

developing risk adjustment mortality models. The in-hospital mortality in SVG PCI is reliably predicted by incorporating only a few clinical variables known prior to starting the procedure. The ability to accurately assess risk will aid in patient counseling and case selection.

1028-14

### Does the Beneficial Effect of Distal Protection in Saphenous Vein Graft Interventions Vary With Lesion Length? A SAFER (Saphenous Vein Graft Angioplasty Free of Emboli Randomized) Substudy

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**Background:** The SAFER trial demonstrated a dramatic reduction in Major Adverse Clinical Events (MACE: a composite of death, MI or revascularization) acutely and at 30 days following saphenous vein graft (SVG) percutaneous intervention (PCI) with the use of the Percutaneous GuardWire™ distal protection device. This benefit was attributed to the prevention of distal migration of atherosclerotic debris with the device.

**Methods:** We sought to evaluate if the reduction in MACE seen in the SAFER trial varied with the length of the treated lesion. We divided lesion lengths into quartiles and performed a stratified analysis to evaluate for effect modification by lesion length on the reduction in MACE with the GuardWire™ compared to patients treated with no distal protection.

**Results:** Of the 751 lesions treated, longer lesions were associated with a higher incidence of MACE in both the control group ( $p=0.011$ ) and GuardWire™ group ( $p=0.001$ ). As demonstrated in the table, use of the GuardWire™ was associated with a reduction in MACE in each quartile of lesion length. With multivariable modeling, shorter lesions showed a trend toward a greater relative reduction in MACE with use of the GuardWire™ ( $p=0.097$ ).

Lesion Length Quartile (mm)	N	30-Day MACE Without GuardWire	30-Day MACE With GuardWire	Odds Ratio (95% CI)	Relative Reduction MACE	P-value
>22	188	23%	18%	0.72 (0.36-1.48)	22%	0.47
14.8-22	197	15%	10.5%	0.65 (0.28-1.52)	30%	0.39
10-14.8	187	17.2%	8.5%	0.45 (0.18-1.10)	51%	0.08
<10	179	8.1%	2.2%	0.25 (0.05-1.26)	73%	0.09

**Conclusion:** The reduction in MACE seen with GuardWire™ occlusion balloon distal protection in SVG PCI is upheld regardless of the length of lesion being treated. There is a trend toward more relative benefit with the GuardWire™ for shorter lesions despite the finding that shorter lesions convey a lower risk of MACE.

1028-15

### Supported Elective Angioplasty Procedures Without On-Site Cardiac Surgery Is Associated With Low Risk of Adverse Events

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**Background:** The safety of elective percutaneous coronary intervention (PCI) at community hospitals without on-site cardiac surgery is uncertain.

**Methods:** A cooperative plan to support PCI was implemented by Mayo Clinic cardiologists and cardiac surgeons at Saint Marys Hospital (SMH, tertiary care facility) and Immanuel St Joseph's Hospital (ISJ, no cardiac surgery). These hospitals are separated by 85 miles. Patient selection criteria (ACC/AHA type A or B1 lesion type), contingency plans and a telecommunications network to support consultation between physicians and surgeons during PCI were developed. Success and complications observed at ISJ over the first 28 months of operation were compared to pts treated at SMH, matched for lesion type. Expected mortality risk was estimated using the New York State angioplasty database.

**Results:** Between 3/99 and 7/01, elective PCI was performed in 206 pts at ISJ (stents in 94.6%) and 690 similar pts at SMH (stents in 86.4%). Unmatched variables were similar, except SMH pts had more severe angina, myocardial injury, prior bypass surgery or heart failure. Abciximab was used in 76% ISJ and 23% SMH pts ( $p<0.001$ ). Procedures were successful in 99.5% ISJ and 97.2% SMH pts ( $p=0.053$ ). No patient required transport for urgent cardiac or vascular surgery. Table shows estimated and observed mortality at both hospitals.

Follow-up for at least 6 months showed no differences in late outcomes.

**Conclusions:** Supported elective PCI in selected low risk patients is safe. On-site cardiac surgical services may no longer be required.

Location	Expected Deaths	Actual Deaths	CABG
SMH (n=690) Frequency	11.0	5	3
Percent (95% C.I.)	1.60 (0.9, 2.9)	0.72 (0.2, 1.7)	0.43 (<0.1, 1.3)
ISJ (n=206) Frequency	2.7	1	0
Percent (95% C.I.)	1.30 (0.4, 4.2)	0.49 (<0.1, 2.7)	0.00 (0, 1.8)

1028-16

### Percutaneous Interventions of the Internal Mammary Artery Graft: Immediate and Long-Term Clinical Outcome

**Marco Boccialatte**, Paulino Sousa, Remy Choussat, Bruno Farah, Rossella Gottilla, Jean Fajadet, Jean Paul Bouhnoire, Jean Marco, *Clinique Pasteur, Toulouse, France.*

**Background:** Safety of percutaneous treatment of the internal mammary artery (IMA) graft has been reported in small numbers of patients series. However, information is needed regarding utility of stent implantation, radial approach and long term clinical outcome. **Methods:** We report the immediate results and long-term clinical outcome of percutaneous coronary intervention (PCI) of the IMA graft. Between June 1995 and June 2000, 88 consecutive pts underwent PCI of the IMA graft, by either balloon angioplasty or stenting. These procedures represent 0.9% of the 9649 PCI procedures performed in our institution in this period. We analysed clinical and procedural predictors of survival and event-free survival defined as freedom from death, myocardial infarction and target vessel coronary revascularization. **Results:** Clinical Follow-up (mean 41.3±17.8 months) was obtained in all the patients. The procedure was performed by radial approach in 39 and by femoral approach in 49. IMA graft was Left for 60 PTS and Right for 28 PTS. A total of 93 lesions (78 located at the distal anastomosis, 9 at the body of the graft and 6 at the ostium) were treated: 61 by balloon, 29 by stenting after predilatation and 3 by direct stenting. Mean lesion length, reference vessel diameter and preprocedural percentage of stenosis were 11.2±6.2 mm, 2.6±0.4 mm and 81±8% respectively. Procedural success was achieved in all patients. In-hospital MACE included only one Q wave myocardial infarction. Three years overall survival was 90.8±4.3% (mean±SEE) and event free survival 87.9±4.2%. At 1 and 3-years follow-up, freedom from any coronary revascularization was 87.3±4.2% and 81.9±5.1% respectively. Neither lesion location on the graft, nor stent implantation were found to be independent predictors of cardiac events at follow-up. **Conclusions:** This report suggests that PCI of IMA graft, performed by radial or femoral approach, is associated with low procedural risk and satisfactory long term clinical outcome and can be an effective alternative to surgery.

## POSTER SESSION

### 1029 Angiogenesis: Advancing Therapeutic Concepts, Methods, and Materials

Sunday, March 17, 2002, Noon-2:00 p.m.  
Georgia World Congress Center, Hall G  
Presentation Hour: Noon-1:00 p.m.

1029-17

### FGF-1 Gene Therapy Plasmid for Patients With Critical Limb Ischemia: Final Results

**Timothy D. Henry**, Anthony Comerota, Nicolas Chronos, John Laird, Rafael Sequeira, Bruce Kottke, Craig Kent, Juha-Pekka Salenius, Maria Pyle, Richard Pilsudski, *Hennepin County Medical Center, Minneapolis, Minnesota, University of Minnesota, Minneapolis, Minnesota.*

Angiogenic growth factors represent a novel treatment for patients (Pts) with critical limb ischemia (CLI) who are not amenable to standard revascularization. We evaluated the safety and tolerability of increasing doses of IM delivery of a nonviral plasmid encoding fibroblast growth factor (NV1FGF) in Pts with CLI (rest pain and/or non-healing ulcers) and not eligible for revascularization based on angiography < 1 month were randomized to receive IM NV1FGF into the ischemic thigh and calf. 27 Pts received 1 treatment (500 to 16,000 ug.) and 24 pts received 2 treatments at 0 and 3 weeks (500 to 8000 ug x2). FGF-1 levels, plasmid biodistribution, transcutaneous oxygen (TcPO<sub>2</sub>), ankle brachial index (ABI), pain assessment by a visual analog scale, and ulcer healing were assessed at baseline, 2, 3, and 6 months. **Results:** For the 33 completed Pts (Final results 11/01), NV1FGF was well tolerated with no serious adverse side effects related to the NV1FGF including no death, myocardial infarction, or cancer. FGF-1 was not detected and there was only limited and transient biodistribution of plasmid in plasma. A significant reduction was noted in pain and ulcer size, with a significant increase in TcPO<sub>2</sub> and a trend for ABI compared to baseline values (see table). **Conclusion:** In the first trial using FGF gene therapy for Pts with CLI, NV1FGF was well tolerated with encouraging initial clinical results. These results support a randomized, double blind, placebo controlled trial in Pts with CLI using NV1FGF.

Change from BL (p=)	Pain	Ulcer Size	TcPO <sub>2</sub>	ABI
2 Months	-51 (0.001)	NA	+12 (0.01)	+0.07 (0.07)
3 Months	-50 (0.001)	NA	+18 (0.001)	+0.09 (0.05)
6 Months	-60 (0.001)	-53% (0.002)	Not Done	+0.08 (0.07)