Real- World Effectiveness and Safety of Rivaroxaban in Patients with NON-Valvular Atrial Fibrillation (NVAF) and Venous Thromboembolism (VTE) in Saudi Arabia

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Introduction

- Rivaroxaban is potent, oral, highly selective direct inhibitor of factor Xa with high oral bioavailability. It is effective for the treatment of DVT and PE as well as primary and secondary thromboprophylaxis.
- Direct factor Xa inhibitors inhibit platelet activation and fibrin clot formation via direct, selective and reversible inhibition of factor Xa.
- These agents have several advantages over the vitamin K antagonists such as rapid onset of action, no requirement for dose adjustment, and few drug and food interactions . Thus, these agents become widely used in the treatment and prevention of all VTE related diseases.
- Although the efficacy and safety of the factor Xa inhibitor for the prevention of VTE and stroke in patients with NVAF were shown in global clinical trials, the safety and effectiveness data from unselected patients in everyday clinical practice are yet limited.
- Recently, the use of those medications were increase which raise a concern about it risk-benefit ratio specially in real practice in our region. Real-world data on Factor Xa inhibitor are essential in determining whether evidence from randomized controlled clinical trials translate into meaningful clinical benefits for patients in everyday practice.

Objectives

- To investigate the safety and effectiveness of Factor Xa inhibitor (rivaroxaban) in real-world clinical practice in the Kingdom of Saudi Arabia (KSA).

Methods

- In this real-life cohort study, rivaroxaban appears to be more effective with a dose of 20 mg for patients with VTE and NVAF. Rivaroxaban was also associated with a lower risk of safety events such as recurrent thrombosis, recurrent stroke, MI, major bleeding, and non-major bleeding in patients with VTE and NVAF.

Results

- A total of 2316 patients taking rivaroxaban recruited through several departments in king Khalid University Hospital with a mean age of 60.9 years (±17.8) were enrolled in this study. More than half (55.3%) of the patients were over 60 years of age. 58% of which were females. The prescriptions for VTE (DVT and PE) were relatively higher than NVAF.
- The incidence rates of recurrent thrombosis and recurrent stroke were 0.2 %.

Results

Whereas, the incidence rate was 0.04 % for MI. 50% of these patients who had recurrent thrombosis and stroke were using 15 mg/day and the other 50% using 20 mg/day of rivaroxaban. The incidence rate of major bleeding was 1.1 %. More than 50% of the patients who had major bleeding were on 20 mg daily dose of rivaroxaban. 48% of the patients who had major bleeding has a high risk for bleeding according to HAS-BLED Score (>2 score). The incidence rate of non-major bleeding was 0.6 %. Likewise, 40% of the patients who had non-major bleeding were on 20 mg daily dose of rivaroxaban. Only 6.6% of these patients had a high risk for bleeding according to HAS-BLED Score

Table 1. Effectiveness and safety outcomes of patients

Variables		Dose of Rivaroxaban				
	Overall (n=2316)	10mg (n=579)	15mg (n=537)	20mg (n=1168)	30mg (n=32)	P-value
Effectiveness outcomes						
Recurrent Thrombosis; n (%)	4 (0.2)	0	2 (0.4)	2 (0.2)	0	0.513
Recurrent Stroke; n (%)	4 (0.2)	0	2 (0.4)	2 (0.2)	0	0.513
Myocardial Infarction; n (%)	1 (0.04)	0	0	1 (0.1)	0	0.805
Safety outcomes						
Major Bleeding; n (%)	25 (1.1)	4 (0.7)	6 (1.1)	15 (1.3)	0	0.652
Minor Bleeding; n (%)	15 (0.6)	4 (0.7)	5 (0.9)	6 (0.5)	0	0.748

Table 4: Association between effectiveness and safety outcomes and

Variables		Risk of stroke according to CHADS2-Score		
	Overall (n=2316)	Low risk (n=730)	Intermediate Risk (n=1149)	High Risk (n=437)
Effectiveness outcomes				
Recurrent Thrombosis; n (%)	4 (0.2)	0	0	4 (0.9)
Recurrent Stroke; n (%)	4 (0.2)	0	0	4 (0.9)
Myocardial Infarction; n (%)	1 (0.04)	0	0	1 (0.2)
		Risk of bleeding according HAS-BLED Score		
		Low risk (n=622)	Intermediate Risk (n=1418)	High Risk (n=276)
Safety outcomes				
Major Bleeding; n (%)	25 (1.1)	0	13 (0.92)	12 (4.3)
Minor Bleeding; n (%)	15 (0.6)	0	14 (0.98)	1 (0.35)

Conclusion

- In this real-life cohort study, rivaroxaban appears to be more effective with a dose of 20 mg for patients with VTE and NVAF.
- Rivaroxaban was also associated with a lower risk of safety events such as recurrent thrombosis, recurrent stroke, MI, major bleeding, and non-major bleeding in patients with VTE and NVAF.
- The study findings provide an important information able to inform clinicians' behavior in prescribing anticoagulants for patients with thromboembolic events. Future nationwide study is required to validate the findings of this study.