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A PROSPECTIVE AND RETROSPECTIVE STUDY ON SAFETY AND CLINICAL OUTCOMES OF NOVEL ORAL ANTICOAGULANT (NOAC) DRUGS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Introduction: Anticoagulants are highly effective in preventing thromboembolic events but are often used cautiously in clinical practice, sometimes leading to undertreatment despite a lower burden of certain risk factors. In this context, assessing the safety and clinical outcomes of NOAC therapy using real-world data, alongside clinical trials is essential to support informed clinical decision-making. **Materials and Methods:** This is a prospective and Retrospective (Ambispective) observational cohort study conducted over a period of six months in a tertiary care hospital setting. Data collection was performed using the electronic medical record system. All the data collected were analyzed based on the standard protocol. **Results:** The safety and clinical outcome parameters include mortality rate, which was found to be 1.7%, liver dysfunction which was seen 28.3% of patients and renal dysfunction which was seen in 24.16% all points toward a favorable safety profile of NOACs. HAS BLED Score, which assesses the risk for major bleeding was found to have been 0-1 in 18.3% patients 2 in 18.3% patients and 3or >3 in 63.3% patients. **Conclusion:** This study found that, in a real-world population of patients requiring NOAC therapy, treatment was associated with a favorable safety profile and excellent clinical outcomes. Conducted as both a prospective and retrospective observational study in a tertiary care hospital in Kannur, Kerala, it highlights the long-term performance of these medications in real-life clinical settings.

KEYWORDS: NOAC; Safety; Clinical Outcomes.

INTRODUCTION

Warfarin is unquestionably an effective anticoagulant treatment, but its use carries a very high risk of bleeding, necessitating strict dietary, alcohol, and co-medication control as well as frequent, sometimes fierce monitoring of coagulation parameters. Despite this, warfarin therapy continues to present challenges, particularly for older adults due to polypharmacy, drug non-adherence, and falls. The alternate strategy is aspirin, whose effectiveness is questionable until taken in conjunction with clopidogrel; nonetheless, the risk of bleeding when using aspirin alone is not insignificant and is significant when used in conjunction with clopidogrel. Consequently, the use of anticoagulant/antithrombotic medication has been uneven and frequently incorrect, and neither doctors nor patients have been confident in it.[1]

These established limitations have prompted the creation of non–vitamin K antagonist oral anticoagulants (NOACs), comprising four medications, among which Dabigatran, a direct thrombin inhibitor, was the first to receive FDA approval in 2010.[2] It prevents fibrinogen division, thrombin-triggered platelet aggregation, and the activation of XI, XIII, V and VIII factors among other thrombin-mediated actions. Dabigatran is a powerful, non-peptide, synthetic thrombin inhibitor that is reversible. Thrombin inhibition prevents the formation of thrombus by reducing fibrin production and thrombin-mediated platelet aggregation.[3] It is available as Dabigatran etexilate and is transformed to Dabigatran by serum Esterase.[4] Direct factor Xa inhibitors, such as rivaroxaban, edoxaban and apixaban were authorized in 2011, 2015, and 2014 respectively.[2] These medications prevent prothrombin from becoming transformed into thrombin by directly attaching to the factor Xa. In the blood coagulation system, factor Xa is a coagulation factor that functions at the intersection of the intrinsic and the extrinsic pathways. The last stage of the coagulation cascade that results in the creation of fibrin and the clot is the point of conversion of Factor II (prothrombin) to its activated form Factor IIa (thrombin), which is catalyzed by factor Xa. It is essential to produce thrombin because it catalyzes the breakdown of prothrombin.[3] All four of these Novel oral anticoagulants have a quick onset of action and achieve complete anticoagulation within a few hours of consumption, according to randomized clinical trials. These newer oral anticoagulants (NOACS), which emerged in the span of a decade hold great potential over the vitamin K antagonists such as warfarin.[2]

Aristophanes study (Anticoagulants for reduction in stroke: Observational pooled analysis on health outcomes and experience of patients) compared major bleeding (MB) and stroke/systemic embolism (SE) in a large number of patients with non-valvular atrial fibrillation who were using warfarin to those using NOACs utilizing data from multiple sources. Rivaroxaban, Dabigatran, and Apixaban, were all linked to decreased rates of stroke/SE when compared to warfarin. While patients taking Apixaban or Rivaroxaban had reduced rates of ischemic stroke when compared to those taking warfarin, and rivaroxaban had a greater rate of MB when compared to warfarin. All NOACs were linked to reduced incidences of hemorrhagic stroke.[2] Both edoxaban once-daily regimens (high dose of 60 mg and Low dose of 30 mg) which were compared to the Warfarin in the Clinical trial ENGAGE AF-TIMI 48(NCT00781391) were found to be associated to significantly decreased rates of bleeding and mortality from cardiovascular causes, and they were noninferior to warfarin in terms of preventing stroke or systemic embolism.[5]

NOACs causes fewer medication interactions, less food interactions, and has quicker onset of action that eliminates requirement for bridging therapy. The most noteworthy advantage is the fixed dosage schedule that prevents the need for constant monitoring of parameters like the INR. They do, however, have multiple disadvantages when compared to

the warfarin which includes increased expense, higher gastrointestinal adverse reactions in case of the dabigatran, twice-daily dose for apixaban as well as dabigatran, and absence of an easily accessible laboratory test to confirm compliance. Furthermore, patients with significant kidney disease cannot safely utilize these medicines.[1] NOACs typically have fewer adverse effects and are generally well tolerated. Bleeding is the primary adverse effect, and it can vary from mild to severe. Bleeding may encompass nosebleeds, oral bleeding, heavy menstrual bleeding, and potentially lethal bleeding in the digestive tract, brain, and eyes. Dyspepsia has also been documented as a side effect of Dabigatran, in addition to bleeding issues such as gastrointestinal hemorrhage, cerebral hemorrhage and hematuria, which are all directing to a dose related link. If severe bleeding is not promptly and efficiently treated, it might lead to substantial morbidity and even fatalities.[6]

Detaining one or possibly two doses of medication is typically adequate for minimal bleeding. The strategy for more severe bleeding is the same as for warfarin, with the exception that vitamin K administration is ineffective; the patient must be revitalized with fluids along with blood products as needed, the bleeding site should be located and controlled, and the anticoagulant and any other antiplatelet medications must be discontinued. The degree of anticoagulation will be determined by coagulation testing, and kidney function should be evaluated in order to compute the drug's half-life. Orally administered activated charcoal could potentially limit absorption of drugs taken during the past four hours, especially in cases of overdose, and the timing of the last anticoagulant dose taken is crucial for this.[2] Idarucizumab is authorized to reverse dabigatran in people who are bleeding excessively or who need immediate surgery or medical attention. By binding factor Xa inhibitors like Rivaroxaban and Apixaban, andexanet alfa, a recombinant, inactive form of factor Xa, functions as a decoy, neutralizing their effects and restoring normal clotting. Another reversal drug that is presently being studied is ciraparantag.[2]

Previous findings indicate that the Indian patients are often underdosed or undertreated compared to Western populations, largely due to physician concerns about NOAC-related bleeding risks.[7] This study provides evidence of safety and clinical outcomes to support more confident clinical decision-making.

METHOD

The proposed study was conducted in a Tertiary Care Hospital, Kannur. It is a Retrospective and Prospective (ambispective) observational cohort study during the period from November 2023- April 2024. Patients were selected based on inclusion and exclusion Criteria. Data collection was performed using the electronic medical record system. Demographics (Age, Gender, Weight), presence of comorbidities (diabetes mellitus, systemic hypertension, dyslipidemia), HAS- BLED score, creatinine clearance was calculated using weight independent method MDRD (Modification of Diet in Renal Disease Study), liver function, left ventricular function and data regarding background anticoagulant therapy prior to NOAC initiation were noted. Events of thromboembolism while on NOAC, drugs used along with NOAC such as ACEs or ARBs, amiodarone, betablocker, digoxin, CCBs, statins, NSAIDs and gastric acid reducing agents were noted. CHA2DS2-Vasc score was calculated in patients with non-valvular atrial fibrillation. Indications for starting NOAC therapy, the incidence of discontinuation of the drug and the reason were analyzed (Figure 1).

RESULT

A total of 120 patients who were on Novel Oral Anticoagulant treatment during the study period of November 2023 to April 2024 were taken for this study from a Tertiary care hospital, Kannur. Out of which 53(44%) were male and

67(56%) were female. the mean age of study population was 63.81 ± (16.337). 40 (33.3%) were under the age of 60, while 80 (66.6%) were above and equal to 60. The majority of the patients belong to above and equal to 60 years. The study population had a mean body weight of 67.03 ± 11.82 kg. The majority of participants (60.8%) had body weights between 51 and 70 kg, followed by 30.8% in the 71–90 kg range. Only a small proportion of participants fell at the extremes of weight distribution.

HAS BLED Score assess the risk for major bleeding by going through parameters such as hypertension, abnormal liver or renal function, stroke history, bleeding history or predisposition, labile INR, elderly, drug or alcohol usage. A score of 0-1 indicates low risk of major bleeding, a score of 2 indicates moderate risk of major bleeding and Patient with HAS BLED Score ≥3 indicates high risk of bleeding. Out of 120 Patients, 22(18.3%) patients had HAS-BLED score 0-1, 22 (18.3%) patients had HAS-BLED score 2 and 76 (63.3%) patient had a score 3 or more than 3.

CHA2DS2- VASc score assesses the risk of thromboembolic events. The score 1 indicates lower risk, 2 indicates moderate risk and ≥3 indicates high risk. Out of 120 patients, 29 were with AF as indication. Oral anticoagulant recommended about 2 (6.8%) patients were under CHA2DS2-VASc score 1, 4 (13.7%) patients were CHA2DS2-VASc score 2, and the rest ≥3 CHA2DS2-VASc score for 23 (79.3%) patients. And out of 120 patients, 16 (13.3%) were having reduced Ejection Fraction and abnormal renal function was seen in about 29(24.16%) patients. Of the 29 patients having renal dysfunction, 9 was female and 20 were male. About 28.3% (34) of the study population suffered from hepatic dysfunction.

Table 1 shows different indications for initiating NOAC therapy. Out of 120 patients, 27 patients started on NOAC because of stroke/TIA, 35 with DVT, 4 with PVOD, 7 with PE, 2 with severe LV dysfunction, 7 with Atrial Flutter, 1 with stroke and severe LV dysfunction, 5 with AF and stroke, 2 with stroke and DVT, 1 with PE and TIA, 1 with AF and PVOD, 2 with AF and DVT, 20 with Atrial Fibrillation, 1 with PE and DVT. 5 patients with other indications such as Portal vein thrombosis, renal vein thrombosis and AV fistula thrombosis.

In the study population, 19 patients (15.8%) were transitioned from vitamin K antagonist (VKA) therapy to novel oral anticoagulants (NOACs), primarily due to the lack of requirement for routine international normalized ratio (INR) monitoring and improved treatment convenience. And one patient switched back from NOAC to VKA due to high cost of medication. Minor bleeding events were observed in 3 patients (2.5%). During the study period, 2 patients (1.7%) died due to cardiac arrest and septic shock, while the majority of patients (98.3%) remained alive. Comorbidities observed in patients receiving NOAC therapy included hypertension, which was present in 85 patients (70.8%), diabetes mellitus observed in 61(50.8%) patients , and dyslipidemia in 66 patients (55.0%). Concomitant medications co-administered with NOAC therapy included angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, amiodarone, beta-blockers, antiplatelet agents, digoxin, calcium channel blockers, statins, nonsteroidal anti-inflammatory drugs, and gastric antacids (Figure 2).

Table 1: Indications for starting NOAC Therapy.

Indication for starting NOAC	Frequency(N)
STROKE/TIA	27
DVT	35
PVOD	4
PULMONARY EMBOLISM	7

SEVERE LV DYSFUNCTION	2
ATRIAL FLUTTER	7
STROKE, SEVERE LV DYSFUNCTION	1
AF, STROKE	5
STROKE, DVT	2
PE, TIA	1
AF, PVOD	1
AF, DVT	2
AF	20
DVT, PE	1
OTHERS	5

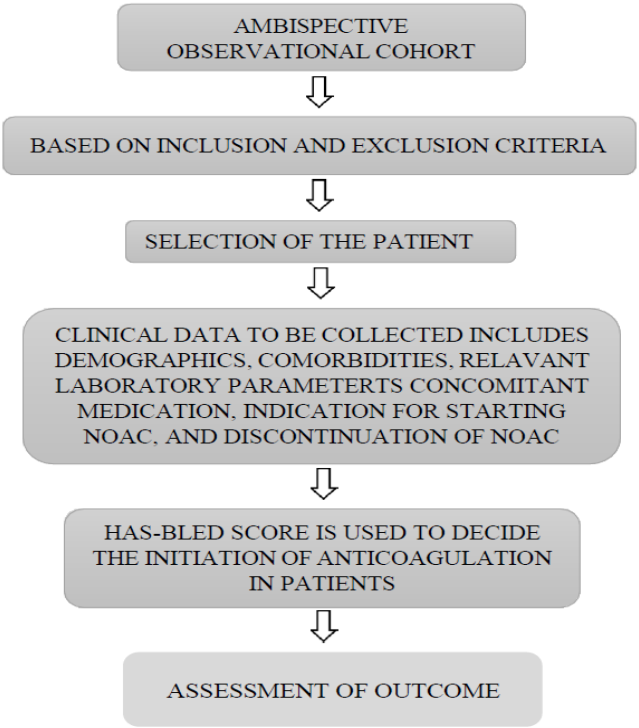

Figure 1: Methodology of study.

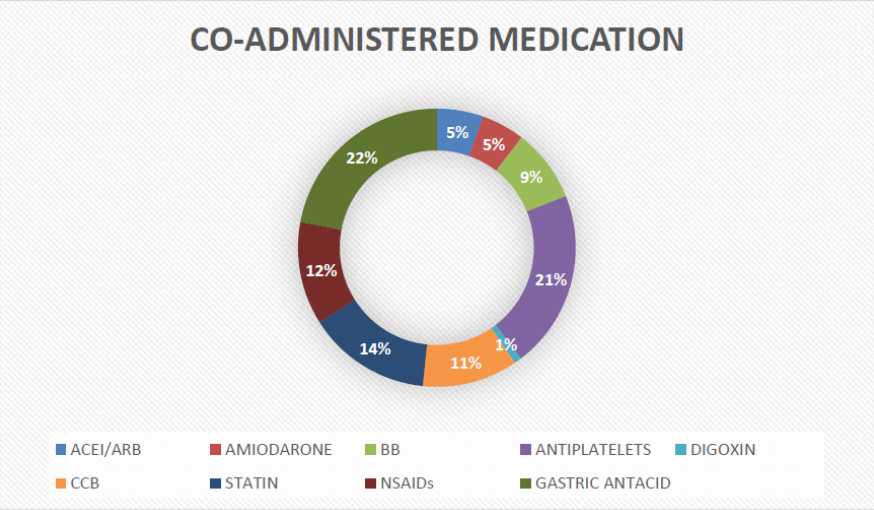

Figure 2: Co-administered medications.

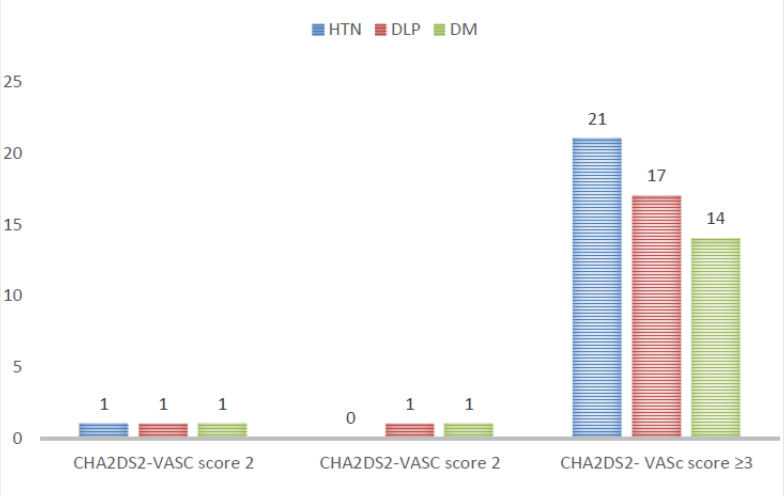

Figure 3: CHA2DS2-VASC score with co-morbidities.

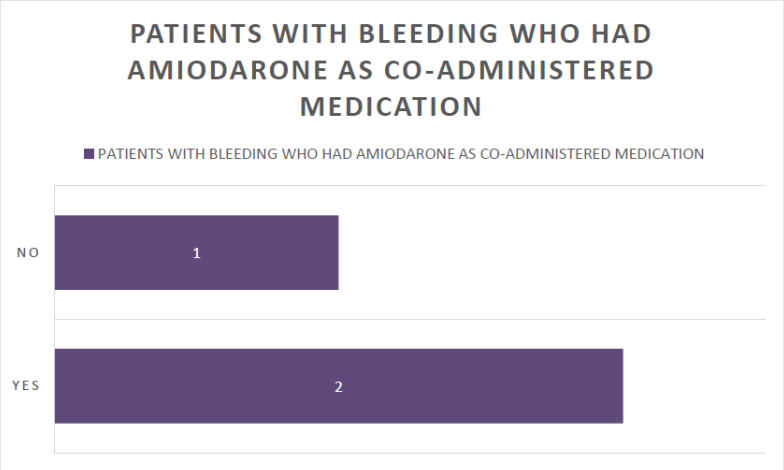

Figure 4: Co-administered medication (Amiodarone) with bleeding events.

DISCUSSION

This is a prospective and retrospective observational study examining the safety and clinical outcomes of patients who received NOAC therapy for established indications. This study demonstrated significant reduction of thromboembolic events with low bleeding events in patients with atrial fibrillation, atrial flutter, prior stroke, TIA, pulmonary embolism, peripheral arterial embolism, deep vein thrombosis, severe LV systolic dysfunction, and LV clot.

In our study, 34 individuals (28.3%) exhibited liver disease. Only two patients had stopped NOAC therapy. According to Spearman's test, they both have a statistically significant correlation (P value = 0.023). Clinically, these two patients who quit NOAC had comorbidities and co-administered drugs, which could lead to the discontinuation of anticoagulant therapy. Meanwhile, the remaining 32 patients with hepatic dysfunction got NOAC therapy at a decreased dose without being terminated, resulting in a clinically effective outcome. According to "Oral Anticoagulation in Patients with Chronic Liver Disease" Study by *Raluca S. Costache et al* suggests that DOACs may be administered safely in Child–Pugh A cirrhotic patients and carefully in Child–Pugh B patients, with comparable effectiveness and potentially greater safety than warfarin.[8] This study was comparable with our study which demonstrated the safe use of NOAC in patients with liver disease.

An elevated CHA2DS2-VASC score suggests that anticoagulants are strongly recommended. The majority of the participants in our research had CHA2DS2-VASC scores greater than or equal to 2. As a result, the dosage of NOAC is dependent on the score; that is, the dosage of the medication should be raised anytime the score rises. Dabigatran 110 mg, Apixaban 2.5 mg, and Rivaroxaban 10 mg are the NOAC doses administered. However, there are instances where the medication does not rise in tandem with a higher score due to variations in scores such as HAS-BLED score and parameters like LFT and RFT, which affect the dosage of NOAC. Luis Alberto García Rodríguez et al conducted a study shows, there was a trend towards dose reduction with increasing renal impairment. Among patients with severe renal impairment, the majority received a reduced dose NOAC: apixaban, 91.1%, dabigatran, 80.0%, rivaroxaban, 83.0%.[9] This study shows comparable effects with our study.

The 29 subjects had an indication of AF, and patients with a CHA2DS2-VASC score greater than or equal to 2 had the majority of the comorbidities (Figure 3). Patients with a score of less than 2 had few or no comorbidities. There is a statistically significant correlation between the CHA2DS2-VASC score and comorbidities, similarly theoretical correlation as well. Yunli Xing et al conducted a study shows that the study had a high prevalence of cardiovascular diseases and relevant risk factors such as hypertension (93% of patients), diabetes (35.7%), heart failure (20.9%), and vascular disease (46.2%), which caused the high incidence of stroke.[10] This study was found to be comparable with our study.

There were 44 participants with HAS-BLED scores ranging from 0 to 2, and the remaining 76 had scores greater than or equal to 3. Three subjects with HAS-BLED scores of 5, 5, and 4 experienced bleeding incidents. The T-test reveals a highly significant correlation between HAS-BLED score and bleeding occurrences (CI=95% (2.95-3). The study shows that three of the patients experienced bleeding events, were predisposed to bleeding, and were on Aspirin medication. So, we cannot conclude that the bleeding events were caused by NOAC administration alone. “Revised HAS-BLED score for bleeding prediction in atrial fibrillation patients with oral anticoagulants” by Komsing Methavigul shows that the HAS-BLED score could predict bleeding events in anticoagulated patients.[11] This study was found to be comparable with our study.

There was a statistically significant correlation between CHA2DS2-VASC score and liver function. The P-value was found to be 0.002. In AF patients with abnormal liver function, the CHA2DS2-VASC score was greater than or equal to two. The fact that the majority of individuals with scores greater than or equal to 2 exhibit abnormal liver functions support the theoretical significance. In patients with impaired liver function, an intervention was discovered that lowered the dose of NOACs. “Oral Anticoagulation in Patients with Liver Disease” by Arman Qamar MD et al shows that an optimal anticoagulation strategy in patients with liver disease with either warfarin or NOACs needs to be better defined and dose adjusted accordingly.[12]

Co- administered medication (Amiodarone) and bleeding events showed a statistical significance with P value 0.037 on Spearman’s correlation but not proved theoretically (Figure 4). A study by Zi Wang et al “Combination of Rivaroxaban and Amiodarone Increases Bleeding in Patients with Atrial Fibrillation” shows that the combination of rivaroxaban and amiodarone increased the risk of bleeding in patients with atrial fibrillation, especially clinically relevant nonmajor and minor bleeding. Physicians prescribing rivaroxaban and amiodarone together should be concerned about an increase in the risk of nonmajor bleeding.[13] The result of our study does not go in harmony with Zi Wang et al study.

In the trial, two patients died after discontinuing NOAC therapy. However, it is not certain if the death was caused by the discontinuation of NOAC therapy because both patients had multiple medical issues, other co-administered drugs, and were beyond the age of 70. In GARFIELD-AF, the rate of discontinuation was 13.0%. Discontinuation for ≥7 consecutive days was associated with significantly higher all-cause mortality, stroke/SE, and MI risk. Caution should be exerted when considering any OAC discontinuation beyond 7 days.[14]

The T-test revealed a statistically significant correlation between the patient's age and the occurrence of bleeding events, with a 't' value of 42.786 and a P value of 0.000 (95% CI= (60.86-66.76). In the trial, only three people from the total population over the age of 65 years with other medical conditions had minor bleeding incidents demonstrated the safety of NOAC therapy. “Current Use of Oral Anticoagulation Therapy in Elderly Patients with Atrial Fibrillation: Results from an Italian Multicenter Prospective Study—The ISNEP Study” by *Francesco De Stefano et al* concludes that, small but nonnegligible proportion of elderly AF patients is still treated with VKAs, probably due to clinicians’ therapeutic inertia, the reluctance to prescribe NOACs in patients with poor renal function, or the lack of INR monitoring with NOAC. Finally, the patients treated with NOACs showed a higher level of satisfaction with the therapy, which can be associated with complete adherence throughout the course of it.[15]

CONCLUSION

We found that in a real-world population of patients who needed NOAC therapy, the treatment was associated with a good safety and excellent clinical outcome in this prospective and retrospective observational study, which was conducted in Tertiary care hospital, Kannur, Kerala. It is quite evident that NOAC has given clinicians a wider choice of treatment options for patients with AF and other proved indications for NOAC therapy. We were able to highlight the long-term performance of these medications in real-life situations as a consequence of this investigation. This real-world data will contribute to the creation of an adaptable practical document for the use of NOACs in India, and this may serve as a foundation for future guidelines, training, and education for the use of NOACs in this part of the world.

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