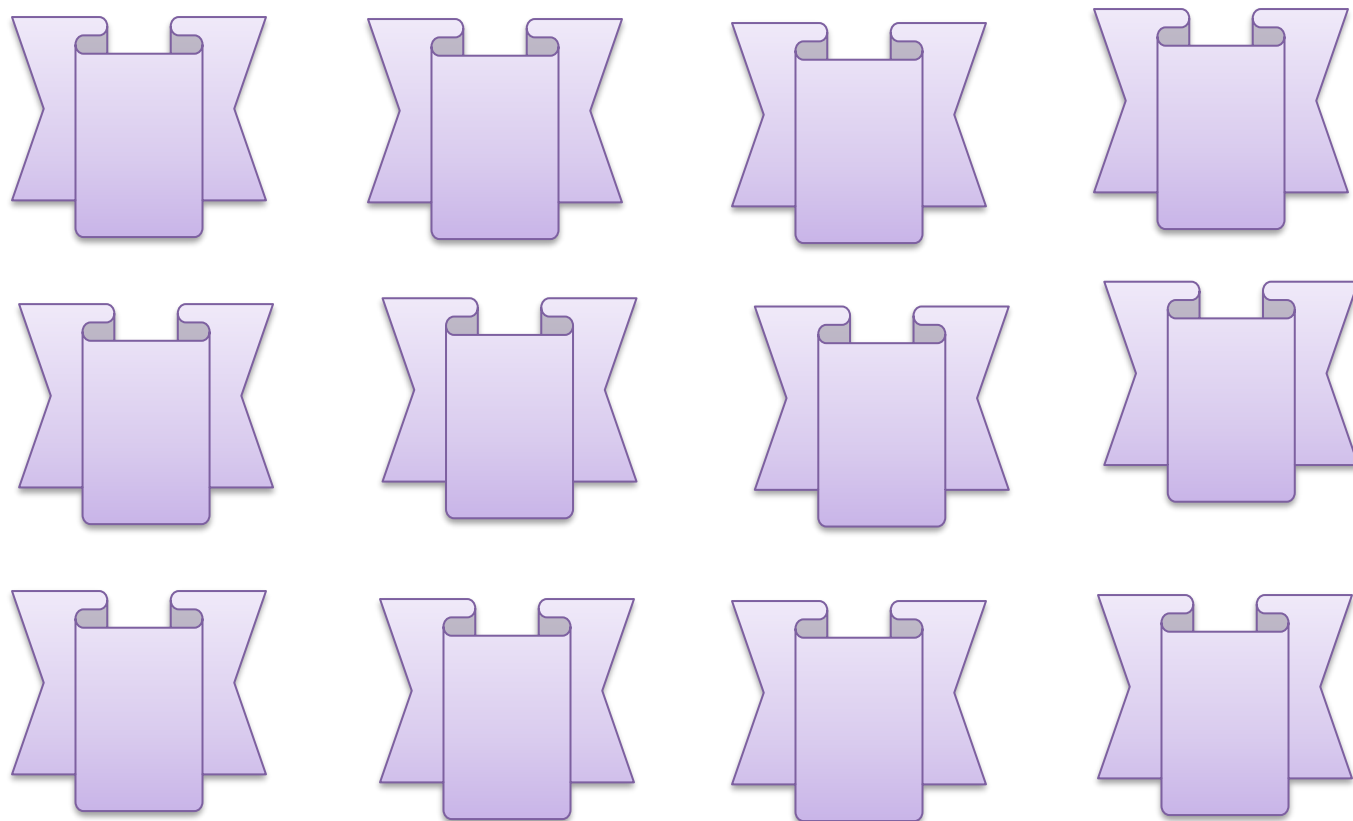


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Original Article

The Use of Direct Oral Anticoagulants Compared to Vitamin K Antagonists [Warfarin] in Patients with Left Ventricular Thrombus

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ABSTRACT

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Background: Myocardial infarction [MI] and some non-ischemic cardiomyopathies are related to the development of left ventricular thrombus [LVT]. As recently as the pre-perfusion period, LVT rates after a MI varied from 21 percent to as high as 46 percent.

The Aim of the work: To compare the efficacy and safety of Direct Oral Anticoagulants [DOACs] versus Vitamin K Antagonists [VKA] [warfarin] in treatment of Left Ventricular thrombus.

Patients and Methods: This clinical research was performed at the national heart institute from January 2022 to July 2023. This study was conducted on 120 patients with LV thrombus. All cases were separated into 3 groups: each group 40 individual [40 patients were treated with DOACs as Apixaban, 40 patients with Rivaroxaban & 40 patients with vitamin K antagonists as warfarin].

Results: INR showed a significant elevation in association with warfarin administration. There was a significant distinction seen across the groups in terms of, demographic data specific cardiac characteristics, ECG characteristics, thrombus characteristics and outcome of treatment.

Conclusion: DOACs [Rivaroxaban and Apixaban] and VKA [warfarin] have similar efficacy and safety in treating LVT.

Keywords: Direct oral anticoagulants; Vitamin K antagonists; Left ventricular thrombus; Rivaroxaban; Apixaban.



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INTRODUCTION

Individuals who have experienced a significant myocardial infarction [MI] and subsequently developed left ventricular dysfunction are more susceptible to the occurrence of Left ventricular thrombus [LVT], a potentially life-threatening condition. People with LVT have a higher likelihood of experiencing stroke, systemic embolism and subsequent mortality and morbidity [1].

Anticoagulant therapy with vitamin K antagonists [VKAs] for three months or six months is recommended according to current guidelines for LVT resolution [2]. Direct oral anticoagulants, also known as DOACs, are alternatives to the conventional treatment for anticoagulation that have been developed for the treatment and prevention of venous thromboembolism and the prevention of stroke among individuals who have atrial fibrillation [AF] [3].

DOACs have the benefit over VKA therapy in that they have a consistent and predictable anticoagulant action without the requirement for close monitoring. Increased drug compliance is another benefit of using DOACs [4]. DOACs offer a good risk-benefit ratio in patients with AF because they significantly lower the risk of cerebral hemorrhage and overall mortality [5].

Non-valvular atrial fibrillation, venous thromboembolism and other hypercoagulable illnesses are all FDA-approved indications for DOACs. Most patients who are eligible for therapy now choose for these drugs, which can be taken orally and have a known pharmacokinetic profile and safety profile; this off-label use even includes those with LVT [6].

Our study was conducted prior to the recent guideline recommendations for the use of anti-coagulation in the treatment of left ventricular thrombus. At the time of our study, which took place between January 2022 and July 2023., the guidelines did not provide specific recommendations regarding the use of Direct Oral Anticoagulants in treatment of LVT. We compare the safety and efficacy of direct oral anticoagulants [DOACs] versus vitamin K antagonists [VKA] as [warfarin] in the treatment of Left ventricular thrombus [LVT].

PATIENTS AND METHODS

The study was performed at The National Heart Institute from January 2022 to July 2023.

The study was done on 3 groups, each group 40 patient [40 patients were treated with DOACs as Apixaban, 40 patients with Rivaroxaban and 40 patients with VKAs as warfarin] were obtained pro or retrospectively and the duration of the study follow-up period within 90 days. However, it is important to note that there may have been additional follow-up days beyond the initial 90-day period, possibly up to 20 days. These additional days were included to capture any late occurrences or outcomes that might have occurred during that extended period.

Inclusion criteria: Adult patients with age more than 18 years, individuals having LV thrombus and Patients treated with Apixaban, rivaroxaban, and warfarin.

All patients had review of medical history including and Full clinical examination

Twelve leads ECG was done for each patient and Baseline transthoracic echocardiography and measuring of LVT by 2 D on Philips Echo machine, as well as duration of anticoagulation.

Exclusion criteria: Patient with valve replacement, patient with AF, moderate to severe rheumatic mitral stenosis and patients with active bleeding.

Sample size: This sample size was calculated based on the study carried out by **Steinberg** Epi Info was used to calculate the sample size by considering the following assumptions: - 95% two-sided confidence level, with a power of 80%. & α error of 5%. The sample size taken from the Epi- Info output was 109. To avoid the risk of drop out during follow up, the sample size was increased to 120 [7].

Procedure: Baseline clinical, and transthoracic echocardiographic information were recorded, as well as duration and timing of anti-coagulation regimens. The clinical interpretation of echocardiographic data pertaining to the morphological properties and movement of thrombi were included. Both the most recent transthoracic echocardiogram and the last one during the study period were analyzed for their imaging features including the changes of Left ventricular thrombus characteristics. Patients follow up was conducted throughout the study period, utilizing both in person visits to the hospital and phone communication.

All patients had review of medical history including: Age, sex, Risk Factors of coronary artery disease [DM, HTN and smoking], prior history of coronary artery disease, prior history of intervention, other comorbidities, drugs, time of presentation from the start of symptoms.

Full clinical examination: With particular emphasis on vital signs as [pulse, blood pressure and RBS] of the patients, general examination, local examination, auscultation of the heart for the presence of third heart sounds or audible murmurs.

Twelve leads ECG was done for each patient and Baseline transthoracic echocardiography: All patients were evaluated by Trans thoracic echocardiogram [TTE] for the assessment of regional wall abnormalities and overall left ventricular systolic function, any valvular affection, pulmonary hypertension and the presence of LV thrombus was assessed using a 2D, employing two distinct views and the largest measured size of the LV thrombus was recorded for analysis [8].

Statistical Analysis: We employed Microsoft Office Excel 2010 for Windows [Microsoft Corporation, Redmond, Washington, United States] and SPSS 22.0 for Windows [IBM Corporation, Chicago, Illinois, United States] in order to gather, tabulate, and analyze all of the data. The categorical qualitative variables have been defined as absolute frequencies [number], while the continuous quantitative variables were expressed as mean, standard deviation, and median [range], correspondingly. The Shapiro-Wilk test was utilized in order to investigate whether or not the continuous data were normally distributed. The Kruskal Wallis H test was applied in the process of analyzing the three different groups of non-normally distributed data. The Chi-square test was applied in order to analyze the differences and similarities between the groups of category data. It was deemed significant if the p-value was lower than 0.05.

RESULTS

This study was conducted on 120 patients with LV thrombus. All cases were separated into 3 groups: each group 40 individual [40 patients were treated with DOACs as Apixaban, 40 patients with Rivaroxaban & 40 patients with vitamin K antagonists as warfarin]. Patient demographic and clinical characteristics are presented in Table [1], and all of these parameters demonstrated no significant amongst the three study groups.

Table [2] showed that there was no significant variation amongst the three groups Regarding Heart Failure, IHD, CAD, MI, Type of MI, Cardiac enzymes, Atrial fibrillation and ToP [hrs]. INR showed a significant elevation in association with warfarin administration and this difference is due to the mechanism of action of the two classes of the drugs [9].

Table [3] showed that no significant difference between the study groups regarding presence of the Thrombus, mean and median size and the mobility of the thrombus. But according to distribution of number of patients there's significant differences were observed between the studied groups as follows; each group was divided into two categories based on the size of thrombus. Category 1: Thrombus less than 2 cm, 16 patients [40%] treated with Warfarin, 26 patients [65%] treated with Rivaroxaban and 13 Patients [32.5%] treated with Apixaban. Category 2: thrombus more than 2 cm, 24 patients [60%] treated with warfarin, 14 patients [35%] treated with Rivaroxaban, and 27 patients [67.5%] treated with Apixaban.

Table [4] showed that there was no significant distinction among the investigated groups as regard thrombus characteristics after treatment.

Table [5] showed that there was no significant variation amongst the studied groups as regard outcome of treatment.

Table [1]: Comparison amongst the examined groups concerning demographic & basic characteristics

Demographic & basic characteristics	Warfarin Arm [N=40]		Rivaroxaban Arm [N=40]		Apixaban Arm [N=40]		Test	p-value [Sig.]
	No.	%	No.	%	No.	%		
Sex								
Male	36	90%	38	95%	35	87.5%	1.401 ^a	0.496
Female	4	10%	2	5%	5	12.5%		
Age [years]								
Mean ± SD	60.45±10.45		55.65±12.12		59.70±10.87		3.491 ^b	0.175
Median [Range]	63 [40 – 78]		56 [33 – 76]		60.50 [36 – 77]			
Age group								
40 -60 years	16	40%	23	57.5%	20	50%	2.467 ^a	0.291
> 60 years	24	60%	17	42.5%	20	50%		
Smoking								
Never smoking	5	12.5%	2	5%	4	10%	3.788 ^a	0.435
Ex-smoker	6	15%	4	10%	2	5%		
Current smoker	29	72.5%	34	85%	34	85%		
History of prior intervention								
Absent	36	90%	38	95%	37	92.5%	0.721 ^a	0.697
Present	4	10%	2	5%	3	7.5%		

Table [2]: Comparison amongst the examined groups concerning specific cardiac characteristics

Specific cardiac characteristics	Warfarin Arm [N=40]		Rivaroxaban Arm [N=40]		Apixaban Arm [N=40]		Test	p-value [Sig.]
	No.	%	No.	%	No.	%		
Heart Failure								
Absent	26	65%	21	52.5%	23	57.5%	1.303 ^a	0.521
Present	14	35%	19	47.5%	17	42.5%		
Ischemic heart diseases								
Present	40	100%	40	100%	40	100%		-
Coronary artery disease								
Present	40	100%	40	100%	40	100%		-
Myocardial infarction								
Absent	6	15%	6	15%	4	10%	0.577 ^a	0.749
Present	34	85%	34	85%	36	90%		
Type of MI								
Absent	6	15%	6	15%	4	10%	0.579 ^a	0.965
STEMI	33	82.5%	33	82.5%	35	87.5%		
Non-STE-ACS	1	2.5%	1	2.5%	1	2.5%		
Cardiac enzymes								
Absent	7	17.5%	7	17.5%	5	12.5%	0.500 ^a	0.779
Present	33	82.5%	33	82.5%	35	87.5%		
Atrial fibrillation								
Absent	37	92.5%	39	97.5%	38	95%	1.053 ^a	0.591
Present	3	7.5%	1	2.5%	2	5%		
INR								
Mean ± SD	2.52±0.44		1±0		1±0		112.840 ^b	<0.001
Median [Range]	2.50 [2 – 3.5]		1 [1 – 1]		1 [1 – 1]			
ToP [hrs]								
Mean ± SD	34.20±10.71		31.80±11.70		30±9.79		3.402 ^b	0.182
Median [Range]	36 [24 – 48]		24 [12 – 48]		24 [24 – 48]			

STEMI: ST elevated myocardial infarction; Non-STE-ACS: non-ST elevated acute coronary syndrome; ToP: Time of presentation from starting symptoms.

Table [3]: Comparison between the studied groups concerning thrombus characteristics before treatment

Thrombus characteristics before treatment		Warfarin Arm [N=40]		Rivaroxaban Arm [N=40]		Apixaban Arm [N=40]		Test	p-value
		No.	%	No.	%	No.	%		
Size group	≤ 2 cm ²	16	40%	26	65%	13	32.5%	9.331 ^a	0.009
	> 2 cm ²	24	60%	14	35%	27	67.5%		
Size [cm²]	Mean ± SD	2.89±2.07		2.50±1.36		2.85±1.20		2.664 ^b	0.264
	Median	2.20		2.02		2.76			
Mobility									
Non-organized		37	92.5%	36	90%	38	95%	0.721 ^a	0.697
Organized		3	7.5%	4	10%	2	5%		

Table [4]: Comparison amongst the groups concerning thrombus characteristics after treatment

Thrombus characteristics after treatment		Warfarin group [N=40]		Rivaroxaban group [N=40]		Apixaban group [N=40]		Test	p-value [Sig.]
		No.	%	No.	%	No.	%		
Thrombus	Absent	35	87.5%	37	92.5%	34	85%	1.132 ^a	0.568
	Present	5	12.5%	3	7.5%	6	15%		
Size [cm²]	Mean ± SD	0.08±0.36		0 ± 0		0.05 ± 0.17		4.038 ^b	0.133
	Median	0 [0 – 2]		0 [0 – 0]		0 [0 – 0.75]			
Mobility									
Absent		35	87.5%	37	92.5%	34	85%	2.932 ^a	0.569
Non-organized		2	5%	0	0%	3	7.5%		
Organized		3	7.5%	3	7.5%	3	7.5%		

Table [5]: Comparison among the examined groups regarding outcome of treatment

Outcome of treatment		Warfarin group [N=40]		Rivaroxaban group [N=40]		Apixaban group [N=40]		Test	p-value
		No.	%	No.	%	No.	%		
Efficacy end point	Absent	5	12.5%	3	7.5%	6	15%	1.132 ^a	0.568
	Present	35	87.5%	37	92.5%	34	85%		
Thrombus persistence	Absent	35	87.5%	37	92.5%	34	85%	1.132 ^a	0.568
	Present	5	12.5%	3	7.5%	6	15%		
Stroke	Absent	40	100%	40	100%	39	97.5%	2.017 ^a	0.365
	Present	0	0%	0	0%	1	2.5%		
Systemic embolism	Absent	40	100%	40	100%	39	97.5%	2.017 ^a	0.365
	Present	0	0%	0	0%	1	2.5%		
Safety end point									
Absent		40	100%	40	100%	40	100%	0.000 ^a	1.000
Blood transfusion									
Absent		40	100%	40	100%	40	100%	0.000 ^a	1.000
Hemorrhagic stroke									
Absent		40	100%	40	100%	40	100%	0.000 ^a	1.000
Bleeding complications	Absent	40	100%	40	100%	38	95%	2.922 ^a	0.232
	Present	0	0%	0	0%	2	5%		
Systemic embolism	Absent	40	100%	40	100%	39	97.5%	2.017 ^a	0.365
	Present	0	0%	0	0%	1	2.5%		
Thrombus resolution	Absent	5	12.5%	3	7.5%	6	15%	1.132 ^a	0.568
	Present	35	87.5%	37	92.5%	34	85%		
All-cause mortality									
Alive		40	100%	40	100%	40	100%	0.000 ^a	1.000

DISCUSSION

To eliminate the contribution of any confounding factor that may affect the final outcome the current study enrolled three well-matched groups in baseline data, as no significant variations

were found among the groups in terms of demographics, baseline characteristics, comorbidities, or clinical outcomes. Our study in agreement with Alcalai *et al.* [10], who assessed apixaban against warfarin for the treatment of LV thrombus following MI, found similar

results in a trial with similar inclusion and exclusion criteria. The study enrolled seventeen individuals in the warfarin group and eighteen individuals in the apixaban group, and the two groups were well-matched for baseline characteristics. They reported that no significant was found among the two studied groups regarding demographics and comorbidities. Also, **Iqbal *et al.*** ^[11] enrolled 62 individuals in the VKA group and 22 participants in the DOAC group [which involves 13 individuals who were prescribed rivaroxaban, eight people who were prescribed apixaban, and one individual who was prescribed dabigatran]. The average age of the seventy-five patients was 62 ± 14 years. In 73 [87%] participants, LV impairment was a result of ischemic heart disease. At baseline, the groups shared comparable characteristics.

Also, comparison among the examined groups regarding specific cardiac characteristics, showed that heart Failure, IHD, CAD, MI, Type of MI, cardiac enzymes, atrial fibrillation and duration between symptom initiation and presentation were comparable among the studied groups. The present study consisted with **Alcalai *et al.*** ^[10], who revealed that no statistically significant difference was found among the two studied groups regarding prior IHD and CKD.

Regarding management beside the anti-coagulation medications among the studied groups, it was revealed that none of our patients were commenced on aspirin for one month. Clopidogrel was commenced for 82.5% of cases in the warfarin and rivaroxaban groups and for 87.5% in the apixaban group. In addition, cardiac catheter was needed for 65%, 67.5%, and 57.5% of cases in the same groups, respectively, while 10%, 15% and 10% of cases in the same groups received thrombolytic therapy. Management, beside anticoagulation, did not show statistical variation among the 3 groups [$p > 0.05$]. Similarly, **Daher *et al.*** ^[12] enrolled 42 in VKA group and 17 patients on rivaroxaban group, both groups were well-matched in baseline data. The study showed that 76 percent [12/17] of those administered DOACs and 71.4% [30/42] of those administered VKAs achieved thrombus resolution [$p = 0.9$].

Regarding the change in thrombus characteristics with treatment, the current study showed that most patients showed resolution of the thrombus, that occurred in 87.5% in the warfarin group, 92.5% in the rivaroxaban group, and 85% in the apixaban group. The resolution rate was statistically

comparable between the three treatment anti-coagulation approaches [$p = 0.357$]. The remaining patients showed either thrombus with a rim, or thrombus with a decreased size.

In addition, **Zhang *et al.*** ^[13] enrolled a total of 31 individuals in the VKA group and 33 individuals in the rivaroxaban group. The baseline data for both groups were comparable to one another. According to the study, there was not a significant variation in LVT resolution between rivaroxaban & VKA over the follow-up period [HR [log-rank test] 1.57 [95% CI 0.89–2.77], $p = 0.096$; Adjusted HR 1.70 [95% CI 0.89–3.22], $p = 0.104$]. Triple treatment with rivaroxaban showed significantly faster resolution than VKA [$p = 0.049$ at 6 months, $p = 0.044$ at 12 months, & $p = 0.045$ at 18 months]. In contrast, our results disagreed with **Iqbal *et al.*** ^[11] who revealed that there was not a significant distinction in the rate of thrombus resolution [76% vs 65%, $P = 0.33$].

Regarding outcomes, all patients were followed-up for three months after treatment and there may have been additional follow-up days beyond the initial 90-day period, possibly up to 20 days. Persistent thrombus was detected in 12.5, 7.5%, and 15% of cases in the warfarin, rivaroxaban, and apixaban groups, respectively. Stroke and systemic embolism occurred in only one case in the apixaban group. [2.5%]. Additionally, BC and SSE occurred in 5% and 2.5% of cases in the same group, respectively. The previously mentioned complications did not occur in the other two groups. No patients required blood transfusion, no mortality was encountered in the present research, and we showed that treatment outcome was comparable between the three study groups [$p > 0.05$].^[11]

Iqbal *et al.* ^[11] found that there were no significant variances amongst VKA & DOAC in terms of stroke [2% vs. 0%, $P = 0.55$], other thromboembolic events [2% vs. 0%, $P = 0.55$], or clinically severe bleeding [10% vs. 0%, $P = 0.13$] with a mean follow-up of 3.0 1.4 years. This finding agreed with the present study. The median time between cardiac imaging examinations was 233 ± 251 days, and there was no significant disparity among groups [$P = 0.83$]. Rehospitalization [50 % versus 45 %; $P = 0.53$] and all-cause mortality [10 % versus 14 %; $P = 0.61$] were also comparable. Furthermore, **Bass *et al.*** ^[14] demonstrated that there was no substantial variation observed among the two therapies in terms of new onset thromboembolic stroke

[DOAC: 7.8% vs warfarin: 11.7%, $p = 0.13$]. There was no significant distinction observed in the composite of thromboembolic events [33% vs 30.6%, $p = 0.53$] or in bleeding [10.9% vs 7.8%, $p = 0.40$] when comparing warfarin to the alternative treatment. A higher proportion of patients using warfarin were administered blood products in comparison to those taking a direct oral anticoagulant [25.8% vs 13.9%, $p < 0.001$].

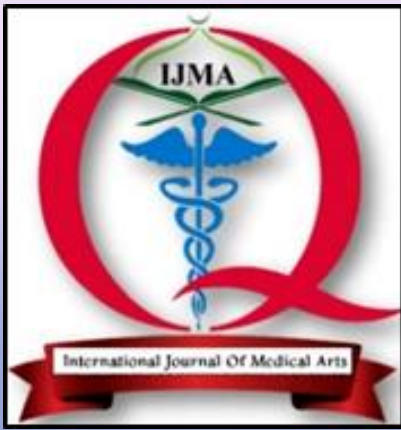
Limitation of the study: The current study was limited by small sample size, being a single center study and relatively short follow up period. Further comparative studies with larger sample size and longer follow-up are needed to confirm our results and to identify risk factors of adverse events.

Conclusion: DOACs [Rivaroxaban and Apixaban] and VKA [warfarin] have similar efficacy and safety in treating left ventricular thrombus. The study showed that DOACs are a convenient alternative to warfarin and have been demonstrated to be efficacious and safe in other indications. Our data show similar rates of LV thrombus persistence, stroke, or systemic embolism as well as hemorrhagic stroke or bleeding requiring transfusion in patients treated with a DOAC as compared with warfarin. In terms of patient satisfaction and adherence, DOACs may be an optimal alternative to VKAs as they have a fast onset of action, a stable drug concentration, no requirement to determine the INR, fewer interactions, and a lower rate of bleeding events.

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