

Title: Dabigatran versus Warfarin for the Treatment of Pediatric Thromboembolism: A Randomized, Active-Controlled Trial

Category: Acute Coronary Syndromes

ABSTRACT

INTRODUCTION: Venous thromboembolism (VTE) is still a problematic situation in children. Warfarin dosing is constantly monitored to avoid bleeding and clotting. In contrast, it is not necessary to monitor dabigatran dosing. Due to minimal data about dabigatran effects in childhood VTE, this study was designed with the aim of comparing the efficacy of dabigatran etexilate with warfarin in children aged ≤ 18 years who were on enoxaparin therapy.

METHODS: This randomized and active-controlled study was done in Amir-Kabir Hospital, Arak, Iran. Twenty-five children who aged between 2 years and 18 years with VTE were included. Study subjects were randomized 1:1 to enoxaparin 1 mg/kg twice daily and daily 0.2 mg/kg warfarin or enoxaparin 1 mg/kg twice daily and 220 mg/m² divided dose of dabigartan etexilate. Enoxaparin therapy was continued for 5 days and treatment with warfarin and dabigatran continued for 6 months. Patients were monitored for minor and major bleeding events, and thrombus extension or recurrence.

RESULTS: A total of 22 patients presented with deep-vein thrombosis were studied and followed up. Dabigatran had similar effects to warfarin with respect to the thrombus cure, which occurred in 10 patients in the dabigatran group (90 %) and 9 patients in the warfarin group (81%). The safety outcome occurred in 1 patient (9%) in the dabigartan group and 4 patients (36.3%) in the warfarin group ($P < 0.01$). The rates of other adverse events were similar in the two groups.

CONCLUSIONS: Dabigartan administered once daily after initial treatment with enoxaparin was similar to warfarin and caused significantly less bleeding in children with venous thromboembolism.