Reduced Anticoagulation for On-X Heart Valves: A Prospective Multicenter Experience Using Home Monitoring*

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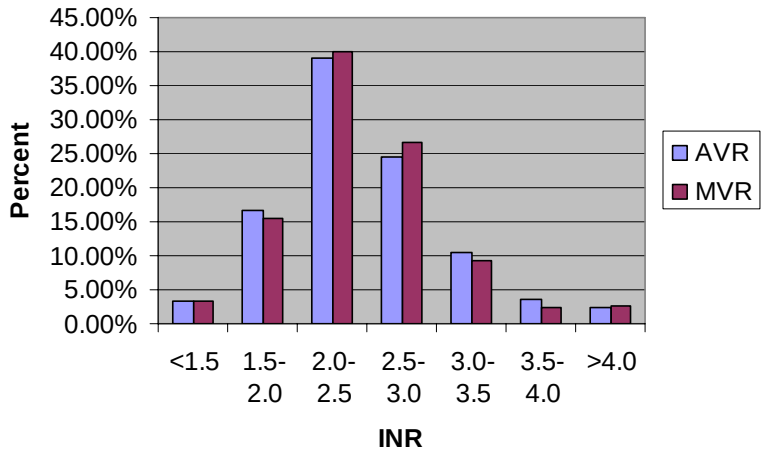
BACKGROUND: Low-dose therapy with home monitoring confers morbidity reduction with warfarin. This study was performed to determine the safety and effectiveness of this combination in patients receiving the On-X mechanical prosthesis.

METHODS: Between March 2004 and August 2007, 82 consecutive unselected patients in 4 US centers were prospectively followed with home monitoring, low-dose anticoagulation and 81 mg aspirin following isolated On-X implantation. There were 39 aortic valve replacements (AVR) and 43 mitral valve replacements (MVR). International normalized ratio (INR) was targeted at the lower range of AHA/ACC guidelines (2.0 AVR, 2.5 MVR). Adverse events were reported according to AATS/STS criteria.

RESULTS: Mean follow-up was 2.7 years (range 0.1-5.0 yrs). Total follow-up was 223 patient-years (pt-yr). Mean age was 55±11 years (range 24-85), 51%(42) were male. Mean INR was 2.41±0.64 with 37±15 measurements/pt/year. Maintenance of target INR was achieved in 63.5%(2142/3375) AVR and 36.1%(1507/4176) MVR (above target 16.5% AVR(557/3375), 5.0%(207/4176) MVR; below target 20.0%(676/3375) AVR, 59.0%(2462/4176) MVR). Anticoagulation non-compliance was 17.1%(14/82). There were no operative mortalities. There were no thromboembolic events. There was one gastrointestinal hemorrhage requiring transfusion. There were 3 late deaths, 2 non-valve-related and 1 valve-related. A non-compliant MVR patient consumed excess vitamin K immediately prior to thrombosis. Linearized rates of thrombosis, bleeding and valve related mortality were 0.45 %/pt-yr (0.01-2.50: 95% CI).

CONCLUSIONS: Low-dose anticoagulation and home monitoring is safe in On-X valve recipients. Adverse event rates in this early experience seem comparable with those seen in biological valves. Expanded investigation is warranted to confirm these findings.

Figure 1 - INR Frequency Distribution



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