

Original article

Cost-effectiveness analysis of warfarin and direct oral anticoagulants for the treatment of venous thromboembolism in Ramathibodi Hospital

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Abstract:

Background: Direct oral anticoagulants (DOACs) are increasingly used, as they are non-inferior to warfarin in treating venous thromboembolism (VTE). However, the cost-effectiveness of DOACs relative to warfarin requires further investigation. **Objectives:** The study aimed to evaluate the cost-effectiveness of DOACs versus warfarin in treating VTE from a societal perspective and to examine the rates of recurrent VTE and bleeding associated with anticoagulant treatment in the Thai population. **Materials and Methods:** The study comprised a retrospective cohort from 2015 to 2019 and a prospective cohort from 2020 to 2021. Patients with newly diagnosed VTE who were treated with warfarin or DOACs were included. Direct medical costs were retrieved from hospital billing databases, while indirect medical costs were surveyed through interviews. The incremental cost-effectiveness ratio (ICER) for case avoided was calculated from a societal perspective. **Results:** A total of 135 patients were included, with 87 (64.4%) receiving warfarin and 48 (35.5%) receiving DOACs. Bleeding events occurred in 15 (17%) of the warfarin-treated patients and 4 (8%) of the DOAC-treated patients, with major bleeding in 1 (1%) warfarin patients and none among DOAC patients. Recurrent VTE occurred in 5 (5.7%) warfarin patients and 4 (8.3%) DOAC patients. No significant difference in bleeding or recurrent VTE was observed between the warfarin and DOAC groups. The decision tree model showed the ICER of 11,181.63 USD per bleeding case avoided. **Conclusion:** There were no significant differences in recurrence or bleeding rates between VTE patients receiving warfarin and those receiving DOACs. However, at its current price, DOACs appear to be less cost-effective than warfarin in prevent bleeding complications in the Thai population. A reduction in cost may improve their overall value and support broader adoption in clinical practice.

Keywords : ● Direct oral anticoagulants ● Warfarin ● Venous thromboembolism ● Economic evaluation
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นิพนธ์ต้นฉบับ

การศึกษาต้นทุนประสิทธิผลของการใช้ยา warfarin และ direct oral anticoagulant ในการรักษาผู้ป่วยลิ่มเลือดอุดตันในหลอดเลือดดำในโรงพยาบาลรามารับดี

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บทคัดย่อ

บทนำ ยาต้านการแข็งตัวของเลือดชนิดรับประทานที่ออกฤทธิ์โดยตรง (direct oral anticoagulant, DOAC) มีประสิทธิภาพไม่ด้อยกว่ายา warfarin ในการรักษาภาวะหลอดเลือดดำอุดตัน (venous thromboembolism, VTE) อย่างไรก็ตาม DOAC มีราคาสูงกว่า warfarin ในบริบทของประเทศไทย ความคุ้มค่าของ DOAC จึงยังไม่แน่ชัด **วัตถุประสงค์** เพื่อศึกษาต้นทุนประสิทธิผล (cost-effectiveness analysis) ของการใช้ยา DOAC และ warfarin ในการรักษาผู้ป่วย VTE ในมุมมองทางสังคม (societal perspective) ในการลดภาวะเลือดออกและภาวะหลอดเลือดดำอุดตันกลับเป็นซ้ำ **วัสดุและวิธีการ** การศึกษานี้ประกอบด้วยการศึกษาย้อนหลังในกลุ่มผู้ป่วยระหว่างปี พ.ศ. 2558-2562 และการศึกษาแบบไปข้างหน้าในกลุ่มผู้ป่วยระหว่างปี พ.ศ. 2563-2564 โดยคัดเลือกผู้ป่วยที่ได้รับการวินิจฉัย VTE รายใหม่ และได้รับการรักษาด้วย warfarin หรือ DOAC ข้อมูลต้นทุนทางตรงถูกรวบรวมจากฐานข้อมูลการเบิกจ่ายค่ารักษาพยาบาลของโรงพยาบาล ส่วนข้อมูลต้นทุนทางอ้อมได้จากการสัมภาษณ์ผู้ป่วย ทั้งนี้ ได้ทำการวิเคราะห์อัตราส่วนต้นทุนต่อประสิทธิผลส่วนเพิ่ม (incremental cost-effectiveness ratio: ICER) ต่อจำนวนกรณีเลือดออกที่สามารถหลีกเลี่ยงได้โดยพิจารณาจากมุมมองของสังคม **ผลการศึกษา** จากผู้ป่วยจำนวน 135 คน ผู้ป่วย 87 ราย (64.4%) รักษาด้วย warfarin และ 48 ราย (35.5%) รักษาด้วย DOAC ผู้ป่วยที่รักษาด้วย warfarin และ DOAC เกิดภาวะเลือดออก 15 ครั้ง (17%) และ 4 ครั้ง (8%) ตามลำดับ ผู้ป่วยที่รักษาด้วย warfarin มีภาวะเลือดออกรุนแรง 1 ครั้ง (1%) โดยไม่มีภาวะเลือดออกรุนแรงในผู้ป่วยที่รักษาด้วย DOAC ผู้ป่วยที่รักษาด้วย warfarin และ DOAC มีการเกิดภาวะหลอดเลือดดำอุดตันกลับเป็นซ้ำ 5 ราย (5.7%) และ 4 ราย (8.3%) ตามลำดับ อัตราส่วนต้นทุนต่อประสิทธิผลส่วนเพิ่ม (ICER) เท่ากับ 373,572.67 บาท (11,181.63 USD) สามารถป้องกันการเกิดภาวะเลือดออกได้ 1 คน **สรุป** DOAC และ warfarin มีประสิทธิภาพในการรักษา VTE ไม่ต่างกัน อย่างไรก็ตามในบริบทของประเทศไทย DOAC มีความคุ้มค่าต่ำกว่า warfarin ดังนั้นหากในอนาคตราคา DOAC ลดลงก็อาจจะนำมาใช้เป็นยาพื้นฐานในเวชปฏิบัติอย่างแพร่หลายมากขึ้น **คำสำคัญ** : ● ยาต้านการแข็งตัวของเลือดชนิดรับประทานที่ออกฤทธิ์โดยตรง ● Warfarin ● ภาวะหลอดเลือดดำอุดตัน

● การศึกษาต้นทุนประสิทธิผล

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต. 2569;36:31-8.

Introduction

Direct oral anticoagulants (DOACs) have been increasingly used worldwide for the treatment of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).¹ Several clinical trials have demonstrated that the efficacy of DOACs is non-inferior to warfarin in preventing recurrent VTE and reducing major bleeding and intracerebral hemorrhage.^{2,3} DOACs also have wide therapeutic windows, allowing for fixed dosing without the need for regular drug monitoring. In contrast, warfarin has a narrow therapeutic window, requiring patients to maintain an international normalized ratio (INR) target between 2 and 3. Additionally, warfarin is associated with frequent food and drug interactions, which can lead to subtherapeutic or supratherapeutic INR levels, necessitating frequent INR monitoring.

Although warfarin is less expensive than DOACs, the frequent outpatient visits required for INR monitoring, the cost of managing adverse events such as bleeding, and indirect costs—including productivity losses and transportation expenses—can significantly increase the overall healthcare costs associated with warfarin use. Whether DOACs are more cost-effective than warfarin for VTE treatment remains to be fully clarified. DOACs are more expensive than warfarin and are not covered under universal healthcare for most of the Thai population. Given the limited resources in low- to middle-income countries like Thailand, identifying the most cost-effective anticoagulant is essential. Therefore, this study examines the cost-effectiveness of DOACs versus warfarin in the treatment of VTE from a societal perspective. Evidence on the cost-effectiveness of DOACs compared to warfarin in Thailand could serve as a reference for other low- to middle-income countries with similar economic and healthcare contexts.

Methods

This research study constitutes a cost-effectiveness analysis of the use of warfarin and DOACs for treating

VTE at Ramathibodi Hospital from a societal perspective. The study was approved by the Ethical Research Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University (approval number COA.MURA2020/580). The study was conducted in accordance with the Declaration of Helsinki.

The study included both retrospective and prospective components. The population consisted of adult patients at Ramathibodi Hospital who were diagnosed with VTE (DVT with or without PE) between January 2015 and December 2020. Inclusion criteria were: ages over 18 years; diagnosis of DVT in the leg confirmed by Doppler ultrasound; and receipt of oral anticoagulants—warfarin, dabigatran, rivaroxaban, apixaban or edoxaban—for at least three months. Patients with cancer-associated VTE were excluded.

Clinical outcomes included the occurrence of any bleeding associated with the use of warfarin or DOACs and the recurrence of VTE, measured from the day of diagnosis.

Direct medical costs, including medication and hospitalization expenses from January 2015 to December 2019, were retrieved from the hospital's computer database and electronic medical records. In addition, indirect costs—lost income of patients and caregivers due to travel to the hospital—and direct non-medical costs, such as travel expenses to the hospital and patient meals, were collected through patient interviews from January 2020 to December 2020. All costs were adjusted for inflation to 2024 and converted to USD (36.797 THB = 1 USD as of 13 May 2024).⁴

The cost-effectiveness of warfarin and DOACs in treating patients with VTE from a societal perspective was then analyzed by estimating the incremental cost-effectiveness ratio (ICER) based on the cost and clinical outcomes described above.

Statistical analysis

Patient baseline characteristics were analyzed and presented using descriptive statistics. Continuous variables were presented as mean and standard deviation.

tion or median and interquartile range, as appropriate. Categorical variables were presented as percentages or proportions. The occurrence of recurrent VTE and bleeding requiring hospitalization in the groups receiving warfarin or DOACs was presented as percentages and compared using simple proportion comparisons. All statistical analyses were performed using STATA software, version 16. The ICER was calculated by comparing the difference in total costs—including direct medical, direct non-medical, and indirect costs—with the difference in the number of bleeding cases avoided between the two interventions. One-way sensitivity analysis was conducted to examine the variation of one variable at a time and was presented through threshold analysis using Microsoft Excel 2021.

Upon reviewing the electronic medical records, it was found that many patients received low-molecular-weight heparin (LMWH) for a period after diagnosis before initiating warfarin. Therefore, patients who received LMWH alone for more than two weeks were excluded from the decision tree analysis. In the model construction, probabilities of recurrent VTE and bleeding were used in each chance node. For bleeding events, the

result at the terminal node was assigned a value of 1 to represent a bleeding case avoided.

Results

A total of 255 patients were screened for eligibility. After applying the inclusion and exclusion criteria, 190 patients were included in the study. Following the exclusion of patients who received LMWH for more than two weeks, 135 patients remained for the cost-effective analysis. Of these, 87 patients (64.4 %) received warfarin treatment, and 48 (35.5 %) received DOACs, as shown in Figure 1. The median age of patients was 65 years (IQR 51-75), and 63% were female. A total of 19 patients (14%) presented with concurrent PE. The most common comorbidities were hypertension (46.6%), hyperlipidemia (33.3%), diabetes (18.5%) and autoimmune diseases (12.6%). Regarding anticoagulant use, 87 patients (64.4%) received warfarin, 13 (9.6%) received dabigatran, 30 (22.2%) received rivaroxaban, and 5 (3.7%) received apixaban. The median durations of treatment was 13.5 months (IQR 8-30 months) in the warfarin group and 9 months (IQR 5-17 months) in the DOAC group. Provoking factors for VTE were identified in 47.5% of

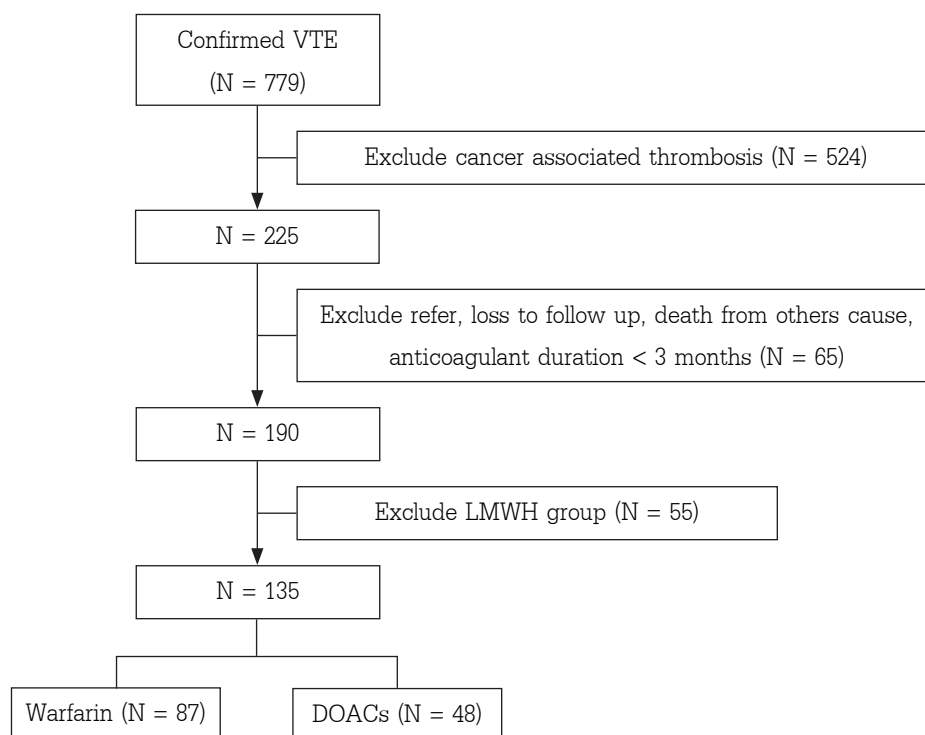


Figure 1 Flow diagram of included patients

cases, with immobility accounting for 28.9%, leg fractures for 4.4% and post-surgery for 1.5%. In the DOAC group, a significantly higher numbers of patients had immobilization, diabetes, hypertension and dyslipidemia compared with the warfarin group (Table 1).

Cost-effectiveness results

The cost-effectiveness of using warfarin and DOACs was evaluated from a societal perspective. The group treated with warfarin had a mean annual cost of 663.05 USD per person, with a total bleeding rate of 0.17. The

Table 1 Baseline Patient Characteristics

Baseline characteristics (total n = 135)	n (%)	Warfarin (n = 87)	DOACs (n = 48)	p-value
Age, median (IQR)	66 (51-75)	65 (48-73)	68.5 (55-76)	0.241
Male	50 (37)	28 (32.2)	22 (45.8)	0.116
Previous history of DVT	7 (2.8)	4 (4.6)	2 (4.2)	0.907
Provoking factors				
- Lower limb fracture	6 (4.4)	4 (4.6)	2 (4.2)	0.907
- Major surgery	2 (1.5)	1 (1.2)	1 (2.1)	0.667
- Hormonal use	4 (2.9)	3 (3.4)	1 (2.1)	0.654
- Immobilization	39 (28.9)	6 (6.9)	33 (68.8)	< 0.001
- May-Thurner syndrome	2 (1.5)	-	2 (4.2)	0.055
- Protein S deficiency	1 (0.7)	-	1(2.1)	0.177
Concurrent PE	19 (14)	12 (13.8)	7 (14.6)	0.899
Comorbidities				
- Cardiac diseases	13 (9.6)	9 (10.3)	4(8.3)	0.688
- Hypertension	45 (33.3)	8 (9.2)	37 (77.1)	<0.001
- Diabetes mellitus	16 (11.9)	4 (4.6)	12 (25)	<0.001
- Dyslipidemia	28 (20.7)	6 (6.9)	22 (45.8)	<0.001
- Autoimmune diseases	17 (12.6)	13 (14.9)	4 (8.3)	0.268
- Morbid obesity	5 (3.7)	4 (4.6)	1 (2.1)	0.459
- HIV infection	5 (3.7)	2 (2.3)	3 (6.3)	0.245
- Endocrine disorders	2 (1.5)	2 (2.3)	-	0.290
- Immune thrombocytopenia	1 (0.7)	1 (1.1)	-	0.456
Anticoagulant at diagnosis				
- Warfarin	87 (64.4)			
- Dabigatran	13 (9.6)			
- Rivaroxaban	30 (22.2)			
- Apixaban	5 (3.7)			
Duration of treatment				0.064
3-6 months	41 (30.4)	22 (25.3)	19 (39.6)	
> 6-12 months	37 (27.4)	22 (25.3)	15 (31.3)	
> 12 months	57 (42.2)	43 (49.4)	14 (29.2)	

Abbreviation, IQR, interquartile range; DVT, deep vein thrombosis; PE, pulmonary embolism; HIV, Human immunodeficiency virus infection

Cardiac diseases included atrial fibrillation, dilated cardiomyopathy, heart failure, and coronary heart disease; cardiovascular risk factors include diabetes milletus, hypertension and dyslipidemia

DOAC group had a mean annual cost of 1,659.12 USD per person, with a bleeding rate of 0.08. Therefore, treatment with DOACs increased the cost by 996.06 USD as compared to treatment with warfarin. DOACs showed a lower bleeding rate than warfarin by 0.09. The ICER was 11,181.63 USD per case avoided, meaning an additional cost of 11,181.63 USD could prevent one case of bleeding) (Table 2).

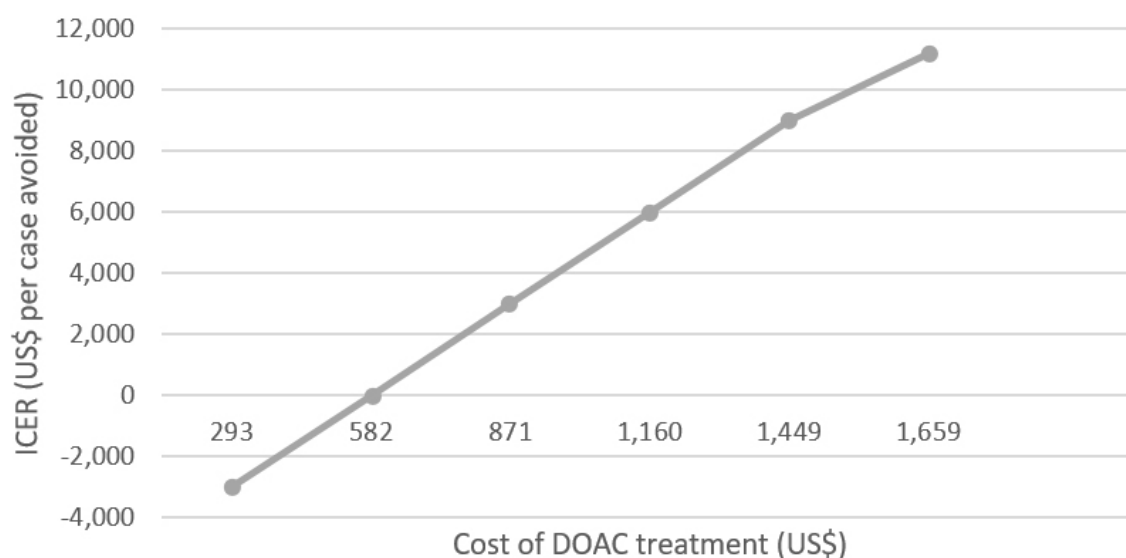
Due to random variation among individuals with similar characteristics, data from various sources may differ. Therefore, uncertainty in the decision-making model was addressed using a sensitivity analysis. This analysis evaluated how changes in the values of model variables would affect the results. A one-way sensitivity analysis was applied, using cost per case avoided as the decision-making criterion for cost-effectiveness. In conclusion, DOACs would be considered cost-effective compared to warfarin when the cost of DOAC treatment is reduced to 582.13 USD (Figure 2).

Clinical outcomes

The total incidence of bleeding among patients receiving warfarin was 15 cases (17%). Among these, major bleeding—specifically a cerebral hemorrhage—occurred in 1 case (6%). Of all bleeding events, five patients (33.3%) required hospitalization for treatment. In the DOAC group, bleeding occurred in four cases (8%), all of which were non-severe. These included non-massive hemoptysis, hematuria, upper gastrointestinal bleeding and superficial ecchymosis. One patient required hospitalization. No fatal bleeding was observed in either group. A comparison between the two groups revealed no statistically significant difference in the incidence of bleeding ($p = 0.15$). Additionally, five patients (5.7%) receiving warfarin and four patients (8.3%) receiving DOACs experienced a recurrence of VTE. There was no statistically significant difference in VTE recurrence between the two groups ($p = 0.56$).

Table 2 The cost-effectiveness of using warfarin and DOACs

	Cost per treatment (US Dollars)	Incremental cost (US Dollars)	Effective (Bleeding rate)	Incremental effective	ICER (US Dollars per case avoided)
Warfarin	663.05		0.17		
DOACs	1,659.12	996.06	0.08	0.09	11,181.63



At the current cost of DOAC treatment (\$1,659.12 USD), the ICER is \$11,181.63 USD per case avoided. The cost of DOACs has to be reduced to \$582.13 USD to avoid one case, compared to warfarin at \$663.05 USD.

Figure 2 One-way sensitivity analysis - cost of DOAC treatment

Discussion

In this study, we investigated the cost-effectiveness of DOACs compared to warfarin among Thai patients from a societal perspective. Our findings indicate that, despite DOACs resulting in fewer bleeding events, they are not cost-effective. DOACs incur a higher cost than warfarin by 35,505.36 Baht (equivalent to 996.06 USD) and exhibit a lower bleeding rate by 9%. Upon calculating the ICER, we found that an additional cost of 398,576.30 Baht (equivalent to 11,181.63 USD) for DOACs could prevent one case of bleeding. Our one-way sensitivity analysis suggests that DOACs could be deemed cost-effective in Thailand when the drug cost is reduced to 21,420.64 Baht (equivalent to 582.13 USD) per treatment.

A systematic review and meta-analysis on the cost-effectiveness and cost-benefit of DOACs in the treatment of VTE revealed that all DOACs were cost-effective, with apixaban associated with the highest annual total medical cost avoidance compared to other DOACs.⁵ However, this meta-analysis primarily included studies from high-income countries such as the US, Canada and England, where the payer context and willingness to pay were higher than those in low- to middle-income or upper-middle-income countries. Therefore, the cost-effectiveness of DOACs in treating VTE among upper to middle-income countries remains to be elucidated.

The cost-effectiveness of DOACs among patients with atrial fibrillation has been demonstrated in several studies.⁶⁻⁸ In a study of Thai patients with atrial fibrillation, apixaban was found to be a cost-effective alternative to warfarin for patients with suboptimal time-in-therapeutic range control.⁹ A systematic review and meta-analysis evaluating economic evaluations of DOACs versus vitamin K antagonists (VKAs) demonstrated that DOACs may be significantly more cost-effective than VKAs in high-income countries from a third-party payer perspective. However, regardless of the perspective, DOACs were not cost-effective in upper-middle-income countries.¹⁰

A recently published study among Thais using a cohort-based state transition model constructed from a societal perspective demonstrated that DOACs were associated with a decreased risk of recurrent VTE and intracranial hemorrhage. All DOACs—including apixaban, rivaroxaban, edoxaban and dabigatran—increased Quality-Adjusted Life Years compared to warfarin, albeit at a higher cost.¹¹ Nonetheless, the use of all DOACs to treat VTE was not deemed cost-effective. The results of our study confirmed that DOACs are effective in preventing recurrent VTE and reducing bleeding risk. However, they were not cost-effective as compared to warfarin, as the additional cost does not support their use unless the price of DOACs is reduced in Thailand.

Our study found that patients receiving DOACs had a higher numerical incidence of recurrent VTE than those on warfarin, although this difference was not statistically significant. However, they did exhibit a lower incidence of bleeding events, most of which were minor and non-fatal. Various factors—including age, comorbidities, abnormal kidney function and INR levels in the warfarin group—may influence the occurrence of recurrent VTE and bleeding events.

Our study has several strengths. It was a real-world-cost-effectiveness analysis, including only patients with a verified DVT diagnosis. We used a patient cohort and collected outcomes objectively. Costs were gathered based on individual patient visits and any hospitalizations that occurred. Indirect costs were captured through interviews, ensuring a comprehensive accounting of all expenses related to hospital visits. However, we also acknowledge some limitations. We did not collect QALY data, which is a more standardized measure in cost-effectiveness studies. In addition, we did not collect long-term costs, such as those related to the management of long-term complications and the impact on quality of life over time. The sample size in our study was small, which might lead to imprecise estimates when comparing outcomes.

Conclusion

Both warfarin and DOACs are effective in preventing recurrent VTE and bleeding events, with no statistically significant difference in clinical outcomes. However, from a societal perspective, DOACs were found to be less cost-effective than warfarin. While DOACs offer the advantage of fewer bleeding events, their higher cost may limit their accessibility and widespread adoption in Thailand. A reduction in price could enhance their viability as a treatment option in routine clinical practice.

Declarations

Ethics approval and consent to participate

This study obtained ethics approval from the Ethics Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Thailand. Written informed consent was obtained from all participants or their caregivers.

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Competing interests

The authors declare that they have no competing interests

Authors' contributions statement

P.C. collected data and wrote the first draft of the manuscript, O.P. designed the study, performed the statistical analysis and provided critical revision to the manuscript. K.B designed the study, analyzed data and wrote the final version of the manuscript. P.A. provided critical revision to the manuscript. All authors reviewed the manuscript.

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