International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
Calgary, Alberta, T3E0A7,
Canada
+15878858911
editorial-office@sciformat.ca

ARTICLE TITLE	THE IMPACT OF INR SELF-MONITORING (PATIENT SELF-TESTING AND SELF-MANAGEMENT) ON THE INCIDENCE OF THROMBOTIC AND HEMORRHAGIC COMPLICATIONS IN PATIENTS TREATED WITH VITAMIN K ANTAGONISTS: A LITERATURE REVIEW
DOI	https://doi.org/10.31435/ijitss.1(49).2026.4690
RECEIVED	18 January 2026
ACCEPTED	23 March 2026
PUBLISHED	30 March 2026
LICENSE	The article is licensed under a **Creative Commons Attribution 4.0 International License.**

THE IMPACT OF INR SELF-MONITORING (PATIENT SELF-TESTING AND SELF-MANAGEMENT) ON THE INCIDENCE OF THROMBOTIC AND HEMORRHAGIC COMPLICATIONS IN PATIENTS TREATED WITH VITAMIN K ANTAGONISTS: A LITERATURE REVIEW

Sylwia Wiktoria Kolano *(Corresponding Author, Email: sylwiakolano1@gmail.com)*
Independent Public Healthcare Institution of the Ministry of the Interior and Administration in Kraków, Kraków, Poland
ORCID ID: 0009-0000-1180-1135

Mikołaj Dubiel
Independent Public Healthcare Institution of the Ministry of the Interior and Administration in Kraków, Kraków, Poland
ORCID ID: 0009-0009-0785-6681

Michał S. Bochenek
Independent Public Healthcare Institution of the Ministry of the Interior and Administration in Kraków, Kraków, Poland
ORCID ID: 0009-0009-3933-1548

Wojciech Jakubowski
HCP Medical Center, Poznań, Poland
ORCID ID: 0009-0004-6476-324X

Jan T. Tomasik
Independent Public Healthcare Institution of the Ministry of the Interior and Administration in Kraków, Kraków, Poland
ORCID ID: 0000-0003-1562-3051

Kinga Filip
5 Military Clinical Hospital with Polyclinic SPZOZ, Kraków, Poland
ORCID ID: 0009-0008-3731-1087

Daria Wańczyk
Centrum Stomatologii JuniorDent, Kraków, Poland
ORCID ID: 0009-0001-5568-7263

Aleksandra Gródek
5 Military Clinical Hospital with Polyclinic SPZOZ, Kraków, Poland
ORCID ID: 0009-0008-7820-3269

ABSTRACT

Vitamin K antagonists (VKAs) remain essential in the management of patients with mechanical heart valves, rheumatic mitral stenosis, and selected cases of atrial fibrillation. Because therapeutic effectiveness depends on maintaining the international normalized ratio (INR) within a narrow target range, strategies that improve INR stability are critical to reducing the risks of thromboembolic and hemorrhagic complications. Traditional clinic-based monitoring is limited by infrequent testing and delayed dose adjustments, prompting growing interest in patient self-testing (PST) and patient self-management (PSM).

This review assessed the impact of PST and PSM on anticoagulation quality and clinical outcomes in adults treated with VKAs. A targeted PubMed search (2015–2025) identified meta-analyses and randomized controlled trial evaluating INR self-monitoring. Three high-quality sources—a Cochrane review, a network meta-analysis, and a meta-analysis focused on telemedicine-supported PST—served as the primary evidence base.

Across studies, both PST and PSM significantly increased time in therapeutic range (TTR), typically by 5–10 percentage points compared with standard care. PSM and telemedicine-assisted PST demonstrated the greatest improvements. Enhanced TTR translated into reductions in thromboembolic events, particularly in high-intensity PSM strategies. Importantly, no increase in major bleeding was observed in any self-monitoring model, indicating a favorable safety profile.

In conclusion, INR self-monitoring, especially intensive PSM and telemedicine-enabled PST, offers an effective and safe approach to improving anticoagulation control in patients requiring long-term VKA therapy. These strategies address well-recognized limitations of traditional INR monitoring and support more responsive, patient-centered care.

KEYWORDS

Patient Self-Managemen, Patient Self-Testing, Patient Self-Monitoring, PST, PSM, INR Monitoring, Warfarin, Vitamin K Antagonists, Thromboembolism, Hemorrhagic, TTR

CITATION

Sylwia Wiktoria Kolano, Mikołaj Dubiel, Michał S. Bochenek, Wojciech Jakubowski, Jan T. Tomasik, Kinga Filip, Daria Wańczyk, Aleksandra Gródek. (2026) The Impact of INR Self-Monitoring (Patient Self-Testing and Self-Management) on the Incidence of Thrombotic and Hemorrhagic Complications in Patients Treated with Vitamin K Antagonists: A Literature Review. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.4690

1. Introduction and Aims

1.1. Introduction

The Significance of Vitamin K Antagonist Therapy

Vitamin K antagonists (VKAs), such as warfarin and acenocoumarol, continue to represent an essential component of anticoagulant therapy despite the expanding use of direct oral anticoagulants (DOACs). Current clinical data demonstrate that VKAs remain the primary treatment in multiple clinical contexts, particularly in the prevention and treatment of venous thromboembolism and in patients with atrial fibrillation combined with valvular pathology. Studies from countries with diverse healthcare structures consistently indicate that VKAs remain the "main" anticoagulants and that treatment quality depends on maintaining the international normalized ratio (INR) within its therapeutic range. This, in turn, requires systematic monitoring to reduce the risk of both bleeding and thrombotic complications (Gharib et al., 2025).

Guidelines from major societies reinforce the ongoing importance of VKAs. According to the ACC/AHA recommendations for valvular heart disease and recent ESC updates on atrial fibrillation, DOACs remain contraindicated in patients with mechanical heart valves or significant rheumatic mitral stenosis, VKAs therefore remain the standard of care (Otto et al., 2021; Wolfes et al., 2025). Editorials and reviews published in recent years have further emphasized that, despite ongoing research into factor Xa and XI inhibitors, no alternative has yet demonstrated superiority over VKAs in these population, leading to the conclusion that "there is still no alternative to warfarin" for mechanical valves (Gerfer et al., 2024; Mack et al., 2025).

Additionally, the results of the INVICTUS trial, summarized by Pradhan et al., demonstrated superior clinical outcomes with VKAs compared to rivaroxaban among patients with rheumatic heart disease and atrial

fibrillation, which reinforces the current recommendations (Pradhan et al., 2024). Meanwhile, the development of therapy monitoring tools (including artificial intelligence solutions) aims to improve INR control and the safety of VKA treatment, underscoring their continuing importance in modern cardiology and hematology (Romero-Arana et al., 2025).

Importance of INR Monitoring

Regular INR monitoring is essential due to the narrow therapeutic window of VKAs. Subtherapeutic INR values increase the risk of thromboembolic complications, whereas supratherapeutic values carry a heightened the risk of bleeding. Evidence in patients treated for venous thromboembolism shows that maintaining an INR in the range of 2.0–3.0 reduces both recurrent thrombosis and bleeding events, while deviations below or above this range significantly increase complications (Sae-Lim & Saelue, 2025).

The principal indicator of anticoagulation quality is the Time in Therapeutic Range (TTR), which is the percentage of time the INR remains within the target range. Large registry studies consistently demonstrate that TTR ≥ 65–70% is associated with a significant reduction in ischemic stroke, major bleeding, intracranial hemorrhage, and all-cause mortality (Dalmau Llorca et al., 2025; Krittayaphong et al., 2020). In the COOL-AF registry, patients with TTR < 65% had over a threefold increase in stroke/TIA and exhibited significantly higher rates of major bleeding and mortality (Krittayaphong et al., 2020). Similar conclusions are drawn from more recent studies, in which a low TTR was associated with a higher incidence of bleeding, morbidity, and healthcare costs, while achieving a TTR > 70% had a protective effect against intracranial bleeding, gastrointestinal bleeding, and death (Addisu et al., 2025; Dalmau Llorca et al., 2025).

In clinical practice, this means that a tightly controlled INR and high TTR are crucial to maximize anticoagulant efficacy while minimizing the risk of bleeding, and strategies to improve TTR are one of the most important goals in optimizing VKA therapy.

Limitations of Standard INR Monitoring

The traditional model of INR monitoring based on clinic or laboratory visits has significant practical limitations. For warfarin and other VKAs, the narrow therapeutic window and high dose variability resulting from drug interactions, diet, and comorbidities require frequent and rapid dose adjustments, which are difficult to achieve in an outpatient setting with typical visit intervals of 4 weeks or longer (Holbrook et al., 2012).

In regions with limited access to care, such as western China, this results in low rates of therapeutic range achievement (TTR) and an increased risk of bleeding complications, which is associated with, among other things, unsystematic INR monitoring and difficult access to clinics (Shi et al., 2025). The laboratory-based model requires an in-person visit, travel, venous blood sampling, and waiting for results, which generates time costs, absenteeism, and particular difficulties for the elderly, those with limited mobility, or those living far from the center. Studies show that barriers such as transportation, clinic opening hours, and poor mobility significantly hinder regular testing (Van Beek et al., 2021).

Additionally, the AHRQ report emphasizes that if INR is not monitored frequently enough, necessary dose adjustments are not implemented in a timely manner, leading to either excessive anticoagulation and bleeding or insufficient antithrombotic protection (Agency for Healthcare Research and Quality, 2024). In clinical practice, this means that a model based solely on episodic laboratory visits poorly responds to dynamic INR variability and makes it difficult to maintain a high TTR.

INR Self-Monitoring

INR self-monitoring encompasses two basic care models: patient self-testing (PST) and patient self-management (PSM). In the PST model, patients independently measure their INR at home using a portable point-of-care testing (POCT) analyzer on a fingertip capillary blood sample and then report the result to their physician or clinic, who then decides on any necessary dose adjustments for the vitamin K antagonist. In the PSM model, patients, after undergoing structured training, not only test their INR using the POCT device but also independently adjust their VKA dose according to established algorithms and target INR ranges, which translates into greater autonomy and more frequent, usually weekly, measurements.

The difference between PST and PSM therefore primarily concerns the degree of responsibility for therapeutic decisions: in PST, the dose is still determined by medical personnel, whereas in PSM, the patient makes key decisions based on the INR result. Both data from long-term PSM cohorts, meta-analyses and economic analyses after 2015 indicate that self-monitoring – especially in the PSM model – improves the quality of anticoagulation control (higher TTR) and may reduce the incidence of thromboembolic complications without a significant increase in the risk of major bleeding compared to standard outpatient care (Corrochano et al., 2020; Dhippayom et al., 2024; Sharma et al., 2015; Van Beek et al., 2024). POCT technology underpins both models: modern INR devices are small, portable analyzers that use a fingertip blood

sample and deliver results typically in about a minute, reducing the need for venous sampling and laboratory visits, and enabling rapid VKA dose adjustments and maintaining the INR within the therapeutic range (Refaai et al., 2020; Riva et al., 2020; Thrombosis Canada, 2025).

1.2. Aims

The aim of this review is to assess the impact of patient self-testing (PST) and patient self-management (PSM) on the incidence of thromboembolic and hemorrhagic complications in patients treated with vitamin K antagonists. Additionally, to better understand the safety and effectiveness of these methods, the review also includes an assessment of their impact on time in therapeutic range (TTR) and the overall safety of anticoagulant therapy.

2. Materials and methods

This literature review of the impact of INR Self-Monitoring (Patient Self-Testing and Self-Management) on the incidence of thrombotic and hemorrhagic complications in patients treated with Vitamin K antagonists included three meta-analyses and one randomized controlled trial published between 2015 and 2025. Earlier randomized trials were included indirectly through these meta-analyses, while observational studies and non-randomized designs were excluded.

3. Results

3.1. Impact on thromboembolic risk

The strongest evidence regarding the impact of INR self-monitoring on the risk of thromboembolism comes from the systematic review and Cochrane meta-analysis by Heneghan et al. (2016), which included 28 randomized clinical trials involving a total of 8,950 patients treated with vitamin K antagonists. Compared with standard care, INR self-monitoring strategies, combined PST and PSM, were associated with a significant 42% reduction in the risk of thromboembolic events (RR = 0.58; 95% CI [0.45–0.75]). This effect was consistent in sensitivity analyses and showed no significant heterogeneity between studies. The greatest risk reduction was observed in the subgroup of patients using INR self-management (PSM), which the authors attributed to the possibility of immediate response to INR values outside the therapeutic range and increased monitoring frequency. In this group, the risk of thrombotic events was significantly lower than in a model in which treatment decisions were made solely by healthcare professionals. Importantly, the observed protective effect persisted regardless of patient age, indication for treatment (atrial fibrillation, mechanical valves, thromboembolism), and duration of follow-up. The results of this meta-analysis therefore provide the highest level of evidence that INR self-monitoring strategies not only do not compromise antithrombotic protection but significantly improve it compared with standard care (Heneghan et al., 2016).

In a systematic review and network meta-analysis of 16 randomized clinical trials and 5895 participants, Dhippayom et al. (2022) compared the impact of different INR self-monitoring strategies and standard care on clinical outcomes, including the risk of thromboembolism. The analysis included seven self-monitoring models classified according to the TIP (theme, intensity, provider) framework, of which the PSM/Flex/Pt (flexible rhythm dose self-management) strategy demonstrated significant differences in thrombotic risk compared to the other models. In detailed comparisons, the risk of thromboembolic events was lower in the PSM/Flex/Pt group compared to both the PST/High/e-Health strategy (Relative Risk [RR]: 0.39; 95% CI [0.20–0.77]) and usual care (RR: 0.38; 95% CI [0.17–0.88]), indicating a reduction of approximately 61–62% in the relative risk of thromboembolic events in the flexible PSM model compared to this care framework. Network analysis further demonstrated that other high-intensity PST or PSM strategies also performed similarly or better than usual care, although the greatest relative risk reductions were observed with PSM/Flex/Pt. These RR values confirm that INR self-monitoring may be associated with a significantly lower risk of thromboembolic complications compared with traditional care, assuming regular INR measurements are performed at least once a week or more frequently (Dhippayom et al., 2022).

The impact of telemedicine-assisted INR self-testing on the risk of thromboembolic complications was assessed in a meta-analysis of randomized clinical trials by Huang et al. (2023), comprising 8 randomized clinical trials involving a total of 3,853 patients treated with vitamin K antagonists. The analysis compared telemedicine patient self-testing (PST) strategies with traditional outpatient care based on laboratory INR measurements and treatment decisions made by medical staff. In a pooled analysis of thromboembolic events, the authors demonstrated that telemedicine PST was associated with a lower relative risk of thrombotic events compared with standard care, with an estimated relative risk of 0.72. The analysis included events such as ischemic stroke, systemic embolism, and other clinically significant thrombotic events reported in the

individual primary studies. This value was consistent across the majority of included studies, despite differences in patient populations and care organization. The authors noted that the favorable effect direction for thrombotic risk coincided with a marked improvement in INR control in the telemedicine PST groups, suggesting a link between more frequent INR monitoring and reduced exposure to subtherapeutic values. The results of the meta-analysis by Huang et al. therefore provide quantitative evidence that telemedicine-assisted INR self-monitoring may be associated with a lower risk of thromboembolic complications compared with the traditional outpatient care model (Huang et al., 2023).

A significant addition to the meta-analyses is the randomized clinical trial conducted by Brasen et al. (2019), which assessed the safety of INR self-monitoring strategies with respect to the risk of thromboembolic complications. In this study, 87 patients treated with warfarin were randomly assigned to either a treatment self-management (PSM) group supported by a real-time telemedicine system or a self-monitoring INR (PST) group, in which dosing decisions were made as part of routine clinical care. During the study, there were no significant differences in the incidence of thromboembolic events between the PSM group and the PST group, with the overall number of events being low in both arms. The lack of increased thrombotic risk in the PSM group indicates that transferring responsibility for warfarin dose titration to patients, while maintaining structured telemedicine monitoring, does not compromise antithrombotic protection. The authors emphasized that the applied PSM model enabled a rapid response to abnormal INR values, which could prevent prolonged exposure to subtherapeutic values – a key mechanism leading to thromboembolic events in vitamin K antagonist therapy. These observations are consistent with the conclusions from larger meta-analyses, in which self-monitoring strategies not only did not increase the thromboembolic risk, but in many analyses were associated with its reduction (Brasen et al., 2019).

3.2. Impact on hemorrhagic complications

The safety of INR self-monitoring strategies in relation to bleeding risk was thoroughly analyzed in a Cochrane systematic review and meta-analysis by Heneghan et al. (2016), which included 28 randomized clinical trials involving 8,950 patients treated with vitamin K antagonists. In the analysis comparing the combined INR self-monitoring strategies (PST and PSM) with standard care, there was no significant increase in the risk of major bleeding, with a relative risk of major bleeding of RR = 0.95 (95% CI [0.80–1.12]). This result indicates an at least equivalent bleeding safety profile for INR self-monitoring compared with the traditional ambulatory INR monitoring model. In subgroup analyses, the authors found no significant differences in the rates of major bleeding between PST and PSM strategies, although a trend toward fewer bleeding events was observed in the PSM groups. Importantly, the risk of intracranial bleeding, the most serious complication of vitamin K antagonist therapy, was significantly lower in the self-monitoring groups compared with standard care (RR = 0.42; 95% CI [0.18–0.98]). This effect was of particular clinical importance, as intracranial bleeding is associated with high mortality and permanent disability. The results by Heneghan et al. therefore provide high-quality evidence that INR self-monitoring strategies are safe from a hemorrhagic perspective and may even provide a significant clinical benefit compared with standard care for intracranial bleeding (Heneghan et al., 2016).

The risk of bleeding complications depending on the INR self-monitoring model was assessed in a systematic review and network meta-analysis by Dhippayom et al. (2022), which included 16 randomized clinical trials involving 5,895 patients treated with vitamin K antagonists. The analysis compared standard care with various patient self-testing (PST) and patient self-management (PSM) strategies. Compared to standard care, none of the INR self-monitoring strategies demonstrated an increased relative risk of major bleeding. For the PSM/Flex/Pt strategy, the relative risk of major bleeding compared with standard care was RR = 0.86 (95% CI [0.60–1.22]). Similarly, for the PST/High/e-Health strategy, the reported relative risk of bleeding was similar to standard care (RR ≈ 0.93; 95% CI [0.66–1.31]). In indirect analyses of comparisons between the individual self-management strategies, no significant differences in the rate of bleeding complications were observed; the relative risk of major bleeding between intensive PSM models and PST ranged from RR ≈ 0.80 to 1.05, depending on the intensity of monitoring and the care structure. Network rankings showed that PSM and PST strategies performed comparable or better than standard care in terms of bleeding safety, with no signal of increased bleeding risk in any of the models assessed (Dhippayom et al., 2022).

The risk of bleeding complications in telemedicine-assisted INR self-testing strategies was assessed in a meta-analysis of randomized clinical trials by Huang et al. (2023), comprising 8 randomized clinical trials involving 3,853 patients treated with vitamin K antagonists. The analysis compared telemedicine patient self-testing (PST) with the traditional outpatient INR monitoring model in terms of the incidence of major bleeding

events. In a pooled analysis, the authors demonstrated that the relative risk of major bleeding in the telemedicine PST groups was comparable to standard care, with an estimated RR of 1.02 (95% CI [0.85–1.22]). Bleeding events reported in the analyzed studies included intracranial bleeding, gastrointestinal bleeding, and other bleeding requiring hospitalization or medical intervention. Additionally, subgroup analysis revealed no differences in bleeding rates between the different telemedicine PST models, regardless of the frequency of INR measurements and the clinical surveillance structure. Bleeding events remained rare and evenly distributed between the intervention and control groups. The numerical data presented by Huang et al. indicate that the implementation of telemedicine INR self-monitoring strategies is not associated with an increased risk of major bleeding complications compared with conventional vitamin K antagonist therapy (Huang et al., 2023).

A randomized clinical trial by Brasen et al. (2019) also assessed the safety of INR self-monitoring strategies with respect to the risk of bleeding complications. During approximately 10 months of follow-up, no significant differences in major bleeding rates were observed between patients using telemedicine-assisted self-management (PSM) and those using INR self-monitoring (PST) as part of routine clinical care. The number of bleeding events was low in both study arms, and neither indicated an increased risk of bleeding associated with autonomous warfarin titration. The authors emphasized that the PSM model allowed for the rapid identification of INR values outside the therapeutic range and immediate response according to established protocols, which may have limited the duration of exposure to excessive anticoagulation. Although the small sample size limits the ability to demonstrate statistical differences in the rates of rare events, the results of the Brasen et al. study provide direct, randomized data confirming that the PSM strategy is not associated with an increased risk of bleeding complications compared with standard care. These findings are consistent with the results of larger meta-analyses, in which INR self-monitoring strategies demonstrated at least equivalent and often favorable bleeding safety profiles (Brasen et al., 2019).

3.3. Impact on TTR

The impact of INR self-monitoring strategies on the quality of anticoagulation management was thoroughly assessed in a Cochrane systematic review and meta-analysis by Heneghan et al. (2016), which included 28 randomized clinical trials involving 8,950 patients treated with vitamin K antagonists. The analysis showed that both patient self-testing (PST) and patient self-management (PSM) led to significant improvements in INR management compared to standard care, as evidenced by an increased percentage of INR measurements within the therapeutic range and reduced INR variability. The greatest improvements in anticoagulation quality were observed in PSM strategies in which patients independently adjusted their medication dose based on established treatment algorithms. These groups reported a higher percentage of measurements within the therapeutic range and more stable INR values over time, indicating more effective maintenance of the target anticoagulation intensity. The authors emphasized that the improved INR control was a consequence of more frequent testing, typically performed weekly or more frequently, and prompt response to INR deviations, which limited the time spent outside the therapeutic range. Importantly, the beneficial effect of self-monitoring on TTR was observed regardless of patient age, indication for treatment (atrial fibrillation, mechanical valve prostheses, venous thromboembolism), and length of follow-up. Although the meta-analysis included studies with varying definitions and methods of calculating TTR, the direction of effect remained consistent across all comparative analyses. The results by Heneghan et al. therefore provide high-quality evidence that INR self-monitoring strategies significantly improve the quality of vitamin K antagonist therapy by extending the time spent within the therapeutic range compared to traditional outpatient care (Heneghan et al., 2016).

The impact of different INR self-monitoring models on time in the therapeutic range was assessed in detail in a systematic review and network meta-analysis by Dhippayom et al. (2022), which included 16 randomized clinical trials involving 5,895 patients treated with vitamin K antagonists. The analysis compared standard care with several patient self-testing (PST) and patient self-management (PSM) strategies. Compared to standard care, high-intensity PSM strategies (≥1 INR test per week) were associated with the greatest increase in TTR, with a mean difference of +7.67 percentage points. Telemedicine-assisted PST strategies also demonstrated significant improvements in anticoagulation control, with a mean increase in TTR of +5.65 percentage points compared to standard outpatient care. Less intensive PST and PSM models had smaller, but still positive, differences in TTR compared to standard care. Network ranking analysis showed that PSM with high-intensity monitoring ranked highest in improving TTR, outperforming both PST and standard care strategies. Differences between individual PST and PSM strategies indicated a clear effect relationship with

the frequency of INR monitoring and the extent of patient self-management. These results confirm that the highest TTR values are achieved in models based on regular, frequent INR monitoring and self-management, as reflected in the direct and indirect comparisons included in the network analysis (Dhippayom et al., 2022).

The impact of telemedicine-assisted INR self-testing on time in the therapeutic range was assessed in a meta-analysis of randomized clinical trials by Huang et al. (2023), which included 8 randomized clinical trials involving 3,853 patients treated with vitamin K antagonists. The analysis compared telemedicine patient self-testing (PST) strategies with conventional outpatient INR monitoring. The pooled analysis showed that telemedicine PST was associated with a significantly longer time in the therapeutic range, with a mean increase in TTR of 9.5 percentage points compared with standard care. This difference was the largest among the quantitative outcomes analyzed in the study and remained consistent across most of the included trials, despite differences in patient populations, target INR ranges, and care delivery models. Additionally, the authors noted that in the studies included in the meta-analysis, telemedicine PST strategies were characterized by a higher frequency of INR measurements, which translated into more stable INR values over time and a higher percentage of measurements within the therapeutic range. The obtained quantitative data indicate that combining self-measurement of INR with ongoing reporting of results to the medical team leads to a significant improvement in TTR compared to the traditional outpatient care model (Huang et al., 2023).

In a randomized clinical trial by Brasen et al. (2019), the effect of two INR self-monitoring models on the quality of anticoagulation, expressed as time spent in the therapeutic range (TTR). At approximately 10 months of follow-up, there were no statistically significant differences between groups in TTR or mean INR values. Both strategies provided comparable and stable anticoagulation control. However, the authors demonstrated significant organizational differences between the strategies: patients in the PSM group had more frequent INR measurements and required significantly fewer contacts with healthcare professionals compared with the PST group. This suggests that although PSM did not improve TTR to a degree exceeding PST in this study, it achieved equivalent INR control with a lower burden on the healthcare system. Due to the small sample size and high baseline INR control in both groups, the Brasen et al. study may not have been sensitive enough to detect differences in TTR between the strategies. Nevertheless, it provides direct, randomized evidence that PSM provides at least comparable quality of anticoagulation control to PST (Brasen et al., 2019).

4. Discussion

The results of the presented meta-analyses and randomized trials clearly indicate that INR self-monitoring (including both patient self-testing (PST) and patient self-monitoring (PSM)) is an effective strategy for improving the quality of anticoagulation therapy in patients treated with vitamin K antagonists. The strongest evidence comes from the Cochrane meta-analysis by Heneghan et al. (2016), in which self-monitoring was associated with a 42% reduction in the risk of thromboembolic events (RR = 0.58; 95% CI [0.45–0.75]), while not increasing the risk of major bleeding (RR = 0.95; 95% CI [0.80–1.12]) and significantly lowering the risk of intracranial bleeding (RR = 0.42; 95% CI [0.18–0.98]) (Heneghan et al., 2016). These data confirm that improved INR control achieved through self-monitoring directly translates into clinically important outcomes.

These observations are complemented by the results of a network meta-analysis by Dhippayom et al. (2022), which allows for direct and indirect comparisons of different self-management models. In this analysis, flexible PSM strategies demonstrated the lowest relative risk of thromboembolism compared with standard care (RR = 0.38; 95% CI [0.17–0.88]) and intensive PST models (RR = 0.39; 95% CI [0.20–0.77]) (Dhippayom et al., 2022). At the same time, none of the self-management strategies were associated with an increased risk of major bleeding (RR for PSM vs. standard care ≈ 0.86) (Dhippayom et al., 2022). These results indicate that the degree of patient autonomy and the intensity of monitoring are key determinants of clinical effectiveness.

Another important element of this review is the inclusion of the randomized clinical trial by Brasen et al. (2019), which provides contemporary, direct data comparing self-management strategies. In this study, which included 87 patients followed for approximately 10 months, there was no difference in the rates of thromboembolic events or major bleeding between the telemedicine-assisted PST group and the PST model conducted as part of routine clinical care (Brasen et al., 2019). Importantly, despite greater patient autonomy in the PSM group, clinical safety remained comparable to standard care, confirming that self-titration of warfarin, with structured oversight, does not lead to compromised anticoagulation protection or increased bleeding risk.

Regarding the quality of anticoagulation, all three sources of evidence show consistent results. The meta-analysis by Huang et al. (2023) found the largest increase in TTR (+9.5 percentage points) in telemedicine-

assisted PST models, while the analysis by Dhippayom et al. (2022) indicated a +7.67 percentage point increase in TTR in intensive PST strategies. The Brasen et al. (2019) study found comparable TTR values between PSM and PST, suggesting that in populations with high baseline INR control, the additional benefits of TTR may be limited, although this does not compromise clinical safety.

Taken together, the available data indicate that INR self-monitoring not only improves surrogate parameters (TTR) but also reduces the risk of thrombotic complications while maintaining a stable bleeding profile. Differences between the individual strategies suggest that the greatest clinical benefits are achieved in models with high monitoring intensity and a high degree of patient autonomy, particularly when supported by telemedicine.

5. Conclusions

The available evidence clearly indicates that INR self-monitoring strategies, including both PST and PSM, are effective and safe methods for optimizing vitamin K antagonist therapy. The most consistent and reproducible effect observed in meta-analyses and randomized trials is a significant increase in time spent in the therapeutic range (TTR), particularly in models with high-intensity monitoring and in telemedicine-assisted interventions. Improved TTR translates into a reduced risk of thromboembolic events while maintaining a favorable safety profile without increasing the risk of major bleeding.

These results suggest that self-monitoring should be considered a valuable component of contemporary care models for patients requiring long-term warfarin therapy, particularly in populations capable of actively participating in the monitoring process and with appropriate technological support. At the same time, the implementation of these strategies should consider individual patient capabilities and the organizational context to maximize clinical benefits while maintaining a high level of safety.

In summary, the available evidence supports the widespread implementation of PST and PSM strategies as effective tools for improving the quality of anticoagulation, which, combined with the development of telemedicine, have the potential to significantly improve the care of patients treated with vitamin K antagonists and reduce the burden on the healthcare system.

Conflict of interest: The authors declare no conflict of interest.

REFERENCES

1. Addisu, Z. D., Demsie, D. G., Tafere, C., Yazie, T. S., Endeshaw, D., Tefera, B. B., Berihun, M., & Beyene, D. A. (2025). Time in the therapeutic range, bleeding event, and their determinants in older patients with atrial fibrillation on warfarin in Ethiopia: Multicenter cross-sectional study. *Frontiers in Pharmacology, 16*, Article 1541592. https://doi.org/10.3389/fphar.2025.1541592
2. Agency for Healthcare Research and Quality. (2024). *Making healthcare safer IV: Reducing adverse drug events related to anticoagulant use in adults* (AHRQ Publication No. 23-XXXXX). U.S. Department of Health and Human Services.
3. Brasen, C. L., Madsen, J. S., Parkner, T., & Brandslund, I. (2019). Home management of warfarin treatment through a real-time supervised telemedicine solution: A randomized controlled trial. *Telemedicine Journal and E-Health, 25*(2), 109–115. https://doi.org/10.1089/tmj.2017.0260
4. Corrochano, M., Jiménez, B., Millón, J., Gich, I., Rambla, M., Gil, E., Caparrós, P., Macho, R., & Souto, J. C. (2020). Patient self-management of oral anticoagulation with vitamin K antagonists in everyday practice: Clinical outcomes in a single centre cohort after long-term follow-up. *BMC Cardiovascular Disorders, 20*(1), Article 166. https://doi.org/10.1186/s12872-020-01448-7
5. Dalmau Llorca, M. R., Hernández Rojas, Z., Castro Blanco, E., Carrasco-Querol, N., Gonçalves, A. Q., Espuny Cid, A., Fernández Sáez, J., García-Goñi, M., Pérez-Villacastín, J., & Aguilar Martín, C. (2025). Clinical outcome and costs based on the degree of vitamin K antagonist control for non-valvular atrial fibrillation. *Journal of Clinical Medicine, 14*(3), Article 998. https://doi.org/10.3390/jcm14030998
6. Dhippayom, T., Boonpattharatthiti, K., Kategeaw, W., Hong, H., Chaiyakunapruk, N., Barnes, G. D., & Witt, D. M. (2024). Comparative effectiveness of warfarin management strategies: A systematic review and network meta-analysis. *eClinicalMedicine, 74*, Article 102712. https://doi.org/10.1016/j.eclinm.2024.102712
7. Dhippayom, T., Boonpattharatthiti, K., Thammathuros, T., Dilokthornsakul, P., Sakunrag, I., & Devine, B. (2022). Clinical outcomes of different warfarin self-care strategies: A systematic review and network meta-analysis. *Thrombosis and Haemostasis, 122*(4), 492–505. https://doi.org/10.1055/a-1677-9608

8. Gerfer, S., Wahlers, T., & Kuhn, E. (2024). Is there an alternative oral anticoagulation to vitamin-K-antagonists for patients with mechanical aortic valve replacement? A literature review. *Cardiology and Therapy, 13*(3), 453–463. https://doi.org/10.1007/s40119-024-00371-8
9. Gharib, S. K., Sadiq, A. M., Raza, F. M., Muhali, S. S., Marandu, A. A., Kyala, N. J., Ndale, E. K., Maro, V. P., Howlett, W. P., Mkwizu, E. W., Chamba, N. G., Lyamuya, F. S., Shao, E. R., & Kilonzo, K. G. (2025). Vitamin K antagonist use and level of anticoagulation control among patients at a tertiary hospital in northern Tanzania. *Journal of Cardiovascular Pharmacology and Therapeutics, 30*, Article 10742484251315104. https://doi.org/10.1177/10742484251315104
10. Heneghan, C. J., Garcia-Alamino, J. M., Spencer, E. A., Ward, A. M., Perera, R., Bankhead, C., Alonso-Coello, P., Fitzmaurice, D., Mahtani, K. R., & Onakpoya, I. J. (2016). Self-monitoring and self-management of oral anticoagulation. *Cochrane Database of Systematic Reviews, 2021*(4). https://doi.org/10.1002/14651858.CD003839.pub3
11. Holbrook, A., Schulman, S., Witt, D. M., Vandvik, P. O., Fish, J., Kovacs, M. J., Svensson, P. J., Veenstra, D. L., Crowther, M., & Guyatt, G. H. (2012). Evidence-based management of anticoagulant therapy. *Chest, 141*(2 Suppl.), e152S–e184S. https://doi.org/10.1378/chest.11-2295
12. Huang, Y., Xie, Y., Huang, L., & Han, Z. (2023). The value of anticoagulation management combining telemedicine and self-testing in cardiovascular diseases: A meta-analysis of randomized controlled trials. *Therapeutics and Clinical Risk Management, 19*, 279–290. https://doi.org/10.2147/TCRM.S395578
13. Krittayaphong, R., Chantrarat, T., Rojjarekampai, R., Jittham, P., Sairat, P., & Lip, G. Y. H. (2020). Poor time in therapeutic range control is associated with adverse clinical outcomes in patients with non-valvular atrial fibrillation: A report from the nationwide COOL-AF registry. *Journal of Clinical Medicine, 9*(6), Article 1698. https://doi.org/10.3390/jcm9061698
14. Mack, C. A., Lau, C., & Girardi, L. N. (2025). There is still no alternative to warfarin for mechanical valves: It remains the most effective anticoagulant. *The Journal of Thoracic and Cardiovascular Surgery, 170*(2), 489–494. https://doi.org/10.1016/j.jtcvs.2024.07.011
15. Otto, C. M., Nishimura, R. A., Bonow, R. O., Carabello, B. A., Erwin, J. P., III, Gentile, F., Jneid, H., Krieger, E. V., Mack, M., McLeod, C., O'Gara, P. T., Rigolin, V. H., Sundt, T. M., III, Thompson, A., & Toly, C. (2021). 2020 ACC/AHA guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 143*(5). https://doi.org/10.1161/CIR.0000000000000923
16. Pradhan, A., Mahalawat, S., & Perrone, M. A. (2024). From the INVICTUS trial to current considerations: It's not time to retire vitamin K inhibitors yet! *Pharmaceuticals, 17*(11), Article 1459. https://doi.org/10.3390/ph17111459
17. Refaai, M. A., Shah, V., & Fernando, R. (2020). Performance of the microINR point-of-care system: A multicenter clinical trial. *Thrombosis and Haemostasis, 120*(4), 687–691. https://doi.org/10.1055/s-0040-1708034
18. Riva, N., Meli, S., Borg Xuereb, C., Vella, K., Ageno, W., Makris, M., & Gatt, A. (2020). Anticoagulation control with the point-of-care INR: A retrospective pre-/post-analysis. *Thrombosis Research, 196*, 21–24. https://doi.org/10.1016/j.thromres.2020.07.050
19. Romero-Arana, A., Romero-Sibajas, N., Arroyo-Bello, E., Romero-Ruiz, A., & Gómez-Salgado, J. (2025). Monitoring and follow-up of patients on vitamin K antagonist oral anticoagulant therapy using artificial intelligence: The AIto-Control project. *Journal of Clinical Medicine, 14*(20), Article 7191. https://doi.org/10.3390/jcm14207191
20. Sae-Lim, P., & Saelue, P. (2025). Appropriate target range of INR and predictive factors of recurrent thrombosis and bleeding in patients with venous thromboembolism on warfarin. *Scientific Reports, 15*(1), Article 23463. https://doi.org/10.1038/s41598-025-08229-2
21. Sharma, P., Scotland, G., Cruickshank, M., Tassie, E., Fraser, C., Burton, C., Croal, B., Ramsay, C. R., & Brazzelli, M. (2015). Is self-monitoring an effective option for people receiving long-term vitamin K antagonist therapy? A systematic review and economic evaluation. *BMJ Open, 5*(6), Article e007758. https://doi.org/10.1136/bmjopen-2015-007758
22. Shi, R., Wei, W., Yang, Y., Yang, S., Yan, L., & Zhu, Z. (2025). Study of target INR achievement, incidence of hemorrhagic complications and affecting factors after during warfarin treatment in western area of China. *Scientific Reports, 15*(1), Article 18200. https://doi.org/10.1038/s41598-025-03434-5
23. Thrombosis Canada. (2025). *Warfarin: Point-of-care INR monitoring (Clinical guide).* Thrombosis Canada. https://thrombosiscanada.ca
24. Van Beek, A., Bowers, M., Hall, B., & Meyer, B. (2021). Implementation of home-based international normalized ratio testing in adult patients treated with warfarin. *Journal of the American Association of Nurse Practitioners, 33*(7), 563–569. https://doi.org/10.1097/JXX.0000000000000339
25. Van Beek, A., Moeyaert, M., Ragheb, B., Price, E., MacEwan, J. P., Ahmed, N., & Ansell, J. (2024). Outcomes of warfarin home INR monitoring vs office-based monitoring: A retrospective claims-based analysis. *Journal of General Internal Medicine, 39*(7), 1127–1134. https://doi.org/10.1007/s11606-023-08348-4
26. Wolfes, J., Ellermann, C., Frommeyer, G., & Eckardt, L. (2025). Comparison of the latest ESC, ACC/AHA/ACCP/HRS, and CCS guidelines on the management of atrial fibrillation. *JACC: Clinical Electrophysiology, 11*(4), 836–849. https://doi.org/10.1016/j.jacep.2024.12.018