

## COMPARATIVE EFFICACY OF DIRECT ORAL ANTICOAGULANTS VS. WARFARIN IN ATRIAL FIBRILLATION: A REAL-WORLD COHORT STUDY

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### Abstract

**Background:** Atrial fibrillation (AF) is a major risk factor for thromboembolic events, necessitating long-term anticoagulation. Warfarin has been the conventional treatment; however, direct oral anticoagulants (DOACs) have emerged as alternatives due to their predictable pharmacokinetics and lower monitoring requirements. While randomized controlled trials have demonstrated the efficacy of DOACs, real-world data comparing them with warfarin in routine clinical practice remain limited, particularly in diverse patient populations. This study aims to evaluate the comparative efficacy and safety of DOACs versus warfarin in patients with AF using real-world data. This study aims to compare the efficacy and safety of direct oral anticoagulants (DOACs) and warfarin in patients with atrial fibrillation by assessing thromboembolic event rates, major bleeding complications, and overall mortality. The study also evaluates the adherence and persistence rates of both anticoagulant therapies in a real-world cohort. **Materials and Methods:** A retrospective cohort study was conducted at a tertiary care hospital, including 100 patients diagnosed with atrial fibrillation who received either DOACs or warfarin. Patients were categorized into two groups based on anticoagulation therapy. Clinical outcomes, including thromboembolic events, major bleeding, and mortality, were assessed over a follow-up period of 12 months. Data were extracted from electronic medical records and analyzed using Kaplan-Meier survival curves and Cox proportional hazards models to determine the risk of adverse events associated with each anticoagulant. Statistical significance was set at  $p < 0.05$ . **Result:** Among 100 patients, 52 received DOACs and 48 were on warfarin. The incidence of thromboembolic events was lower in the DOAC group (5.8%) compared to the warfarin group (12.5%). Major bleeding complications occurred in 3.8% of DOAC users and 10.4% of warfarin users, demonstrating a statistically significant reduction in bleeding risk with DOACs ( $p = 0.03$ ). Overall mortality rates were also lower in the DOAC group (3.8%) compared to the warfarin group (8.3%), though this difference did not reach statistical significance ( $p = 0.08$ ). Medication adherence was higher in the DOAC cohort (78%) compared to warfarin users (62%), reflecting a potential advantage in long-term treatment persistence. **Conclusion:** This real-world cohort study demonstrates that DOACs are associated with lower thromboembolic and bleeding risks compared to warfarin in patients with atrial fibrillation. While mortality differences were not statistically significant, the improved safety profile and adherence rates suggest that DOACs may offer a favorable alternative to warfarin for stroke prevention in AF. These findings reinforce the growing preference for DOACs in clinical practice, although further large-scale studies are warranted to confirm long-term benefits.

## INTRODUCTION

Atrial fibrillation (AF) is the most prevalent sustained cardiac arrhythmia, affecting millions of individuals worldwide and contributing significantly to

morbidity and mortality. The condition is associated with a fivefold increase in the risk of ischemic stroke, making anticoagulation therapy a cornerstone of stroke prevention in patients with AF.<sup>[1]</sup> Left untreated or inadequately managed, AF can lead to severe thromboembolic complications, including

transient ischemic attacks (TIA), systemic embolism, and cardiovascular mortality. The choice of anticoagulation therapy remains a crucial decision in clinical practice, balancing the benefits of stroke prevention against the risk of bleeding complications.<sup>[2]</sup>

For decades, vitamin K antagonists (VKAs), particularly warfarin, have been the standard of care for anticoagulation in AF. Warfarin has demonstrated efficacy in reducing stroke risk by nearly 60%; however, its clinical use is challenged by several limitations, including a narrow therapeutic index, the need for frequent monitoring of the international normalized ratio (INR), and numerous drug and dietary interactions.<sup>[3]</sup> Maintaining optimal INR levels (typically between 2.0 and 3.0) is often difficult, leading to suboptimal anticoagulation, either increasing the risk of stroke (when INR is too low) or predisposing patients to bleeding complications (when INR is too high). These challenges have driven the search for alternative anticoagulant therapies with improved safety and ease of use.<sup>[4]</sup>

Direct oral anticoagulants (DOACs) have emerged as a preferred alternative to warfarin for stroke prevention in non-valvular atrial fibrillation (NVAF). This class of anticoagulants includes direct thrombin inhibitors (dabigatran) and factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban), which provide more predictable pharmacokinetics, fewer drug interactions, and do not require routine INR monitoring.<sup>[5]</sup> Several landmark randomized controlled trials (RCTs) have established the efficacy and safety of DOACs. The RE-LY trial demonstrated that dabigatran was non-inferior to warfarin for stroke prevention while significantly reducing the risk of intracranial hemorrhage. The ROCKET AF trial showed that rivaroxaban was comparable to warfarin in preventing thromboembolic events, with a similar bleeding risk. The ARISTOTLE and ENGAGE AF-TIMI 48 trials further reinforced the role of apixaban and edoxaban, respectively, as effective alternatives to warfarin with a lower risk of major bleeding.<sup>[6]</sup>

While these RCTs provide strong evidence for DOAC use, they are conducted under controlled conditions with strict inclusion criteria, potentially limiting their applicability to real-world clinical practice. Real-world data, derived from diverse patient populations with varying comorbidities, medication adherence patterns, and healthcare accessibility, offer crucial insights into the practical benefits and challenges of DOAC therapy compared to warfarin.<sup>[7]</sup> Several observational cohort studies and meta-analyses suggest that DOACs are associated with lower rates of ischemic stroke, intracranial hemorrhage, and major bleeding events compared to warfarin in routine clinical settings. However, variability in patient adherence, renal function considerations, and cost-related factors continue to influence treatment decisions.<sup>[8]</sup>

Given these factors, further research is necessary to evaluate the comparative efficacy and safety of DOACs versus warfarin in real-world settings. This study aims to assess thromboembolic event rates, major bleeding risks, and overall mortality in patients with AF receiving either DOACs or warfarin in a tertiary care hospital. By analyzing real-world clinical outcomes, this study seeks to provide evidence supporting optimal anticoagulation strategies, thereby aiding clinicians in making informed therapeutic decisions for patients with atrial fibrillation.

## MATERIALS AND METHODS

This retrospective cohort study was conducted at a tertiary care hospital to evaluate the comparative efficacy and safety of direct oral anticoagulants (DOACs) and warfarin in patients with atrial fibrillation (AF). The study population included adult patients diagnosed with non-valvular atrial fibrillation (NVAF) who were initiated on either DOACs or warfarin for stroke prevention. Patient data were retrieved from electronic medical records (EMRs) over a defined study period, ensuring a minimum follow-up duration of 12 months to assess clinical outcomes. The study included patients aged 18 years or older with a confirmed diagnosis of AF based on electrocardiographic (ECG) or Holter monitoring findings, who had received at least three months of continuous anticoagulation therapy. Patients with valvular atrial fibrillation, those with mechanical prosthetic heart valves, severe renal impairment (creatinine clearance <15 mL/min), significant hepatic dysfunction, or those with a history of major bleeding disorders were excluded from the analysis.

Patients were categorized into two groups based on the anticoagulant prescribed: the DOAC group (receiving dabigatran, rivaroxaban, apixaban, or edoxaban) and the warfarin group. The choice of anticoagulant was determined by the treating physician based on patient characteristics, comorbid conditions, renal function, and drug availability. Baseline demographic and clinical characteristics, including age, sex, body mass index (BMI), comorbidities (hypertension, diabetes mellitus, prior stroke or transient ischemic attack, coronary artery disease, heart failure), CHA<sub>2</sub>DS<sub>2</sub>-VASc score, HAS-BLED score, renal function parameters, and concomitant medication use, were collected. The primary outcome of interest was the incidence of thromboembolic events, including ischemic stroke and systemic embolism, occurring during the follow-up period. Secondary outcomes included major bleeding events, defined according to the International Society on Thrombosis and Haemostasis (ISTH) criteria, which encompassed fatal bleeding, symptomatic bleeding in a critical organ (intracranial, gastrointestinal, or intra-articular hemorrhage), and bleeding leading to a decrease in hemoglobin of  $\geq 2$  g/dL or requiring transfusion of  $\geq 2$

units of packed red blood cells. Additional outcomes assessed included overall mortality and treatment adherence, measured by prescription refill records and patient-reported compliance.

Patients on warfarin underwent regular INR monitoring, with therapeutic INR levels maintained between 2.0 and 3.0. Time in therapeutic range (TTR) was calculated for warfarin users to assess the quality of anticoagulation control. For DOAC users, appropriate dosing was confirmed based on renal function, age, and body weight, following standard prescribing guidelines. Data collection was performed using a structured case record form, ensuring uniformity and completeness of clinical documentation. Statistical analyses were conducted using SPSS software, with continuous variables expressed as mean  $\pm$  standard deviation (SD) and categorical variables as frequencies and percentages. Between-group comparisons were performed using the independent t-test or Mann-Whitney U test for continuous variables and the chi-square or Fisher's exact test for categorical variables. Kaplan-Meier survival curves were generated to evaluate event-free survival for thromboembolic events and major bleeding, with Cox proportional hazards models used to determine the hazard ratios (HR) and 95% confidence intervals (CI) for adverse outcomes. A p-value of  $<0.05$  was considered statistically significant.

This study was conducted in accordance with ethical principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethics Committee. As this was a retrospective analysis of anonymized

data, informed consent was waived. Patient confidentiality was maintained by de-identifying records before data extraction and analysis. The findings of this study are intended to provide real-world insights into the comparative effectiveness and safety of DOACs versus warfarin, aiding clinicians in optimizing anticoagulation strategies for patients with AF.

## RESULTS

In this study, a total of 100 patients diagnosed with atrial fibrillation (AF) were analyzed, with 52 receiving direct oral anticoagulants (DOACs) and 48 treated with warfarin. The mean age of the study population was  $67.4 \pm 9.2$  years, with a male predominance (58%). Baseline characteristics, including CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores, were comparable between the two groups. The primary outcome of thromboembolic events was lower in the DOAC group (5.8%) compared to the warfarin group (12.5%), indicating a favorable trend toward reduced stroke risk. Similarly, major bleeding complications were significantly lower in DOAC users (3.8%) versus warfarin users (10.4%), with a p-value of 0.03. Mortality rates were also lower in the DOAC group (3.8%) than in the warfarin group (8.3%), though the difference did not reach statistical significance ( $p = 0.08$ ). Treatment adherence was notably higher in the DOAC cohort (78%) compared to warfarin users (62%), suggesting improved compliance with DOAC therapy.

**Table 1: Baseline Characteristics of Study Population**

Variable	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Age (years, mean $\pm$ SD)	66.8 $\pm$ 8.7	68.1 $\pm$ 9.6	0.42
Male, n (%)	31 (59.6%)	27 (56.3%)	0.72
BMI (kg/m <sup>2</sup> , mean $\pm$ SD)	25.3 $\pm$ 3.4	24.9 $\pm$ 3.7	0.58
Hypertension, n (%)	34 (65.4%)	31 (64.6%)	0.93
Diabetes Mellitus, n (%)	21 (40.4%)	19 (39.6%)	0.92
Prior Stroke/TIA, n (%)	10 (19.2%)	11 (22.9%)	0.64
Coronary Artery Disease, n (%)	15 (28.8%)	14 (29.2%)	0.96
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score (mean $\pm$ SD)	3.6 $\pm$ 1.2	3.8 $\pm$ 1.3	0.38
HAS-BLED Score (mean $\pm$ SD)	2.1 $\pm$ 0.9	2.3 $\pm$ 1.0	0.44

This table presents the demographic and clinical baseline characteristics of the study population. The mean age was comparable between the DOAC and warfarin groups, with no significant difference ( $p = 0.42$ ). Hypertension and diabetes mellitus were the most common comorbidities, affecting approximately two-thirds and one-third of the

participants, respectively. Prior stroke or transient ischemic attack (TIA) was slightly more prevalent in the warfarin group, though not statistically significant ( $p = 0.64$ ). CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores, which assess thromboembolic risk and bleeding propensity, were similar across both cohorts, ensuring comparability of the study groups.

**Table 2: Anticoagulation Therapy and Monitoring**

Variable	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Dabigatran, n (%)	12 (23.1%)	—	—
Rivaroxaban, n (%)	18 (34.6%)	—	—
Apixaban, n (%)	20 (38.5%)	—	—
Edoxaban, n (%)	2 (3.8%)	—	—
Mean Time in Therapeutic Range (TTR, %)	—	56.2 $\pm$ 11.8	—

This table outlines the anticoagulation regimens and INR control in the study groups. The majority of DOAC users were prescribed apixaban (38.5%) and rivaroxaban (34.6%), while warfarin users had an average time in therapeutic range (TTR) of 56.2%, indicating suboptimal anticoagulation control.

**Table 3: Thromboembolic Events During Follow-up**

Outcome	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Ischemic Stroke, n (%)	3 (5.8%)	6 (12.5%)	0.11
Systemic Embolism, n (%)	1 (1.9%)	3 (6.3%)	0.19
Composite Thromboembolic Events, n (%)	4 (7.7%)	9 (18.8%)	0.06

This table presents the incidence of thromboembolic complications. The overall risk of ischemic stroke was lower in the DOAC group (5.8%) compared to the warfarin group (12.5%), though statistical significance was not reached (p = 0.11).

**Table 4: Major Bleeding Events**

Bleeding Event	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Intracranial Hemorrhage, n (%)	1 (1.9%)	5 (10.4%)	0.04
Gastrointestinal Bleeding, n (%)	2 (3.8%)	3 (6.3%)	0.57
Other Major Bleeding, n (%)	1 (1.9%)	2 (4.2%)	0.51
Composite Major Bleeding, n (%)	2 (3.8%)	5 (10.4%)	0.03

The incidence of major bleeding was significantly lower in the DOAC group (3.8%) compared to the warfarin group (10.4%) (p = 0.03), primarily driven by a reduced rate of intracranial hemorrhage.

**Table 5: Mortality Outcomes**

Mortality Outcome	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
All-Cause Mortality, n (%)	2 (3.8%)	4 (8.3%)	0.08
Cardiovascular Mortality, n (%)	1 (1.9%)	3 (6.3%)	0.12

The mortality rate was lower in the DOAC group (3.8%) compared to the warfarin group (8.3%), though the difference was not statistically significant (p = 0.08).

**Table 6: Treatment Adherence and Persistence**

Adherence Outcome	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Adherence Rate (>80% compliance), n (%)	41 (78.8%)	30 (62.5%)	0.02
Discontinuation Due to Adverse Effects, n (%)	3 (5.8%)	5 (10.4%)	0.31

Treatment adherence was significantly higher in the DOAC group (78%) compared to warfarin users (62%) (p = 0.02), reflecting better compliance with DOAC therapy.

**Table 7: Renal Function and Dose Adjustments**

Variable	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Mean eGFR (mL/min), mean ± SD	68.5 ± 12.6	67.1 ± 13.2	0.58
Renal Dose Adjustment Required, n (%)	8 (15.4%)	7 (14.6%)	0.89

Renal function and appropriate dose modifications were comparable across groups. Patients with moderate renal impairment (eGFR 30-50 mL/min) were appropriately dose-adjusted for DOACs.

**Table 8: Subgroup Analysis by Age**

Age Group	Major Bleeding (DOAC)	Major Bleeding (Warfarin)	p-value
<65 years (n = 34)	1 (2.9%)	2 (6.7%)	0.44
65-75 years (n = 38)	1 (2.8%)	3 (9.7%)	0.18
>75 years (n = 28)	2 (7.7%)	6 (23.1%)	0.02

DOACs demonstrated a more favorable safety profile in elderly patients (>75 years), with a significantly lower bleeding risk compared to warfarin (p = 0.02).

**Table 9: Time to First Event (Kaplan-Meier Analysis)**

Outcome	Median Time to Event (Days)	HR (95% CI)	p-value
Ischemic Stroke	180 vs. 135	0.72 (0.45-1.16)	0.14
Major Bleeding	220 vs. 160	0.65 (0.38-1.12)	0.08

Kaplan-Meier survival analysis showed a trend towards longer event-free survival in the DOAC group, though statistical significance was not reached.

**Table 10: Composite Outcome (Efficacy and Safety Endpoint)**

Composite Outcome	DOAC Group (n = 52)	Warfarin Group (n = 48)	p-value
Stroke + Major Bleeding, n (%)	5 (9.6%)	12 (25%)	0.04

The composite outcome of thromboembolic and major bleeding events favored DOACs, with a significantly lower risk compared to warfarin ( $p = 0.04$ ).

### Summary

The results of this study indicate that DOACs offer a significant reduction in major bleeding complications while maintaining comparable efficacy in preventing thromboembolic events. The overall mortality rate was lower with DOACs, and adherence was significantly better compared to warfarin users. Subgroup analysis suggests a particularly favorable safety profile for DOACs in elderly patients. Kaplan-Meier analysis indicated longer event-free survival in DOAC users, though statistical significance was not reached. These findings align with existing literature supporting the preferential use of DOACs over warfarin in real-world settings.

## DISCUSSION

The findings of this study suggest that direct oral anticoagulants (DOACs) provide superior safety and comparable efficacy compared to warfarin in patients with atrial fibrillation (AF). The lower incidence of thromboembolic events and major bleeding in the DOAC group aligns with prior randomized controlled trials such as RE-LY, ROCKET AF, ARISTOTLE, and ENGAGE AF-TIMI 48, which demonstrated the non-inferiority or superiority of DOACs in stroke prevention while reducing major bleeding complications.<sup>[9]</sup>

A key observation in this study was the significantly lower incidence of major bleeding in DOAC users (3.8%) compared to warfarin users (10.4%), particularly with regard to intracranial hemorrhage (1.9% vs. 10.4%,  $p = 0.04$ ). This supports the existing evidence that DOACs, due to their predictable pharmacokinetics and reduced dependency on vitamin K metabolism, offer a safer profile, especially in elderly patients. The thromboembolic event rate was also lower in the DOAC group (5.8%) compared to warfarin (12.5%), though statistical significance was not reached ( $p = 0.11$ ). This suggests that while both drug classes are effective in preventing strokes, DOACs provide a more stable anticoagulation effect with fewer fluctuations.<sup>[10]</sup>

Treatment adherence was notably higher in DOAC users (78.8%) versus warfarin users (62.5%), which is likely due to the ease of use, fewer dietary restrictions, and the absence of routine INR monitoring requirements. Additionally, warfarin users demonstrated suboptimal anticoagulation control, with a mean time in therapeutic range (TTR) of only 56.2%, which is below the recommended target for optimal stroke prevention. These findings highlight one of the primary challenges in managing warfarin therapy in real-world settings.<sup>[11]</sup>

Subgroup analysis by age revealed that major bleeding rates were significantly lower in elderly

DOAC users (>75 years) compared to warfarin users (7.7% vs. 23.1%,  $p = 0.02$ ). This suggests that DOACs are particularly beneficial for older patients, who are at increased risk of anticoagulation-related bleeding. Kaplan-Meier analysis demonstrated a trend toward longer event-free survival in the DOAC group, though statistical significance was not reached. However, the composite endpoint of thromboembolic and major bleeding events strongly favored DOACs (9.6% vs. 25%,  $p = 0.04$ ), reinforcing their real-world advantages over warfarin.<sup>[12,13]</sup>

This study has several strengths, including its real-world design, which provides practical insights into the effectiveness and safety of DOACs outside of controlled clinical trial settings. However, the study is limited by its relatively small sample size and observational nature, which introduces the possibility of selection bias. Additionally, the lack of long-term follow-up data restricts the ability to assess whether these benefits persist over extended periods.<sup>[14]</sup>

Future research should focus on larger, multi-center studies with extended follow-up periods to further validate these findings and explore the potential long-term mortality benefits of DOAC therapy.<sup>[15]</sup>

## CONCLUSION

This real-world cohort study demonstrates that direct oral anticoagulants (DOACs) offer a significant safety advantage over warfarin in patients with atrial fibrillation, particularly in reducing the risk of major bleeding, including intracranial hemorrhage. While both DOACs and warfarin were effective in preventing thromboembolic events, the lower stroke incidence in the DOAC group, combined with superior treatment adherence and fewer monitoring requirements, highlights their practical benefits in routine clinical practice. Additionally, DOACs were particularly beneficial in elderly patients, who exhibited a significantly lower risk of major bleeding compared to warfarin users.

Despite the encouraging findings, the study is limited by its observational nature and relatively small sample size. Further large-scale, multi-center studies with long-term follow-up are needed to confirm these real-world benefits and assess potential mortality advantages. Nevertheless, the results support the growing preference for DOACs as first-line anticoagulation therapy for stroke prevention in atrial fibrillation, reinforcing their role in evidence-based clinical decision-making.

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