Review: Self-testing or self-management of anticoagulation is better than clinic monitoring for thromboembolism and mortality

Connock M, Stevens C, Fry-Smith A, et al. **Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anticoagulation therapy: a systematic review and economic modelling.** Health Technol Assess. 2007;11:iii-iv, ix-66.

Clinical impact ratings: GIM/FP/GP ★★★★★★☆ Hematol/Thrombo ★★★★★★☆

QUESTION

Is patient self-testing (PST) or self-management (PSM) of oral anticoagulant therapy more effective than clinic monitoring for anticoagulation control?

METHODS

Data sources: MEDLINE, EMBASE/Excerpta Medica, CINAHL, and HEED (to September 2005); Cochrane Library (CENTRAL, NHS EED, DARE, and HTA databases) (Issue 3, 2005); National Research Register; and reference lists of retrieved articles.

Study selection and assessment: Randomized or nonrandomized trials that compared PST or PSM of oral anticoagulant therapy with monitoring by a specialized anticoagulation clinic or primary care clinic. Exclusion criteria were use of oral anticoagulants other than coumarins. 16 randomized controlled trials (RCTs) (n = 4444, mean age 42 to 75 y, ≥ 60% men) and 8 non-RCTs met the selection criteria. 9 RCTs used PSM, 5 used PST, 1 used both, and 1 compared PSM with PST. 9 RCTs had adequate randomization, 5 had clear allocation concealment, and 4 had dropout rates < 20% in the intervention group; 5 RCTs reported intention-to-treat analysis, 9 reported sample size calculations, and 7 reported group similarity at baseline. No RCTs blinded patients or investigators.

Outcomes: Included anticoagulation control (% time within targeted international normalized ratio [INR] range), bleeding, thromboembolism, death, and quality of life (QOL).

MAIN RESULTS

The PST and PSM groups had INRs within the targeted therapeutic range more often than did controls and fewer thromboembolic events or deaths; the groups did not differ for major bleeding (Table). 3 of 6 RCTs found a benefit of PST or PSM for QOL.

CONCLUSION

Patient self-testing or self-management of anticoagulation may improve anticoagulation control more than primary care–based monitoring and reduces thromboembolic outcomes.

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Randomized controlled trials of PST or PSM vs usual care in patients taking oral anticoagulants*

Outcomes at 2 mo to > 2 yr	Usual care group	Number of trials (person-years)	Time within range (%)†	Difference
INR	Clinic or primary care	15 (4577)	72% vs 62%	10%
	Clinic	8 (1534)	67.1% vs 66.3%	0.6%
	Primary care	5 (2801)	75% vs 60%	15%

		Number of trials (n)	Unweighted event rates	Risk difference (95% CI)	NNT (CI)
Bleeding	Clinic or primary care	15 (4091)	3.3% vs 3.5%	–0.39% (–1.54 to 0. 77)	NS
Thromboembolic events		15 (4091)	1.9% vs 4.0%	–2.24% (–3.34 to –1.15)	45 (30 to 87)
Death		15 (4091)	2.8% vs 4.2%	–1.70% (–2.87 to –0. 53)	59 (35 to 189)

*INR = international normalized ratio; NS = not significant; PSM = patient self-management; PST = patient self-testing; other abbreviations defined in Glossary. NNT and CI calculated from data in article using a fixed-effect model.
†Results of individual trials were weighted by number of patient-years.

COMMENTARY

Anticoagulation management is a practice that requires qualified personnel, INR testing at a laboratory or point-of-care portable INR monitor, and warfarin dose adjustments. The advantages of PST and PSM with portable INR monitors are patient convenience and real-time results. The terms *PST* and *PSM* should not be used interchangeably (1, 2). With PST, patients perform INR testing at home and then contact a clinician who supervises warfarin dose adjustments at least monthly (2). In addition to testing, PSM requires that patients independently interpret INR results, modify warfarin dose using a standardized nomogram, and maintain the INR within the therapeutic range (2).

The results of the review by Connock and colleagues are consistent with those of previous publications (2, 3): Self-monitoring is effective and safe for selected and successfully trained patients. However, the reductions in thromboembolic outcomes and deaths observed with PST or PSM require cautious interpretation because they were not consistently associated with anticoagulation control. In addition, the review combined PST and PSM results under the general term "patient self-monitoring"; PST and PSM data must be analyzed separately because of the different warfarin dosing strategies (qualified personnel vs patient self-dosing) and the different patient populations (1, 2).

What is needed for successful PST and PSM? Clearly defined patient selection criteria for these strategies are required (1, 2). In everyday practice, approximately 25% of patients taking warfarin may be eligible for PST or PSM, half of whom will require caregiver assistance (2); PSM is too demanding for most patients. For successful evaluation of PST and PSM, standardized screening and a structured education program similar to the national strategy in Germany are necessary. Only then will the true clinical and cost-effectiveness of PST and PSM be measured.

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References

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