

Prophylaxis of Venous Thromboembolism in Patients with a Nonsurgical Fracture of the Lower Extremity Immobilized in a Below-Knee Plaster Cast: A Randomized Controlled Trial

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Purpose: Immobilization of the lower leg is associated with deep vein thrombosis (DVT). However, thromboprophylaxis in patients with a below-knee plaster cast remains controversial. We examined the efficacy and safety of nadroparin and fondaparinux in patients immobilized in a below-knee plaster cast.

Methods: The PROTECT (Prophylaxis of Thromboembolism in Critical Care Trial) study was a multicenter study that enrolled adults with a fracture requiring below-knee immobilization. Participants were randomized for either the control group or one of the intervention groups: daily subcutaneous self-injection of either nadroparin (2850 IE anti-Xa = 0.3 mL) or fondaparinux (2.5 mg = 0.5 mL). A venous duplex sonography was performed after removal of the cast or earlier if thrombosis was suspected. Primary outcome was the relative risk of developing DVT in the control group compared with that in both intervention groups.

Results: 467 patients were enrolled and assigned to either the nadroparin group (n = 154), the fondaparinux group (n = 157), or the control group (n = 156). A total of 273 patients (92, 92, and 94 patients, respectively) were analyzed. The incidence of DVT in the nadroparin group was 2 of 92 (2.2%) compared with 11 of 94 (11.7%) in the control group, with a relative risk of 5.4 (95% confidence interval [CI] 1.2 - 23.6; P = 0.011). The incidence of DVT in the fondaparinux group was 1 of 92 (1.1%), yielding a relative risk of 10.8 (95% CI 1.4 - 80.7; P = 0.003) compared with that in the control group.

Conclusion: Thromboprophylaxis with nadroparin or fondaparinux significantly reduces the risk of DVT in patients with an ankle or foot fracture who were treated in a below-knee cast without any major adverse events.