7:45 a.m. **PLENARY SCIENTIFIC SESSION**
(8 minute presentation, 12 minute discussion)
Moderators: Hartzell V. Schaff, MD
Thoralf M. Sundt, III, MD

1. Reduced Anticoagulation After Mechanical Aortic Valve Replacement: Interim Results From the PROACT Randomized FDA IDE Trial

Puskas, John D.[1], Nichols, Dennis[2], Gerdisch, Marc[3], Quinn, Reed[4], Rhenman, Birger[5], Fermin, Lilibeth[5], McGrath, Michael[6], Kong, Bobby[7], Hughes, Chad[8], Sethi, Gulshan[9], Wait, Michael[10], Martin, Thomas[11], Graeve, Allen[2]

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Reduced Anticoagulation After Mechanical Aortic Valve Replacement: Interim Results From the PROACT Randomized FDA IDE Trial

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Objective: The Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) was designed to determine whether it is safe and effective to manage patients with less aggressive anticoagulant therapy than is currently recommend by ACC/AHA guidelines after implantation of an approved bileaflet mechanical valve prosthesis.

Methods: In one limb of the PROACT trial, patients with elevated preoperative risk factors for thromboembolism (TE) requiring aortic valve replacement (AVR) were randomized at 36 centers to either receive lower dose warfarin (treatment International Normalized Ratio (INR) 1.5-2.0) or to continue standard dose warfarin (control INR 2.0-3.0), three months after mechanical AVR. INR was adjusted by home monitoring and aspirin 81 mg daily was given to all patients. The study was conducted under an FDA investigational device exemption, and adverse events were independently adjudicated according to the AATS/STS guidelines for valve studies.

Results: 375 AVR patients were randomized into control (190) and treatment (185) groups between September 2006 and December 2009. Mean age was 55.2 $\pm$ 12.5 yrs; 79% were male; 93% were in sinus rhythm preoperatively. Calcific degeneration was the native valve pathology in 67%; patients with active endocarditis were excluded. Concomitant procedures included CABG (27%), aortic aneurysm repair (14%) and other procedures (25%). Follow-up averaged 3.42 years (675.3 pt-yrs control and 606.4 pt-yrs treatment). Mean INR ($\pm$ STD) was 2.50 $\pm$ 0.63 for the control and 1.89 $\pm$ 0.49 for the treatment

group (p<0.0001). As shown in the table the treatment group experienced significantly lower major and minor bleeding event rates in %/ptyr. There was no significant difference in incidence of stroke, transient ischemic attack (TIA) or total neurological events. All-cause mortality was similar between groups. **Conclusions:** INR may be maintained safely between 1.5-2.0 in AVR patients after implantation of this approved bileaflet mechanical prosthesis. In combination with low-dose aspirin, this therapy resulted in significantly lower risk of bleeding than customary INR 2.0-3.0, without significant increase in TE.

Adverse Event	Control N (%/ptyr)	Treatment N (%/ptyr)	Rate Ratio	Confidence Limits	p-value
Major Bleed	22 (3.26)	9 (1.48)	0.46	0.21-0.99	0.047
Minor Bleed	23 (3.41)	8 (1.32)	0.39	0.17-0.87	0.021
Total Bleed	45 (6.66)	17 (2.80)	0.42	0.24-0.73	0.002
Stroke	3 (0.44)	5 (0.82)	1.86	0.44-7.77	0.397
TIA	5 (0.74)	7 (1.15)	1.56	0.49-4.91	0.448
Neurological Events	8 (1.18)	12 (1.98)	1.67	0.68-4.09	0.261
Overall Mortality	9 (1.33)	10 (1.65)	1.24	0.50-3.04	0.643

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