

3:15 p.m.

1125-4

Prevention of Clinical Events and Restenosis After Percutaneous Transluminal Coronary Angioplasty With Trapidil: Results of the STARC II Study

Aleardo Maresta, Marco Balducelli, Spencer B. King III, Roberto Latini, Tiziano Moccetti, Alessandro Monici-Preti, Elisabetta Varani, Aldo P. Maggioni, for the STARC II Investigators. *Ospedale S. Maria delle Croci, Ravenna, Italy, Istituto Mario Negri, Milano, Italy.*

Background: Still 30-40% of pts have a significant degree of restenosis after PTCA even in the stent era. Trapidil (T), a drug with antiplatelet and antiproliferative activity (platelet-derived growth factor antagonism) was shown to prevent post-PTCA restenosis in humans. STARC I study, showed a significant reduction in restenosis (24.2% T vs 39.7% ASA).

Methods: To confirm these data, STARC II trial tested a 6-month administration of T in 933 pts undergoing elective PTCA (200 mg tid vs placebo (P) on top of ASA), on the 1-year combined end-point of death, reinfarction and need for repeat revascularization. The study was randomized, multicenter, double-blind. A subgroup of 305 pts was also randomized to repeat coronary angiography (CA) at 6 months with central reading.

Results: Baseline clinical and angiographic characteristics were similar in the two study groups. Stent was implanted in 57% of the pts. Primary end-point occurred in 18.0% of P and in 20.4% of T groups (p=0.37). When recurrence or worsening of angina was added as further clinical end-point, this summed up to 23.0% in P vs 27.7% in T group (p=0.12). Treatment had to be discontinued for untoward effects in 5.0% and 9.6% of pts, respectively in P and T groups (p=0.02). The angiographic substudy showed a slightly better final minimal luminal diameter (MLD) for T treated pts (1.7±0.64 mm vs 1.59±0.67 mm) and less MLD late loss (0.48 vs 0.65 mm). This was particularly evident in patients treated with balloon alone (0.21 vs 0.48 mm). Binary restenosis rate (final stenosis ≥ 50%) was 31.7% in stented pts in T vs 21.7% in P group (p=0.29) while was 15.6% in the balloon alone pts in T and 35.3% in P group (p=0.068).

Conclusion: T seems not to influence clinical outcome of pts treated with elective balloon PTCA with/without stenting. Angiographic data suggest a possible favorable effect on restenosis only in pts treated with balloon PTCA alone.

1125-5

Safety Profile of Glycoprotein IIb/IIIa Inhibitors in Octogenarians

H. Mehrdad Sadeghi, Kishore J. Harjai, Harish R. Chandra, Robert D. Safian, William W. O'Neill, Cindy L. Grines, *William Beaumont Hospital, Royal Oak, Michigan.*

Background: Patients ≥ 80 years-old constitute a growing population with CAD who have higher complication rates during percutaneous interventions (PCI). While glycoprotein IIb/IIIa receptor inhibitors (GPI) are increasingly utilized to reduce the incidence of ischemic complications after PCI, there is limited data regarding the use of GPI in this group, especially with respect to the risk of intracranial hemorrhage. We looked at the safety profile of GPI in a cohort of octo- & nanogenarians undergoing PCI. **Methods:** All consecutive pts ≥ 80 years-old undergoing PCI with or without a GPI at William Beaumont Hospital during the period of January 1998 and June 2001 were evaluated for clinical outcomes and bleeding complications. **Results:** 1392 consecutive pts ≥ 80 years-old underwent PCI with a GPI (n=459) and without a GPI (n=933). Patients treated with a GPI were more likely to be male (57% vs 48%) but less likely to have peripheral vascular disease (19% vs 25%). However, there were no baseline differences between the 2 groups with respect to age (83), hypertension (71% vs 75%), diabetes (26% vs 27%), stroke, ulcer disease, hematocrit, or creatinine. Bleeding & transfusion rates are shown in the table below. **Conclusions:** Even though patients ≥ 80 years-old treated with Glycoprotein IIb/IIIa receptor inhibitors have more minor bleeding, there is no increased risk of major bleeding requiring transfusions or intracranial hemorrhage. GPI appear to be safe in octo- & nanogenarians undergoing PCI.

RESULTS

	GPI n=459	NO GPI n=933	p value
Hematoma	18%	13%	0.02
GI/GU bleeds	10%	2.5%	0.004
CNS bleeds	0%	0%	NS
Transfusion	10%	9%	NS
Transfused Unit per Bleed	2.3	2.2	NS
Hospitalization length (days)	4.6±4.6	4.5±6.4	NS
Death	3%	2.8%	NS

1125-6

Mortality After Percutaneous Coronary Intervention in Cardiogenic Shock: A Predictive Model Based on 1,869 Consecutive Patients in the ACC-NCDR Registry

Lloyd W. Klein, Ronald Krone, Peter Block, Ralph G. Brindis, Richard E. Shaw, Charles McKay, Kathleen Hewitt, William S. Weintraub, for the ACC-NCDR Registry. *Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois.*

Background: Although percutaneous coronary intervention (PCI) in the setting of cardiogenic shock (CSHOCK) has high in-hospital mortality, the identity and relative importance of variables predictive of in-hospital death remain controversial.

Methods: Accordingly, we queried the 100,000-plus patient ACC-NCDR registry collected in 1998-2000 and evaluated the procedures in 1,869 consecutive patients undergoing PCI for CSHOCK.

Results: The mean age was 66±13 years with males predominating (62%). 81% underwent PCI for urgent/emergent indication and 54% had ongoing rest angina. The mean LVEF in 1,149 patients with concurrent LV grams was 39±17%. PCI was performed on C-type lesions in 40% and B₂ lesions in 37%. Stents were placed in 71%, PCI at multiple

824FO-6

Emergent Angioplasty for Acute Myocardial Infarction at a Community Hospital Without On-Site Cardiac Surgery

Mandeep Singh, Kirk N. Garratt, Ryan J. Lennon, Michael A. Kjelsberg, Bernard J. Gersh, Peter B. Berger, Farris K. Timimi, Robert J. Houlihan, Kevin T. Cragun, Christopher H. Crocker, David R. Holmes, Jr., Henry H. Ting, *Mayo Clinic, Rochester, Minnesota.*

Background: Percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI) at hospitals without on-site cardiac surgery (CABG) remains controversial. We studied the safety and efficacy of PCI performed for AMI at Immanuel St. Joseph's Hospital (ISJ), with no on-site CABG, with our affiliate, St. Mary's Hospital (SMH), the nearest center (85 miles away) with on-site CABG.

Method and Results: ISJ and SMH are linked by a T3 telemedicine line to enable on line consultation with cardiology and surgical staff at SMH. We compared the results of emergent PCI for AMI (defined as ST-segment elevation/new LBBB, or non-ST-segment elevation MI with ongoing chest pain) from 3/00 to 8/01 at ISJ (n=94) with matched controls at SMH. Multiple logistic regression analysis developed a propensity score based on clinical and angiographic variables. The two groups were balanced for age, ST-segment elevation, anterior infarct, gender, prior revascularization, congestive heart failure, hypertension, smoking status, and renal or peripheral vascular disease. The in-hospital outcomes were similar in the two groups (see Table). No patient required urgent CABG due to procedural related complication.

Conclusion: Our initial experience of emergent PCI for AMI utilizing telemedicine at a community hospital without on-site CABG is favorable, and the results are comparable to those at a tertiary facility with on-site CABG. These data support the new ACC/AHA Guidelines for PCI for AMI at a center without on-site CABG.

Variable	ISJ Hospital N=94 (%)	Saint Mary's Hospital N=94(%)	P-Value
Age, yr	63.1±12.3	62.9±11.8	0.91
Male	72(77)	67(71)	0.41
ST-elevation MI	67(71)	67(71)	1.0
Anterior MI	18(19)	18(19)	1.0
Procedural success	88(94)	90(96)	0.52
In-hospital death	3(3)	2(2)	0.65
CABG<24 hours	0(0)	0(0)	
In-hospital death, QMI, CABG	4(4)	3(3)	0.70

POSTER SESSION

1125 Percutaneous Coronary Intervention and Outcomes

Monday, March 18, 2002, 3:00 p.m.-5:00 p.m.

Georgia World Congress Center, Hall G

Presentation Hour: 3:00 p.m.-4:00 p.m.

1125-3

Late Evolution of Dilated Coronary Lesions

Walter Desmet, Joseph Dens, Jan Piessens, *UZ Gasthuisberg, Leuven, Belgium.*

Background: Smaller studies have suggested late regression of the dilated site after coronary angioplasty. The aim of this study was to evaluate with quantitative coronary angiography (QCA) the natural history of changes that occur in the dilated segment between 6 months and 3 years follow-up after angioplasty.

Methods: We studied a subpopulation of the NICOLE (Nisoldipine for COronary artery disease in LEuven)-study, in which patients underwent a control angiography 6 months and 36 months after coronary angioplasty. Of 826 patients who underwent successful angioplasty of one or more lesions, a total of 359 had a first control angiography after 187±11 days (6M) and a second follow-up angiography after 1050±149 days (36M) without intervening revascularization of any target vessel. The 435 dilated lesions in these patients were subdivided in 4 categories depending on their degree of stenosis (%DS) at the time of the first control angiogram.

Results:

Subgroup %DS 6 M	Number of lesions	%DS at 6 M	%DS at 36 M	Change 36M-6 M	p-value Change
<25	69	19.0 ± 5.6	32.0 ± 12.9	13.1 ± 13.8	< 0.0001
25-50	290	38.0 ± 6.5	38.8 ± 10.2	0.8 ± 10.5	0.2
51-75	71	58.4 ± 6.8	47.6 ± 14.5	-10.9 ± 14.9	< 0.0001
> 75	5	82.2 ± 6.6	54.0 ± 8.0	-28.2 ± 7.1	0.0009

Mean ± SD are given

Conclusion: Dilated coronary lesions with > 50 %DS 6 months after coronary angioplasty show significant regression over the ensuing 2.5 years, while lesions of intermediate severity (25-50 %DS) remain stable and minimal lesions still progress.

These findings may aid in clinical decision making.