



A Prospective Randomized Controlled Trial of the Impact of Home INR Testing on Clinical Outcomes: The Home INR Study (THINRS)

BACKGROUND: Warfarin anticoagulation reduces Thromboembolic complications in patients with atrial fibrillation and mechanical heart valves but effective management is complex and it is common for patients to be above or below target INR range. Point of care INR (patient self testing – PST) devices can be used by patients in their homes. This allows for greater testing frequency and patient involvement. **PURPOSE:** To compare anticoagulation management with frequent patient self-testing using a home monitoring device to high quality anticoagulation management (HQACM) using conventional AC management with monthly testing. **DESIGN:** 28 VA cooperative centers with over 400 AC patients on the roster. THINRS included patients with atrial fibrillation and mechanical heart valves. After assessment of ability of patients to self-monitor (Part I), patients were randomized to either conventional AC monitoring or self-testing with a home monitoring device (Part II). This study was powered to detect a 1.75% absolute risk reduction (5.5%-3.75%).

RESULTS - n=3,746 at 28 VA Med Centers enrolled in Part I. Of those, 78% demonstrated competency in PST (2,923) to go onto Part II. Follow-up = 2.0-4.75 yrs. With 8,700 patient yrs of FUP.

PRIMARY ENDPOINT:

Time to first event: stroke, major bleed, or death.

SECONDARY ENDPOINTS:

Time in target INR range, Satisfaction with anticoagulation (Duke Anticoagulation Satisfaction Scale (DASS), and QOL (Health Utilities Index Mark 3).

CONCLUSION: Compared to monthly clinic INR testing, weekly home INR monitoring may not improve the aggregate outcome of stroke, major bleed or death to the extent previously suggested. However PST monitoring does appear to improve time in target range and patient satisfaction with AC therapy. These results support that PST is an acceptable alternative to routine AC management and may be preferable when patient access to routine care is limited.

Outcome Part II N-2,922	Patient self Testing (PST)	High Quality Anticoagulation Management (HQACM)	P-value, hazard ratio
Primary: Stroke, bleed, or death	7.9%	8.9%	0.87, 95% CI (0.733-1.026), p=0.10
Secondary: Time in target INR range	67.2%	61.7%	P<0.002
Duke Anticoagulation Satisfaction Score (DASS)- (lower score = higher satisfaction)	DASS Score = 47.7	DASS Score = 49.1	P<0.02