A randomized trial of an external Dacron sheath for the prevention of vein graft disease: The Extent study

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The success of coronary artery bypass grafting is limited by poor long-term graft patency. Despite the superior patency of arterial grafts, saphenous vein remains the most commonly used conduit for coronary artery bypass because of its predictable handling qualities and ready availability.[1] Over 40% of vein grafts are thrombosed at 10 years postoperatively,[2] largely as a consequence of vein graft disease that is characterized by neointima formation, atherosclerosis, and plaque rupture. Graft failure results in recurrent angina, myocardial infarction, or death and leads to repeat revascularization procedures with their associated morbidity and costs. To date, with the exception of aggressive lipid lowering, no therapy has been shown to improve long-term vein graft patency in clinical studies. In porcine saphenous vein to carotid artery interposition graft, placement of a loose-fitting external macroporous Dacron sheath inhibits vein graft disease in the long term.[3,4] The aim of this phase I randomized pilot study was to evaluate the effects of placement of the external Dacron stent, or Extent (Vascutek Ltd, Inchinnan, Scotland), on vein graft disease in patients undergoing elective coronary artery bypass grafting.

Materials and Methods

Between March and September 2005, 20 patients undergoing isolated on-pump coronary artery bypass grafting, and who had given informed consent, were randomized to have an Extent placed to either a right coronary system graft or left coronary system target graft. The Extent is an incomplete tube of knitted polyester reinforced with polytetrafluoroethylene ribs at approximately 1-cm intervals to maintain rigidity (Figure 1). The edges of the incomplete tube form a flange. The stent was so designed to maintain the circular cross section of the graft and to facilitate placement after completion of both distal and proximal anastomoses, with the flange preventing migration or kinking of the vein graft through the side of the graft. Two graft sizes were used, 8 mm and 6 mm. Graft sizing was intended to be nonrestrictive with up to 1-mm clearance around the circumference of the vein graft. Patients were eligible if they were to receive a reversed long saphenous vein graft to both the right and left coronary systems in addition to a pedicled left internal thoracic artery graft to the left anterior descending coronary artery. The Extent was placed on the vein graft after the proximal and distal anastomoses had been completed and protamine administered. Where possible, the proximal and distal ends of the graft were sutured to the epicardium distally and to the aortic adventitia to prevent migration; however, in 9 of the grafts, postdeployment trimming of the proximal or distal anastomoses to optimize the graft lie prevented this. The flange was allowed to lie as appeared optimal to the graft curvature around the heart. The study had received local ethical review board approval, and all patients gave informed consent to the procedure. The primary end point of the study was a 20% reduction of wall thickness as assessed by intravascular ultrasound at 6 months after surgery relative to the untreated contralateral vein graft.

Results

Key demographic, operative, and postoperative data are listed in Table 1. One patient randomized to a left-sided Extent had the stent placed on a graft to the posterior descending, inasmuch as the left-sided target was heavily calcified. Two patients refused to attend for follow-up and 1 subsequently reported an allergic reaction to iodinated contrast. At follow-up angiography (9 conventional, 8 computed tomographic) all 17 Extent grafts were thrombosed. All left internal thoracic artery and non-Extent vein grafts were patent.

Figure 1. Extent, a macroporous Dacron sheath reinforced with polytetrafluoroethylene ribs. The flange permits placement after completion of both anastomoses.

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TABLE 1. Extent study demographic, operative, and outcome data

Study No.	Sex	Age (y)	Randomization	Extented vein graft target	Proximal coronary stenosis	Extent size (mm)	Non-Extent vein grafts	Postop complication	Follow-up (mo)	Patent grafts	Occluded grafts	Symptoms/ repeat revascularization
1	M	76	L	Int	75%–90%	6	PDA		6	PDA	Int	
2	M	72	L	PDA	Occluded	8	OM1			OM1	PDA	
3	M	73	L	Int	<75%	6	PDA, OM2		6	PDA, OM2	Int	
4	M	68	L	Int	75%–90%	8	PDA	AF, LRTI	8	PDA	Int	
5	M	62	R	PDA	>90%	8	Int, OM1			Int, OM1	PDA	
6	M	76	R	PDA	75%–90%	6	OM1		19	OM1	PDA	
7	M	66	R	PDA	<75%	8	OM1	AF	19	OM1	PDA	
8	M	73	R	PDA	>90%	8	OM1	AF	6	OM1	PDA	PCI
9	M	66	L	Int	<75%	8	PDA, D1	AF, heart block	7	PDA, D1	Int	
10	M	67	L	OM1	Occluded	8	PDA		18	PDA	OM1	PCI
11	M	72	L	Int	75%–90%	8	PDA		16	PDA	Int	
12	M	76	R	PDA	>90%	8	OM1		16	OM1	PDA	PCI
13	M	71	R	PDA	<75%	8	OM1	AF	6	OM1	PDA	
14	F	72	L	OM1	>90%	8	PDA		8	PDA	OM1	
15	M	70	L	OM1	>90%	6	PDA	LCO, tracheostomy	17	PDA	OM1	
16	F	69	R	PDA	>90%	6	PDA, D1		18	PDA, D1	PDA	
17	M	75	R	PDA	75%–90%	6	OM1, D1	AF, LRTI	17	OM1, D1	PDA	
18	M	66	L	Int	<75%	6	PDA	AF, LRTI	7	PDA	Int	
19	M	70	R	PLV	75%–90%	8	PDA			PDA	PLV	
20	M	63	R	PDA	Occluded	8	OM1	AF	17	OM1		

M, Male; *F,* female; *L,* left; *R,* right; *Int,* intermediate artery; *PDA,* posterior descending artery; *OM,* obtuse marginal; *D,* diagonal; *AF,* atrial fibrillation; *PLV,* posterior left ventricular; *LRTI,* lower respiratory tract infection; *LCO,* low cardiac output; *PCI,* percutaneous coronary intervention.

Discussion

The most likely explanation for the universal thrombosis of Extent vein grafts in this phase 1 study is that stent rigidity, oversizing, or the incomplete tube design resulted in grafts kinking, either at the anastomoses or within the middle part of the graft. This could have occurred as a consequence of stent or graft movement on chest closure or patient repositioning or at some later time. The potential for this to occur was not foreseen. Preclinical studies had been performed in the end to end or end to side porcine carotid artery interposition model where the vessels are shorter and the potential for graft movement and kinking is less, although the degree of graft oversizing was similar.

Despite the poor results of the Extent study, the dramatic and sustained effectiveness of external sheaths in experimental studies suggests that continued research is warranted. One alternative is a nonrestrictive, flexible, biodegradeable, macroporous polyglactin (Vicryl; Ethicon, Inc, Somerville, NJ) external sheath. These features overcome many of the limitations of the rigid Dacron stent and have also demonstrated long-term inhibition of vein graft disease in the porcine model.[5]

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