occurred in 7.3% of patients⁽¹⁹⁾. A Mayo Clinic study⁽²⁰⁾ involving 63 patients with primary balloon angioplasty of an acutely occluded vein graft revealed rates of 1-year mortality, repeat MI, repeat procedure, and any MACE of 30%, 26%, 20% and 52.4%, respectively. The high adverse event rates could be attributed to the high-risk baseline characteristics of these patients, in combination with the unfavorable lesion characteristics of occluded vein graft, consisting predominately of extensive thrombus and atherosclerosis with limited distal runoff.

PERCUTANEOUS CORONARY ULTRASOUND THROMBOLYSIS

The unfavorable results of percutaneous graft interventions during ACS prompted the search for alternative, better techniques, such as coronary ultrasound thrombolysis (CUT). In a preliminary study⁽²¹⁾ this technique showed promising results in the treatment of thrombus-rich lesions in SVBG in 20 patients with an ACS. In 13 patients, the procedure was successful; another patient suffered a non-Q-wave MI, and distal embolization was noted in 1 patient.

The efficacy of CUT was further tested in a multicenter randomized controlled trial: ATLAS⁽²²⁾ (Acolysis during Treatment of Lesions Affecting Saphenous Vein Bypass Grafts). One hundred eighty-one patients were randomly assigned to receive CUT (92 patients) or abciximab (89) followed by percutaneous coronary intervention (PCI). Included were patients with either (1) an ACS and angiographic or clinical evidence of thrombus or (2) acute occlusion of a culprit vein graft. Excluded were patients with inability to cross the total occlusion with a guidewire. The trial was prematurely stopped because of a significantly

higher incidence of adverse clinical events in the patients assigned to the CUT arm. The primary end-point consisting of a combination of minimum lumen diameter < 30%, TIMI-3 flow, and freedom from MACE at 30 days- was achieved in the CUT arm in 53.8% versus 73.1% in the abciximab arm ($p = 0.014$). Angiographic success was achieved in 63% of the patients in the CUT arm versus 82% in the abciximab arm. The occurrence of MACE at 30 days, non-Q-wave MI, and Q-wave MI in the CUT group versus the abciximab group was 25% versus 12% ($p = 0.036$), 19.6% versus 7.9% ($p = 0.03$), and 5.4% versus 2.2% ($p = \text{NS}$), respectively. It was notable that device failure or malfunction of the CUT device occurred in 14 patients, which could partly explain the lower success rate and possibly be responsible for the higher adverse event rate in this group. These disappointing results may most likely be explained by clogging of the microvasculature due to the fragmentation of the thrombus by CUT into smaller particles. It was concluded by the investigators that CUT should not be used during PCI of thrombus containing grafts.

THROMBOATHERECTOMY DEVICE (X-SIZER)

The recently published X-TRACT study⁽²³⁾ in 50 patients (31 vein graft lesions) concluded that the use of X-Sizer prior to percutaneous intervention is safe in high-risk vein grafts and thrombotic lesions and results in a low risk of adverse events as compared to historical controls. This study included 84% of the patients with unstable angina. The X-Sizer device is effective in reducing distal embolisation, side branch occlusion and no reflow. The results of large X-TRACT II trial should define the role of this device.

In presence of large thrombus, mechanical thrombectomy (possibly over the shaft of the embolic protection device) will have a role.

PERCUTANEOUS TREATMENT OF CHRONICALLY OCCLUDED VEIN GRAFTS

Totally occluded SVG are a very different disease entity from that of nonoccluded stenotic vein grafts. Percutaneous treatment of chronically occluded vein grafts is disappointing with low success (71% to 73%), high complication rates (MACE in-hospital event rate of 4% increasing to 13% at 30 days) and a poor long-term prognosis^(24,25). The distal embolization rate was around 11%, and creatinine kinase elevation occurred in up to 43%. The 3-year survival rate was 72% to 80%, and the 3-year event-free survival rate was as low as 26% to 34%. Repeat

angiography demonstrated an occlusion/restenosis rate of at least 44% to even 73%^(24,25).

Thrombolytic therapy (selective infusion of urokinase) has been used to reduce the thrombus burden in a totally occluded graft and to convert the graft into a nonoccluded graft so that angioplasty can be performed with a lower complication rate. The Recanalization of Chronically Occluded Aortocoronary Saphenous Vein Bypass Grafts With Long-Term, Low Dose Direct Infusion of Urokinase Trial (ROBUST)⁽²⁶⁾ was a multicenter study which evaluated the efficacy and safety of prolonged, low dose direct infusion of urokinase into chronically occluded SVG. Pretreatment with 24-hour infusion of urokinase followed by balloon angioplasty did not really improve the acute results, with an initial patency of 69%, a mortality of 6.5%, a Q-wave MI of 5.0%, emergency surgery of 4%, stroke 3%, and creatinine kinase enzyme elevation in 17%, while repeat angiography showed a 60% restenosis rate. Extraction coronary atherectomy, directional coronary atherectomy, laser angioplasty, ultrasound thrombolysis, and Angiojet rapid thrombectomy has been used in an effort to improve the outcome. However, so far, no percutaneous modality has demonstrated satisfactory results in the treatment of a chronically occluded vein graft.

Recently, Gaitonde RS et al⁽²⁷⁾ successfully utilized the combination of distal protection device and rheolytic thrombectomy device to treat a patient with chronically occluded SVG. The utility of this technique needs to be proved in further reports⁽²⁸⁾.

4. NEWER ADVANCES IN SVG INTERVENTIONS ADJUNCTIVE TREATMENT WITH GP IIB/IIIA INHIBITOR

A pooled analysis⁽²⁹⁾ of five randomized IV GP II b / III trials (EPIC, EPILOG, EPISTENT, IMPACT II, and PURSUIT) failed to document any benefits of this therapy at 30 days and 6 months in patients undergoing PCI of bypass grafts. Compared with PCI of native circulation ($n = 13,158$), graft interventions ($n = 627$) were associated with worse outcomes and in particular with a doubling of mortality at 30 days (2.1% versus 1.0%, $p = 0.006$) and 6 months (4.7% versus 2.0%, $p < 0.001$). The pooled analysis concluded that in absence of mechanical embolic protection, IV GP II b / III inhibition is associated with high incidence of death and nonfatal ischemic events.

DISTAL PROTECTION DEVICES

Distal protection devices (Figure 3, 4 and 5) has been a new advance aimed at preventing complications resulting from distal embolization of friable material.

Figure 4

Figure 3 : Guard wire device. A, Guard wire device is advanced from the guide catheter through and beyond the SVG lesion. B, The compliant occlusion balloon at the guide wire tip is inflated to occlude flow before the stent is deployed. C, after stent deployment, an Export catheter is advanced over the guide wire and aspirated to remove stagnant column of the blood with suspended embolic debris. D, Guard wire balloon is deflated to restore antegrade blood flow.

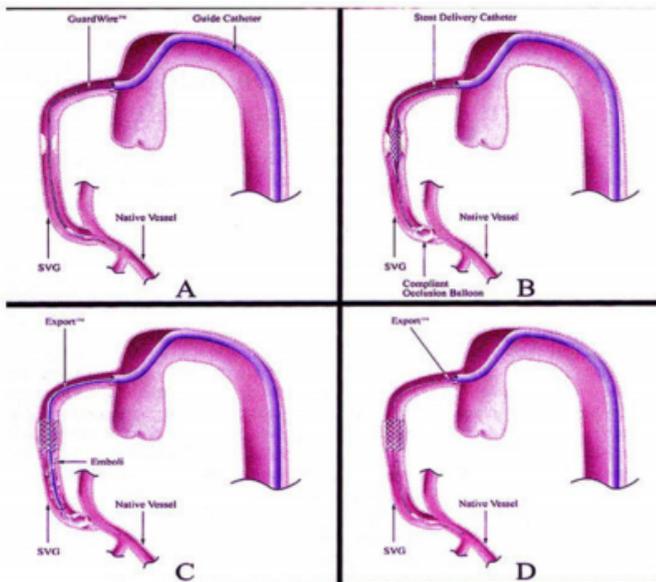


Figure 5

Figure 4 : Filter wire across a SVG lesion with the minimal distances pre-specified

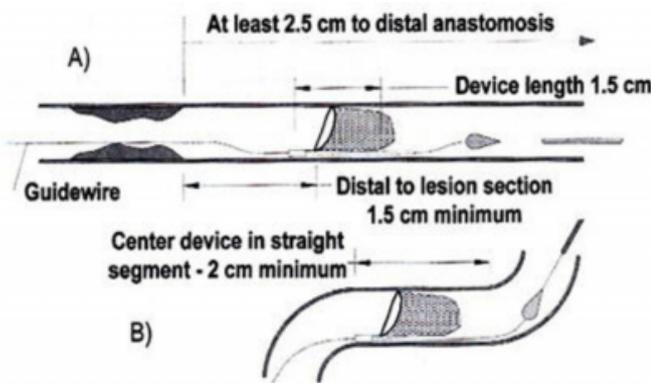
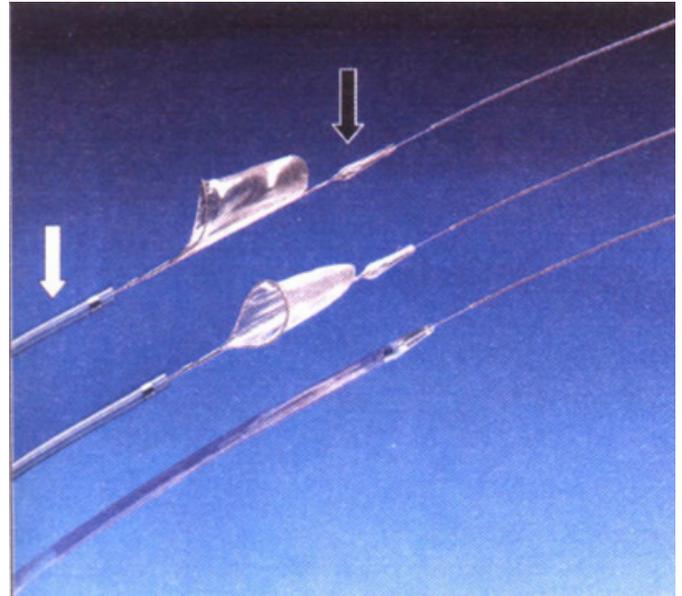


Figure 6

Figure 5: Filter-wire EX, consisting of a 0.014 inch steerable guide wire on which a freely rotating distal polyurethane filter is mounted, shown in its deployed configuration (top and middle) and retracted position (bottom) after being withdrawn into the delivery/retrieval sheath (white arrow). A distal nosecone (black arrow) prevents passage of the sheath beyond the wire tip.



Distal embolic protection device, PercuSurge distal occlusion GuardWire from Medtronic AVE, Santa Rosa, USA involves protection of distal microcirculation by a balloon occlusion and aspiration. This system has been utilized in a large US based multicentric study “The Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) trial” (30) involving 801 patients to undergo either stenting with a conventional guide wire or distal protection device (n = 406 patients). The primary end point : a composite of death, MI, emergency bypass, or target lesion revascularization by 30 days was observed in 65 patients (16.5%) assigned to the control group and 39 patients (9.6%) assigned to the embolic protection device (p = 0.004). The 42% relative reduction in MACE was driven by MI (8.6% versus 14.7, p = 0.008) and no reflow phenomenon (3% versus 9%, p = 0.02). Clinical benefit was seen in even when platelet glycoprotein II b/III a receptor blockers were administered (61% of patients) with composite end points occurring in 10.7% of protection device patients versus 19.4% of controls (p = 0.008). The use of percusurge guard wire balloon occlusion device during stenting of stenotic venous grafts was associated with a highly significant reduction in MACE compared with stenting over a conventional angioplasty guide wire. This

trial demonstrates the importance of a distal embolisation in causing MACE and the superiority of the Guidewire distal protection device in preventing such complications. Table 1 summarises the outcome of contemporary PCI techniques using balloon, stent and GuardWire filter device. The table reiterates the utility of distal protection device in reducing 30 days and 6 months clinical end points. The long term data is awaited.

Figure 7

Table 1 : Outcomes of Contemporary PCI Treatment of SVBG Lesions

	Pooled Analysis (Roff et al ³⁰)		Safer (Brain et al ³¹)	
	Balloon (n = 430)	Stent (n = 157)	Stent (n = 406)	Guardwire (n = 395)
30 Days				
Death/MI, %	≈ 13.0	≈ 13.0	16.5	9.6
6 Months				
Death/MI, %	≈ 19.0	≈ 19.0
Repeat revascularization, %	26	21

As compared to PercuSurge distal occlusion device, filter based devices are easy to use. The safety and efficacy of FilterWire EX (Boston Scientific, Natick, Massachusetts) has been studied in recent trials (31,32). Stone GW et al (31) in a study of 48 patients (60 lesions) showed low rate of periprocedural adverse events in these patients. More recently the use of FilterWire EX has shown equivalence (non-inferiority) to the GuardWire in the 651-patient FIRE trial (32). Several other distal filter device and two devices for proximal occlusion (which allow emboli to be collected into the guiding catheter) are now under study for this indication. To date, however, none of the embolic protection devices have been able to totally eliminate the distal embolic risk in this challenging patient subset and bring the adverse clinical even rate below 9% in a high-risk cohort.

DRUG COATED STENTS

The drug coated stents may improve the long term results of intervention in these patients. Once large diameter drug eluting stents are available (and their benefits in SVG graft stenosis established) they will be utilized in place of bare metal or membrane covered stents.

5. REPEAT CABGS

Repeat operation can be performed in majority of the patients and is very likely to achieve more complete revascularisation. However, reoperation is associated with significantly higher incidence of periprocedural death or MI when compared to both a first bypass operation and to angioplasty. Loop et al (33) in reoperation experience of 2,509 patients reported the death rate to be 2 % to 5 % (in

the various periods reported) and the rate of Q-wave MI as 4%. Younger age, preserved left ventricular function, placement of an arterial graft and lack of significant comorbidity were among the factors predicting improved survival. Similarly, Weintraub et al (34) presented the Emory University experience with repeat CABGS, reporting a rate of death and infarction of 5.7% and 5.6%, respectively, in 2,030 patients. In a smaller series from the Massachusetts General Hospital, Akins et al (35) reviewed the records of 750 patients reoperated for symptomatic ischemia. Death and infarction occurred in 5.3% and 6.2%, respectively. In general, the rates of these events are 1% to 2% and 2% to 4% for a first, elective operation.

The advent of off pump surgery and increased utilization of arterial grafts have significantly improved the short and long term outcome of repeat surgery. The option of repeat CABGS should be seriously considered if arterial grafts can be used.

6. OTHER MEASURES

There are patients who continue to be symptomatic after prior CABG and PCI. These patients have either nonrevascularizable vessels, advanced LV dysfunction or comorbidities. In these patients modalities like percutaneous or surgical transmyocardial laser revascularisation, biventricular pacing with or without defibrillator may be required.

CONCLUSIONS

The percutaneous management of SVG disease is rapidly changing and continues to be an ongoing challenge for the interventional cardiologist (5,36). Given the sub-optimal outcome of percutaneous treatment of SVBG lesions, the following strategies should be adopted.

1. Avoid percutaneous treatment of SVBG lesions, and if possible, attempt to treat the native bypassed coronary arteries even if these arteries are proximally occluded.
2. Seriously consider the alternative of reoperation, which, although associated with a higher mortality and morbidity and less effective relief of angina, may even be the first choice if arterial grafts can be used.
3. If the decision is made for percutaneous treatment of SVBG lesion, the best treatment at this point is probably bare metal stenting of the stenotic

segment performed in association with a distal embolic protection device. Further data is required regarding the use of membrane covered stents. Drug-eluting stents may decrease the restenosis rate and substitute for the existing stents, but we have to await studies to confirm this.

4. Irrespective of the choice of revascularization, these patients should have aggressive risk factor modification along with intense medication with aspirin, clopidogrel, lipid-lowering agents, ACE inhibitors, in an attempt to improve their long-term prognosis.

CORRESPONDENCE TO

Dr. Satyavan Sharma. 104, New Wing, First Floor, Bombay Hospital and Medical Research Centre 12, New Marine Lines Mumbai – 400 020 Telephone and Fax : 022-22054532. E-mail :- drsharma@bom3.vsnl.net.in or drsatyavan@vsnl.net

References

1. Bourassa MG, Enjalbert M, Campeau L, Lesperance J. Progression of atherosclerosis in coronary arteries and bypass grafts. Ten years later. *Am J Cardiol* 1984;53:102C-7C.
2. Johnson WD, Kayser KL, Pednaza PM : Angina pectoris and coronary bypass surgery : Patterns of prevalence and recurrence in 3105 consecutive patients followed upto 11 years. *Am Heart J* 1984 ; 108 : 1190-97.
3. White CJ, Ramee SR, Collins TJ et al : Percutaneous angioplasty of saphenous vein coronary bypass grafts . *J Am Coll Cardiol* 1993; 21 1181 - 85.
4. Brener SJ, Ellis SG : Repeat revascularisation in patients with prior CABG : Angioplasty or surgery ? *ACC current Journal review* 1997, 42 -44.
5. de Feyter PJ : Percutaneous treatment of saphenous vein bypass graft obstructions. A continuing obstinate problem (editorial) . *Circulation* 2003 ; 107 : 2284 - 2286.
6. Sdringola S, Assali AR, Ghani M et al : Risk assessment of slow or no-reflow phenomenon in aorto coronary vein graft percutaneous intervention. *Cathet Cardio Intervent* 2001;54: 318 - 324.
7. Gruentzig AR, Senning A, Siegenthaler WE. Non operative dilatation of coronary artery stenosis. *Percutaneous Transluminal Coronary Angioplasty*. *N Engl J Med* 1979; 301: 61- 68.
8. de Feyter PJ, Van Suylen RJ, de Jaegere PP, et al : Balloon angioplasty for the treatment of lesions in saphenous vein bypass grafts. *J Am Coll Cardiol* 1993 ; 21 : 1539-1549.
9. Hong MK, Mehran R, Dangas G, Mintz GS et al : Are we making progress with percutaneous saphenous vein graft treatment ? A comparison of 1990 to 1994 and 1995 to 1998 results. *JACC* 2001 ; 38: 150 - 154.
10. Savage MP, Douglas Js Jr., Fischman DL, et al : Stent placement compared with balloon angioplasty for obstructed coronary bypass grafts. *Saphenous Vein De Novo Trial Investigators N. Engl J Med* 1997 ; 337 : 740 - 747.
11. Hanekamp CEE, Koolen JJ, den Heijer P, et al : for the Venestent Study Group : Randomized study to compare balloon angioplasty and elective stent implantation in venous bypass grafts. *The Venestent Study. Catheter Cardiovasc Interv* 2003;60: 452-457.
12. de Jaegere PP, Van Domburg RT, Feyter PJ et al : Long term clinical outcome after stent implantation in saphenous vein grafts. *J Am Coll Cardiol* 1996 ; 28 : 89 - 86.
13. Keeley EC, Velez CA, O'Neill WW et al : Long -term clinical outcome and predictors of major adverse cardiac events after percutaneous interventions on saphenous vein grafts. *J Am Coll Cardiol* 2001;38:659-65.
14. Baldus S, Koster R, Reimers J et al : Membrane covered stents : a new treatment strategy for saphenous vein graft lesions. *Cathet Cardiovasc Interv* 2001 ; 53 : 1-4.
15. Schachinger V, Hamm CW, Munzel C et al for the STING (Stents IN Grafts) Investigators : A randomized trial of polytetrafluoroethylene-membrane-covered stents compared with conventional stents in aortocoronary saphenous vein grafts. *J Am Coll Cardiol* 2003 ; 42 : 1360 -1369.
16. Stankovic G, Colombo A, Presbitero P, et al : Randomized evaluation of polytetrafluoro-ethylene covered stent in saphenous vein grafts : the Randomized Evaluation of Polytetrafluoroethylene covered stent in saphenous vein grafts (RECOVERS) trial. *Circulation* 2003 ; 108 : 37 - 42.
17. Labinaz M, Sketch MH Jr, Ellis SG et al : Outcome of acute ST - segment elevation myocardial infarction in patients with prior coronary artery bypass surgery receiving thrombolytic therapy. *Am Heart J* 2001 ; 141 : 469 - 477.
18. Kahn JK, Rutherford BD, McConahay DR et al : Usefulness of angioplasty during acute myocardial infarction in patients with prior coronary artery bypass grafting. *Am J Cardiol* 1990 ; 65 : 698 - 702.
19. Stone GW, Brodie BR, Griffin JJ, et al : Clinical and angiographic outcome in patients with previous coronary artery bypass graft surgery treated with primary balloon angioplasty for acute myocardial infarction. *Second Primary Angioplasty in Myocardial Infarction Trial (PAMI - 2) Investigators. J Am Coll Cardiol* 2000 ; 35 : 605 - 611.
20. A L Suwaidi J, Velianou JL, Berger P B et al : Primary percutaneous coronary interventions in patients with acute myocardial infarction and prior coronary artery bypass grafting. *Am Heart J* 2001 ; 142 : 452 - 459.
21. Rosenschein U, Gaul G, Erbel R et al : Percutaneous transluminal therapy of occluded saphenous vein grafts ; Can the challenge be met with ultrasonic thrombolysis ? *Circulation* 1999 ; 99 : 26 - 29.
22. Singh M, Rosenschein U, HoKLL et al : Treatment of saphenous vein graft with ultrasound thrombolysis ; a randomized study. *Circulation* 2003 ; 107 : 2331-2336
23. Stone GW, Cox DA, Low R et al for the X-TRACT Investigators : Safety and efficacy of a novel device for treatment of thrombotic and atherosclerotic lesions in native coronary arteries and saphenous vein grafts : Results from the multicenter X-sizer for treatment of thrombus and atherosclerosis in coronary applications trial (X-TRACT) study. *Catheterisation and Cardiovascular Interventions* 58; 419-427 : 2003.
24. Kahn JK, Rutherford BD, McConahay DR et al : Initial and long-term outcome of 83 patients after balloon angioplasty of totally occluded bypass grafts. *J Am Coll Cardiol* 1994 ; 23 : 1038 - 1042.
25. Berger PB, Bell MR, Grill DE et al : Influence of procedural success on immediate and long-term clinical outcome of patients undergoing percutaneous revascularization of occluded coronary artery bypass vein grafts. *J Am Coll Cardiol* 1996 ; 28 : 1732 - 1737.

26. Hartmann JR, McKeever LS, O'Neill WW et al : Recanalization of chronically occluded aortocoronary saphenous vein bypass grafts with long-term, low dose direct infusion of urokinase (ROBUST) : a serial trial. *J Am Coll Cardiol* 1996 ; 27 : 60-66.
27. Gaitonde RS, Sharma N, Lohe Edl, Kalaria VG : Combined distal embolization protection and rheolytic thrombectomy to facilitate percutaneous revascularisation of totally occluded saphenous vein grafts. *Catheterisation and Cardiovascular Interventions* 2003 : 60 ; 212-217 .
28. Londero HF : Totally occluded saphenous vein graft recanalisation : A dangerous option. *Catheterisation and Cardiovascular Interventions* 2003: 60 ; 218-220 .
29. Roffi M, Mukherjee D, Chew D P, et al : Lack of benefit from intravenous platelet glycoprotein IIb/ IIIa receptor inhibition as adjunctive treatment for percutaneous interventions of aortocoronary bypass grafts. A pooled analysis of five randomized clinical trials. *Circulation* 2002 : 106 ; 3063-3067.
30. Baim DS, Wahr D, George B, et al. On behalf of the saphenous vein graft Angiography Free of emboli Randomised (SAFER) Trial Investigators. Randomized trial of a distal embolic protection device during percutaneous intervention of saphenous vein aorto-coronary bypass grafts. *Circulation* 2002; 105: 1285 - 1290.
31. Stone GW, Rogers C, Ramee S et al : Distal filter protection during saphenous vein graft stenting : technical and clinical correlates of efficacy. *J Am Coll Cardiol* 2002 ; 40 : 1882-1888
32. Stone GW, Rogers C, Hermiller J et al : Randomized comparison of distal protection with a filter-based catheter and a balloon occlusion and aspiration system during percutaneous intervention of diseased saphenous vein aorto-coronary bypass grafts. *Circulation* 2003 ; 108 : 548 - 553.
33. Loop FD, Lytle BW, Cosgrove DM, et al : Reoperation for coronary atherosclerosis : changing practice in 2509 consecutive patients. *Ann Surg* 1990 : 212 ; 378 - 386.
34. Weintraub WS, Jones EL, Craver JM, et al : In-hospital and long-term outcome after reoperative coronary artery bypass surgery. *Circulation* 1995 : 92(II) ; 50-57.
35. Akins CW, Buckley MJ, Daggett WM, et al : Reoperative coronary grafting : changing profiles, operative indications, techniques, and results. *Ann Thorac Surg* 1994; 58 : 359-364.
36. Baim DS : Percutaneous treatment of saphenous vein graft disease. The ongoing challenge. *J Am Coll Cardiol* 2003; 42 : 1370 -1372 .

Author Information

Satyavan Sharma, MD., DM, MNAMS, FACC, FAMS

Honorary Consultant Cardiologist, Bombay Hospital and Medical Research Centre