EFFICACY AND SAFETY OF NEWER ANTICOAGULANTS AMONG THE PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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ABSTRACT

Background: The use of Direct Oral Anticoagulants (DOACs) has increased in recent decades for non-valvular atrial fibrillation due to their improved safety and efficacy profiles. These agents have demonstrated comparable or superior efficacy and safety profiles compared to VKAs, particularly with a lower incidence of major bleeding events.
Aim: To compare the efficacy and safety of newer anticoagulants among the patients with non-valvular atrial fibrillation.
Methodology: An prospective observational study was conducted over 6 months at the cardiology department of KG Hospital. A total of 75 prescriptions were screened, and 50 patients were included: 22 received apixaban, 19 received rivaroxaban, and 9 received dabigatran.
Result: Apixaban, rivaroxaban, and dabigatran were prescribed to 44%, 38%, and 18% of patients, respectively. Hazardous event rates: apixaban (1.136), rivaroxaban (1.842), dabigatran (1.778). Hazard ratios (HR): apixaban vs rivaroxaban = 0.62 [95% CI]; dabigatran vs rivaroxaban = 0.97 [95% CI]; apixaban vs dabigatran = 0.64 [95% CI].
Conclusion: Apixaban demonstrated lower hazard and higher efficacy compared to the other two drugs. Rivaroxaban and dabigatran showed similar profiles. The study concludes that apixaban may offer the most favorable safety-efficacy balance among the evaluated DOACs.

Keywords: anticoagulants, apixaban, rivaroxaban, dabigatran, non-valvular atrial fibrillation, hazard ratio

INTRODUCTION:

Atrial fibrillation (AF) is a common cardiac arrhythmia characterized by irregular and frequently rapid heartbeats, which can significantly increase the risk of complications such as stroke and heart failure. A major subtype, non-valvular atrial fibrillation (NVAF), refers to AF that occurs in the absence of rheumatic mitral valve disease or prosthetic heart valves.

Management of NVAF primarily involves anticoagulant therapy to mitigate the risk of thromboembolic events, particularly stroke.

Oral anticoagulants fall into two main categories: vitamin K antagonists (VKAs), such as warfarin, and direct oral anticoagulants (DOACs). DOACs—including apixaban, rivaroxaban, dabigatran, and edoxaban—have been increasingly favored in clinical practice over the past decade due to their predictable pharmacokinetics and reduced need for routine monitoring. Apixaban, a factor Xa inhibitor, was approved in December 2012; rivaroxaban, another factor Xa inhibitor, entered the market in October 2011; and dabigatran, a direct thrombin inhibitor, was introduced in December 2010. These agents have demonstrated comparable or superior efficacy and safety profiles compared to VKAs, particularly with a lower incidence of major bleeding events.

AIM:

To compare the efficacy and safety of newer anticoagulants among the patients with non-valvular atrial fibrillation.

Objectives:

1. The objective of this study is to compare the hazard ratios of Apixaban, Rivaroxaban, and Dabigatran in terms of both safety and effectiveness.
2. This analysis was conducted using real-time data from a population treated with standard therapeutic dosages.

METHODOLOGY:

The Prospective observational study was conducted at K.G. Hospital and Postgraduate Institute for period of 6 months. The study protocol was approved by the Institutional Ethics Committee (No:……) , The data collection form was administered and the data were collected. SPSS software was used for statistical analysis.

Study Criteria:

Inclusion criteria:

1. The patients with age of above 18 years and below 80 years
2. The patient with stroke and heart failure
3. The patient taking the drugs like direct oral anticoagulants

Exclusion Criteria:

1. The patient with were on dual anticoagulant therapy.
2. The patient who are not willing to participate in the study.
3. The patient with pregnant or breastfeeding

RESULTS

A total of 60 study population, majority of patients were male 53% (n=26) and female were 47% (n=34) which was shown in Figure 1.

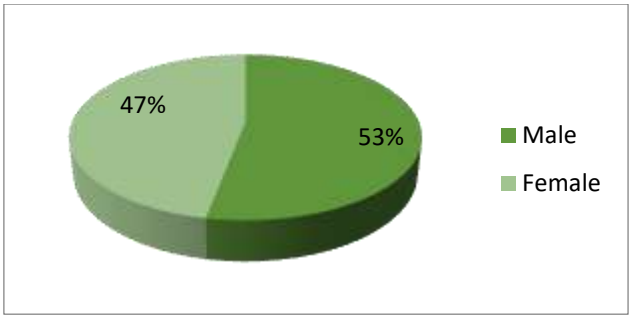


Figure 1: Gender distribution of study population

The age distribution of the study patient was analysed and found that, 70% of patients under the age group of 46 – 55 years, 15% were under the age group of 56 – 80 years. Only 7% were under 18 – 25 years of age group. It was shown in figure 2.

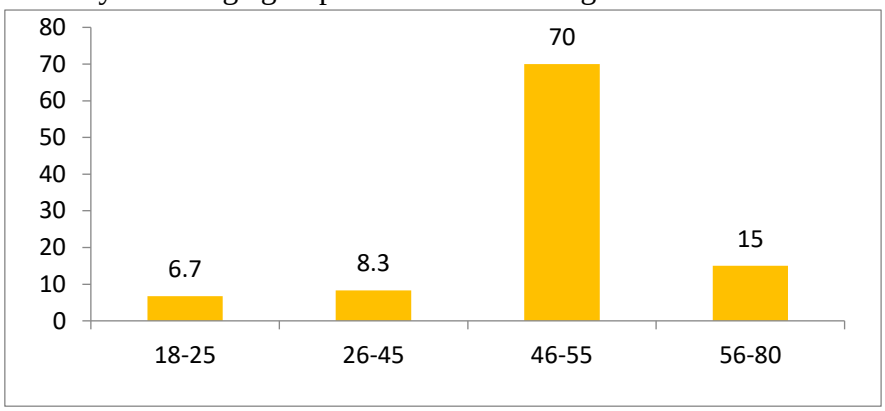


Figure 2: Age distribution of study population

The prevalence of comorbidity among the study population was assessed and found that, 53.3% patients were having Previous stroke, 20% of patients were under diabetes, 13.3% were under congestive heart failure. 6.7% of patient have hypertension. It was shown in figure 3.

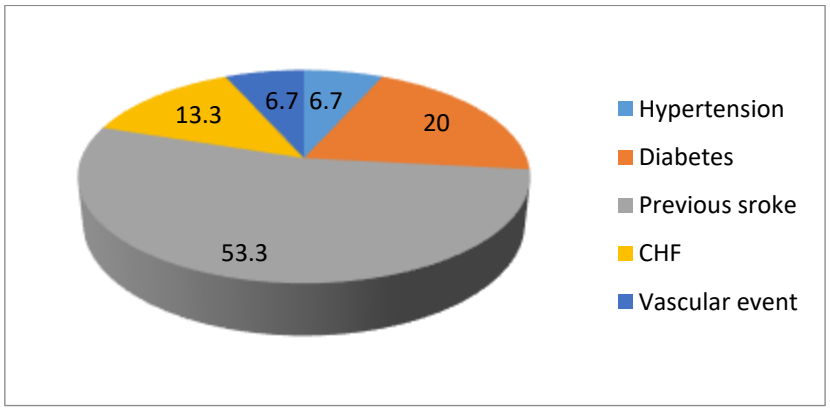


Figure 3: Comorbidities among the study population

The prescription pattern of Direct Oral Anticoagulants (DOACs) drugs were analysed and found that, The drug Apixaban was prescribed in 36.6%, Rivaroxaban was prescribed in 31.6% and Dabigatran was prescribed in 31.6%. It was given in figure 4.

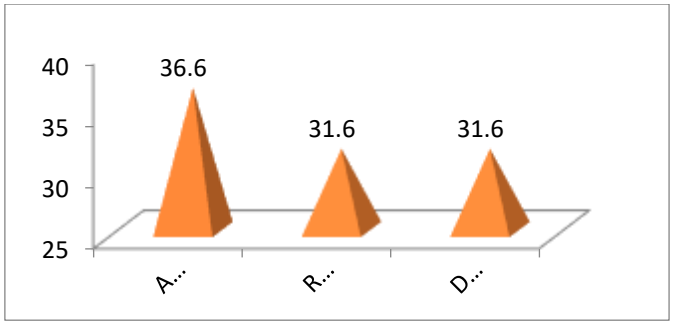


Figure 4: Prescription pattern of drugs study population

The effectiveness of drugs before and after the treatment was analysed and found that, Apixaban group patient were have a chance of 28.3% of high risk to get stroke. After treatment having chance of only 3.3% of chance to get stroke. It was given in table 1.

Table 1: The effectiveness of drugs after the treatment

Score	Before treatment			After treatment		
	Apixaban -Group-1	Rivaroxaban -Group-2	Dabigatran -Group-3	Apixaban -Group-1	Rivaroxaban -Group-2	Dabigatran -Group-3
0-1(Low)	3.3	6.7	10	21.6	20	23.3
1-2(Moderate)	5	8.3	6.7	11.6	6.7	5
>2(High)	28.3	16.6	15	3.3	5	3.3

These values are again analysed for stroke assessment using the CHADS2VASc score. The score shows 0-1 as lowest risk of stroke and equal to or greater than 2 shows higher risk of stroke according to the value. The score is clinical tool to identify the risk of stroke in atrial fibrillation patients. The score marked from 0 to10. It was shown in figure 5.

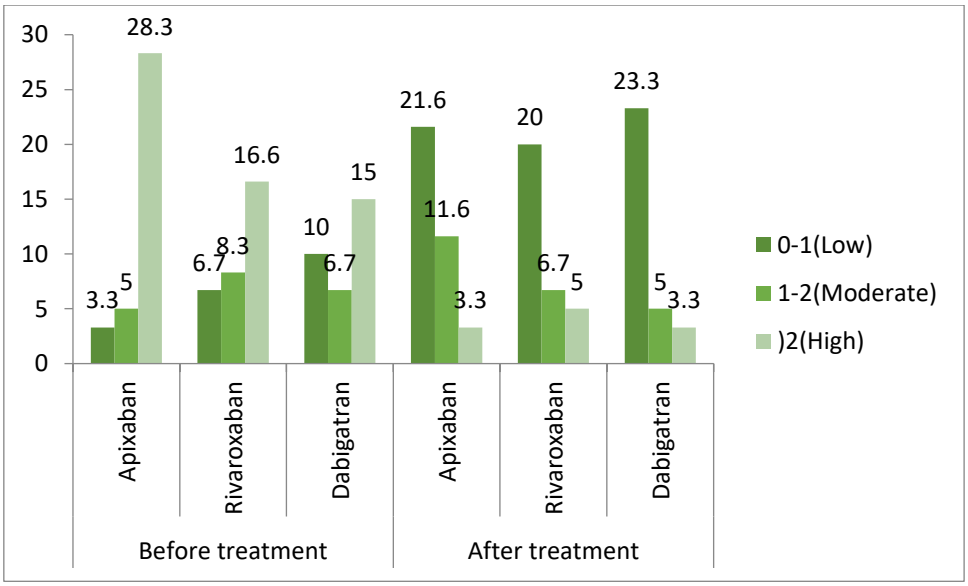
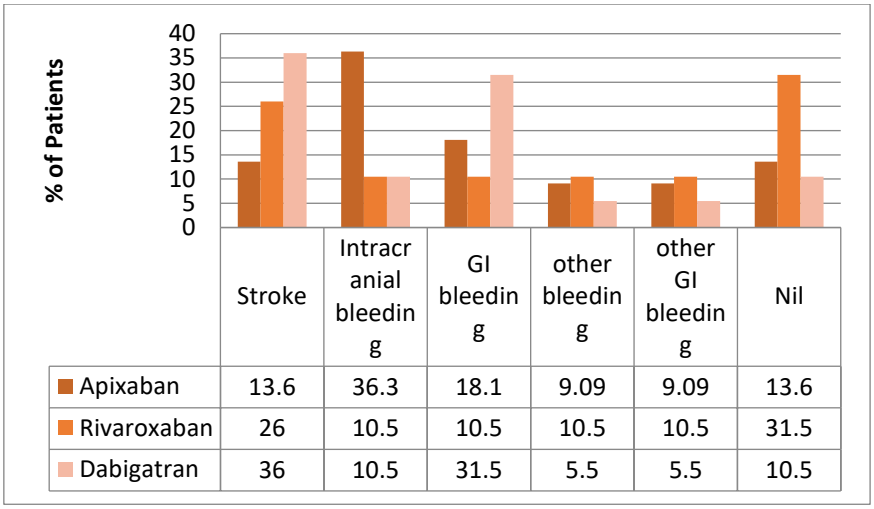


Figure 5: Effectiveness of drugs among study population

The hazard event such as stroke event, intracranial bleeding event, gastrointestinal bleeding and other GI related complaints and other major bleedings are noted through the review with the patients during the follow-up. Some cases needed hospitalisation, some cases can be

treated with OTC medications and in some cases it may be self-curable. These data are manually collected by investigator, through questionnaire-based. The result was shown in figure 6.



	Stroke	Intracranial bleeding	GI bleeding	other bleeding	other GI bleeding	Nil
Apixaban	13.6	36.3	18.1	9.09	9.09	13.6
Rivaroxaban	26	10.5	10.5	10.5	10.5	31.5
Dabigatran	36	10.5	31.5	5.5	5.5	10.5

Figure 6: Risk factors of drugs in study population

The Apixaban group patient was have a chance of 13.6 % of risk to stroke. But, Apixaban group have chance of 26% followed by Rivaroxaban group have chance of 36%. Hence, the drug Apixaban is effective drug for the patients with non-valvular atrial fibrillation.

CONCLUSION:

Based on the findings, apixaban is associated with higher safety and efficacy compared to the other two direct oral anticoagulants. Its use and patient adherence are also notably higher in clinical practice. Therefore, based on both safety and efficacy profiles, apixaban is recommended as the preferred choice over rivaroxaban and dabigatran in the management of non-valvular atrial fibrillation.

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CONFLICTS OF INTEREST: None

REFERENCES:

1. Markides V, Schilling RJ.; Atrial fibrillation: classification, pathophysiology, mechanisms and drug treatment. Heart. 2003; 89(8):939-43.
2. Amin A, Houmsse A, Ishola A, Tyler J, Houmsse M. The current approach of atrial fibrillation management. Avicenna J Med.; 2016; 6(1): 8-16.
3. McManus DD, Rienstra M, Benjamin EJ. An update on the prognosis of patients with atrial fibrillation. Circulation. 2012 ; 126(10): 143-6.
4. Mohanty S, Trivedi C, Gianni C, Natale A.; Gender specific considerations in atrial fibrillation treatment: a review. Expert Opin Pharmacother. 2018; 19(4): 365-374.

5. Peters SAE, Woodward M.; Established and novel risk factors for atrial fibrillation in women compared with men.; Heart.; 2019 ;105(3):226-234.
6. Choi YJ, Choi EK, Han KD, Jung JH, Park J, Lee E, Choe W, Lee SR, Cha MJ, Lim WH, Oh S. Temporal trends of the prevalence and incidence of atrial fibrillation and stroke among Asian patients with hypertrophic cardiomyopathy: A nationwide population-based study. Int J Cardiol.; 2018; 273: 130-135.
7. Laäs DJ, Naidoo M.; Oral anticoagulants and atrial fibrillation: A South African perspective. S Afr Med J. 2018; 108(8):640-646.
8. Wolf PA, Abbott RD, Kannel WB.; Atrial fibrillation as an independentrisk factor for stroke: the Framingham study. Stroke. 1991;22:983–988.
9. Chen RL, Balami JS, Esiri MM, et al. Ischemic stroke in the elderly: an overview of evidence. Nat Rev Neurol. 2010;6(5):256-265.