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The confidence registry: Oral anticoagulation in Indian patients with thromboembolism

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Introduction: Vitamin K Antagonists (VKA) are most widely used oral anticoagulants for prophylaxis of stroke and systemic embolism. Monitoring of VKA therapy is vital, targeted to achieve an optimum international normalized ratio (INR) 2.0 to 3.0 to minimize continuing risk of bleeding and recurrent thromboembolism. Data on outpatient anticoagulation control in the Indian population is limited.

Purpose: The registry aimed to evaluate VKA treatment pattern (dose and duration), INR control (optimum and stable values) and safety of VKA in Indian patients with thromboembolic disorders.

Methods: This interim analysis presents data of 316 newly diagnosed adults treated with VKA for stroke prevention in atrial fibrillation (SPAF), venous thromboembolism (VTE), valvular heart disease (VHD) and post prosthetic heart valve surgery (VS). Enrolled patients were followed for a year for collection of data on VKA treatment and INR values: every week for month 1, every 4 weeks (month 2 and 3) and three-monthly (month 6, 9 and 12).

Results: The mean age of the patients was 48.7 ± 14.7 years and 56.6% were males. VKA was used mostly for VHD (42.7%), followed by SPAF (24.7%), VS (18%) and VTE (14.6%). Mean dose of warfarin ($n=40$) was 3.2 ± 1.3 mg and that of acenocoumarol ($n=281$) was 2.1 ± 0.8 mg. The mean baseline INR was 1.6 which increased to 2.0 by the end of week 1. Around 60% of all patients achieved optimum INR (values between 2.0-3.0 in AF/VTE and 2.5 to 3.5 in case of mechanical valves). The average time needed to achieve optimum INR value was 1.4 ± 2.4 months with mean warfarin dose of 4.3 ± 1.4 mg and mean acenocoumarol dose of 2.3 ± 1.0 mg. Patients with VHD required longer duration (1.8 ± 2.5 months) to achieve optimum INR and pulmonary embolism (PE) required the least (0.6 ± 0.6 month). About one thirds ($n=119$, 37%) maintained optimum INR (for at least 2 consecutive weeks) for an average of 3.6 ± 3.4 months. Duration of optimum INR was maintained maximum for patients with SPAF (5.4 ± 4.3 months) and least for patients with DVT (0.9 ± 1.8 month). At baseline, patients with AF had high risk of stroke with a mean CHA₂DS₂-VASc score of 2.7 ($n=55$) and moderate risk of major bleeding with a mean HAS-BLED score of 1.1 ($n=43$). Risk indices remained comparable till 1 year. Adverse drug reactions (ADR) (mild hematemesis and moderate hematuria) reported in 2 patients resolved and none of the patients reported any serious ADR.

Conclusions: VKA therapy is most commonly prescribed for valvular heart disease. More than half of the patients achieved optimum INR and about one third maintained stable optimal INR for more than 3 months. VKA treatment did not increase the risk of ischemic stroke and thromboembolism when used for duration of 1-year. Overall, oral anticoagulants such as VKA are routinely used by the clinicians in India to achieve favorable clinical benefits.

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