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Excimer Laser for Revascularisation of Saphenous Vein Grafts

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Abstract. Coronary artery bypass grafting has been a major advance in cardiovascular medicine over the past 30 years. Saphenous venous bypass grafts, however, are prone to develop atherosclerotic disease within several years of the procedure. Unfortunately, percutaneous interventional techniques in saphenous venous bypass grafts are associated with significant risks of distal embolisation and resultant non-Q wave myocardial infarction. Preliminary results suggest excimer laser angioplasty may significantly reduce this complication. This article summarises the results of percutaneous interventions in spahenous venous bypass grafts, emphasising the potential role of excimer laser angioplasty in this group of patients.

Keywords: Balloon angioplasty; Excimer laser angioplasty; Ischemia; Thrombus; Saphenous vein grafts

INTRODUCTION

Coronary artery bypass grafting has been a major advance in the field of cardiology over the past several decades. Unfortunately, 15–20% of saphenous vein grafts fail within one year of surgery and 50% develop significant stenoses by ten years [1–4]. These statistics lead to reoperation in 2–3% by 5 years, 12–15% by 10 years, and 30% by 12–15 years [5,6]. The risks involved with repeat coronary artery bypass grafting are higher and the long-term results are not as good as with the initial procedure. Perioperative myocardial infarctions (MI) occur in 10% and in-hospital mortality may be as high as 11%.

As a result, many cardiologists and surgeons favour percutaneous revascularisation to repeat operation whenever possible. Additionally, there are large numbers of patients who are quite symptomatic but have a relatively small amount of myocardium in jeopardy in whom the risks of repeat operation are not felt to be justified. This paper reviews the results of balloon angioplasty as well as other interventional devices in percutaneous intervention of spahenous venous bypass grafts, emphasising the potential role of excimer laser angioplasty in this complex and difficult group of patients.

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BALLOON ANGIOPLASTY

In general, the results for balloon angioplasty in saphenous vein bypass grafts have been favourable, but there are significant limitations to this approach. Although success rates of around 90% have been reported with mortality rates of around 1% [7–13], the risk of periprocedural myocardial infarction is significant. The risk of Q wave myocardial infarction is reported to be only 2% but non-Q wave myocardial infarctions occur in approximately 13%. These adverse effects are directly related to the age of the saphenous vein bypass graft. The reported risk of major adverse cardiac events (MACE) for angioplasty in grafts less than three years of age was 0%, whereas in grafts greater than three years of age there was a 12.5% risk of myocardial infarction, 4% risk of emergency coronary artery bypass grafting, and a 4% mortality [14]. These complications are due in large part to distal embolisation of material from the grafts during the procedure. A variety of devices have been investigated in the hope of reducing the risk of distal embolisation including directional coronary atherectomy, transluminal extraction atherectomy, coronary stents, and excimer laser angioplasty.

DIRECTIONAL CORONARY ATHERECTOMY

Directional coronary atherectomy (DCA) (Devices for Vascular Intervention, Inc., Redwood City, CA) is a percutaneous, over-the-wire cutting and retrieval system which was approved by the Food and Drug Administration (FDA) for coronary use in 1990 as the first non-balloon percutaneous coronary device. The AtheroCath is advanced over a coronary guide wire with the cutting window oriented toward the atheromatous plaque. Balloon inflation pushes the atheroma into the cutting window where advancing the cutting blade as it rotates at 2000 revolutions per minute (rpm) excises the plaque and stores it in a distal nosecone.

There was initial enthusiasm for the use of this device in saphenous vein grafts (SVG) in hopes of tissue removal decreasing the risk of distal embolisation. Numerous observational studies reported success rates of 86–90% and major complications of 0–7% in focal, non-degenerated vein grafts [15–20]. These initial reports led to the CAVEAT II trial of DCA versus PTCA in spahenous vein grafts [21]. In CAVEAT-II there were 305 patients with saphenous vein graft steonoses randomised to either DCA or PTCA. Of these patients 85% had mid-body stenoses. Although DCA was shown to have higher procedural success rates, there was no difference in angiographic restenosis, target vessel revascularisation, or event-free survival compared with PTCA. In fact, despite the removal of atheromatous plaque, the angiographic distal embolisation rate was 13.5% for DCA and 5.1% for PTCA. This led to a non-Q wave myocardial infarction rate of 16% for DCA and 9.6% for PTCA.

TRANSLUMINAL EXTRACTION ATHERECTOMY (TEC)

TEC is a percutaneous over-the-wire cutting and aspiration system that consists of a conical cutting head with two stainless-steel blades attached to the distal end of a flexible hollow torque-tube. The proximal end of the catheter attaches to a battery-powered hand-held motor drive unit and to a vacuum bottle for aspiration of excised atheroma, thrombus, and other debris. A trigger on the bottom of the motor drive unit activates cutting blade rotation and aspiration, and a lever on top of the unit allows advancement/retraction of the cutter.

For vein graft lesions treated with TEC, success rates of 82–92% have been reported [22–26]. Major clinical complications after vein graft TEC include death in 0–10.3%, MI in 0.7–3.7%, and emergency coronary artery bybass graft (CABG) in 0.2% [22–26]. More concerning, however, is the rate of distal embolisation and its sequelae. Distal embolisation has been reported in 2–17%, no-reflow in 8.8% and abrupt closure in 2–5%. The Washington Hospital Center reported their experience with TEC and immediate stenting [27]. In 36 patients with 'high risk' SVG lesions, there was 100% procedural success, but 2.9% abrupt closure, 2.2% no-reflow, and a 15% incidence of non-Q wave MI. Finally, angiographic restenosis has been reported in 64–69% of vein graft lesions treated with TEC, with a 29% incidence of late total occlusion in one report [24,28]. Presently, the exact role of TEC in vein graft lesions is controversial and further study is needed. A randomised trial of 750 patients comparing PTCA and TEC in vein grafts is underway (TECBEST).

CORONARY STENTS

The widespread acceptance of coronary stents by interventionalists is the most important advance in interventional cardiology since the introduction of balloon angioplasty. Because of the disappointing results of balloon angioplasty, directional atherectomy, and transluminal extraction atherectomy, stenting has been proposed for the management of obstructive lesions in aged vein grafts. Stenting decreases early elastic recoil and induces less vessel wall disruption, resulting in lower periprocedural complications and lower rates of restenosis in native coronary arteries. It was hoped that in saphenous venous bypass grafts stenting might trap atheromatous plaque and debris, decreasing the incidence of distal embolisation and non-Q wave myocardial infarction compared to balloon angioplasty. However, the initial results of saphenous vein graft treatment by the self-expanding Wallstent were disappointing [29,30].

A series of 198 consecutive patients treated with the balloon-expandable Palmaz–Schatz coronary stent showed a high procedural success rate of 98.5% [31]. Restenosis occurred in 34% and the long-term event-free survival was 70% for all patients. This led to the Sephaneous Vein de Novo (SAVED) trial in which 215

patients with focal de novo stenoses in vein grafts (mean ge 10 years) and no recent myocardial infarction were randomised to balloon angioplasty or Palmaz–Schatz stenting [32]. Procedural success, procedural complications, and event-free survival were all improved in the stent arm. Additionally, in this group of focal vein graft lesions the non-Q wave MI rate was 2% for stenting versus 7% for PTCA. However, in a subsequent study of saphenous vein graft stenting with the Palmaz–Schatz stent [33] with aspirin and ticlopidine post-procedure (RAVES), the thirty day results were less encouraging. Complications included 8% no-reflow, 2% Q-wave myocardial infarction, and a 19% incidence of peri-procedural CPK greater than three times upper limit of normal (13% CPK 3–8 × normal, 6.5% CPK>8 × normal). The Johnson and Johnson 'Biliary Stent' registry is consistent with these data, demonstrating a non-Q wave myocardial infarction rate of 11%.

EXCIMER LASER ANGIOPLASTY

The idea for a 'laser' was first conceived by Albert Einstein in 1905. The terms 'excimer' and 'laser' are acronyms. Excimer is an acronym for excited dimer whereas laser stands for light amplification by stimulated emission of radiation. Laser energy from the xenon chloride laser is produced when hydrogen chloride gas is excited by electrical energy and emits monochromatic, coherent light at a wavelength of 308 nm. This laser energy ablates inorganic material by photochemical mechanisms that involve the breaking of molecular bonds without generation of heat [34]. The exact mechanisms for tissue ablation are unclear but probably consist of a combination of photochemical, localised thermal, and mechanical effects.

Lasers were introduced into the interventional cardiology armamentarium in the late 1980s and were initially met with enthusiasm. However, there were soon significant concerns regarding laser-related complications, mainly dissections [35] and perforations [36]. Because of this, there was a drastic decline in the number of laser angioplasty procedures performed in the early 1990s. However, over the past several years due to an improvement both in equipment and in technique there has been a renewed interest in laser angioplasty.

Initial FDA approval of the excimer laser was based on results of the excimer laser coronary angioplasty (ELCA) registries. The Spectranetics Laser Registry [37] consisted of 2432 patients with a mean age of 63 years. Clinical success was achieved in 2168 of 2432 patients (89%). Of note, there was no difference in success rate or complications for long lesions, total occlusions crossable with a guidewire, saphenous vein grafts, and aorto-ostial lesions, suggesting that selected complex lesions could be treated with ELCA.

The other large multicentre registry [38] used the AIS Dymer 200+ device. A total of 3000 patients were enrolled with a success rate after laser with adjunct balloon angioplasty of 90%. Major complications included death in 0.5%, emergency coronary bypass surgery in 3.8%, Q wave myocardial infarction in 2.1%, and non-Q wave myocardial infarction in 2.3%. Laser perforations occurred in 1% of lesions but decreased significantly from 1.4% in the first 2592 lesions to 0.3% in the last 1000 lesions. Coronary dissection occurred in 13% of lesions, but sustained occlusions occurred in 3.1% of lesions.

There are six currently FDA-approved coronary applications for the excimer laser. They are saphenous vein grafts, total occlusions crossable with a guide wire, ostial lesions, long lesions, balloon dilatation failures, and moderately calcified lesions. Currently available catheters include both concentric and eccentric rapid exchange catheters. The Vitesse C catheters are 1.4 mm, 1.7 mm, and 2.0 mm concentric devices whereas the Vitesse E eccentric catheters are available in 1.7 mm and 2.0 mm sizes. A new catheter design, the Vitesse Cos, has recently been approved. It provides more ablation area than the Vitesse C and is available in 1.4 mm, 1.7 mm, and 2.0 mm sizes.

A major advance in excimer laser angioplasty occurred in 1995 with the advent of the saline infusion technique [39]. In blood or radiographic contrast media ultraviolet laser energy is avidly absorbed, inducing significant acoustic effects, tissue disruption, and dissection. The saline infusion technique eliminates blood and contrast from the laser field, resulting in a significant decrease in dissections from 24% to 7%.

Currently, laser angioplasty is felt to have the most clinical benefit in the following applications: saphenous vein graft lesions, aorto-ostial lesions, undilatable or uncrossable (with

balloon) lesions, total occlusions crossable with a guidewire, and in-stent restonosis.

The success rate for excimer laser angiplasty in saphenous vein graft lesions has been reported as high as 94% [40], significantly higher than the 77% and 79% success rates for balloon angioplasty in the Heparin Registry Study [41] and Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) II study [21]. The Washington Hospital Center has reported initial results of their experience with TEC/Stent versus ELCA/Stent in saphenous veing grafts [27]. Although the angiographic success rates were 100% in each group, the rates of complications were higher in the TEC/stent group versus the ELCA/stent group: non-Q Wave MI (CPK-MB 5 times normal) 15.6% versus 8.7%, in-lab closure 2.9% versus 0%, and no-reflow 2.2% versus 0%. They also reported six-month follow-up data on a larger group of patients (n=131 with 196 lesions) [42]. The ELCA/stent group had a 6 month TLR of 6.9%. However, the 6 month event-free survival was only 67% due to a high mortality (9%) and frequent non-target lesion revascularisation.

In our own institution we reviewed 44 consecutive patients who underwent excimer laser coronary angioplasty in de novo saphenous vein graft lesions with a mean graft age of ten years. The procedural success rate was 100% with a death rate of 0%, a Q-wave myocardial infarction rate of 0%, and an emergency CABG rate of 0%. More importantly, the incidence of CPK greater than three times the upper limit of normal was 0%. Abciximab was used in 85% of cases.

Abciximab, by providing powerful blockage of the paltelet GPIIb/IIIa receptor modulating platelet aggregation, was shown in both the Evaluation of 7E3 for the Prevention of Ischemic Complications (EPIC) [43] and Evaluation of PTCA to Improve Long-term Outcome by c7E3 GPIIb/IIIa Receptor Blockade (EPILOG) [44] trials to dramatically reduce ischaemic complications of angioplasty and related interventions. In an analysis of these two trials based on baseline lesion morphology, however, there was no benefit from adjunctive abciximab in the degenerated saphenous vein graft cohort [45]. All other lesion subgroups showed a statistically significant advantage (or trend in the case of chronic total occlusions) to the use of abciximab with a relative reduction in complications of approximately 50%. In degenerated saphenous vein grafts the complication rate was 18.6% in the abciximab group and 16.3% in the placebo group (p=ns). Therefore, our results with excimer laser angioplasty in saphenous vein grafts cannot be explained by the use of abciximab and suggest a potential role for this device in this difficult and complex group of patients.

CONCLUSION

Excimer laser technology is an exciting addition to the armamentarium of the interventional cardiologist. Its major niche is the ability to debulk and evaporate tissue. The initial limitations of the device have been markedly improved with the development of new fibres, optimal spacing, and better understanding of laser–tissue interactions, leading to improved technique. A large cohort of patients who would likely benefit from excimer laser angioplasty are those undergoing percutaneous intervention in saphenous vein grafts. Intervention in these grafts is limited by a non-Q wave myocardial infarction rate of approximately 10–15% with the use of balloon angioplasty, directional atherectomy, transluminal extraction atherectomy, or coronary stents. Initial results suggest a much lower incidence with excimer laser angioplasty. A randomised trial comparing balloon angioplasty and excimer laser angioplasty in saphenous vein grafts is currently being developed. Finally, although laser angioplasty shows great promise, it remains an expensive technology and additional studies, especially of long-term outcomes, are needed to establish its place in interventional cardiology.

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