Prolonged Thromboprophylaxis with Dalteparin during Immobilization after Ankle Fracture Surgery: A Randomized, Placebo-controlled, Double Blind Study

Reference:

Scientific Literature Reviews

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Podiatry Relevance:
Orthopedic injuries and immobilization are risk factors for developing a thromboembolic event, such as deep vein thrombosis (DVT) or pulmonary embolism (PE). Ankle fractures are one of the most common lower extremity injuries. This article evaluates whether or not thromboprophylaxis is necessary after an ankle fracture with surgical treatment and immobilization.

Methods:
This is a prospective double-blind, placebo controlled study with 272 consecutive, randomized patients. The study was conducted at a single center, Stockholm Soder Hospital, between May 2000 and March 2004. Patients were randomized into two groups, one receiving 5000 U of subcutaneous Dalteparin once a day (n=136) and the second group receiving a placebo (n=136) for 5 weeks after ankle fracture surgery and immobilization in a plaster cast or orthosis. All patients received one week of initial treatment of Dalteparin prior to randomization.

The inclusion criteria were defined as all patients admitted to the hospital with an ankle fracture within 72 hours of injury and between the ages of 18-75. The exclusion criteria were defined as inability/refusal to sign consent for study, ongoing treatment with an anticoagulant, treatment with ASA 325mg or other platelet inhibitors, known allergy to contrast media, planned follow up at another hospital, known renal disorder or transplant, recent thromboembolic event within 3 months, recent surgery within 1 month, known malignancy, bleeding disorder, pregnancy, and multi-trauma.

All patients were treated with surgery according to basic principles and immobilized after surgery with a plaster cast or orthosis, which was determined by the surgeon. All patients received 1000 mL Dextran 60 on the day of admission and then started on 5000 U Dalteparin for 7 days starting on the evening before or after surgery, depending on if the case was delayed.

The patients were examined at 2 and 6 weeks postoperatively. After removing the cast at day 42-46, both legs were examined for clinical signs of DVT and a unilateral phlebography was performed. If phlebography failed, then a color duplex sonography (CDS) was used. If a PE was suspected, then a spiral CT or ventilation/perfusion scintigraphy was done. Blood samples were measured before randomization and used as a baseline, such as serum creatinine, hemoglobin, platelet count, aPTT, PR, and INR.

The primary endpoint was assessed by the number of patients in each group with phlebography verified distal and/or proximal DVT and/or PE. Secondary endpoints included the incidence of phlebography or CDS verified DVT and/or PE and the incidence of DVT when using plaster cast versus orthosis.
Results:
Over a mean treatment course of 44 days of immobilization by either plaster cast or orthosis, the incidence of developing a thrombosis was 21% (21/101) in the Dalteparin group and 28% (27/96) in the placebo group. The incidence of a thrombosis developing in the proximal veins (proximal DVT) was 4% (4/101) in the Dalteparin group and 3% (3/96) in the placebo group. The incidence of developing a DVT with orthotic immobilization was 8% (3/36) and 28% (45/161) with plaster cast immobilization. Of those treated with a plaster cast, 21% (18/86) developed a DVT, compared to 36% (27/75) in the placebo group. No patient present with clinical signs for a pulmonary embolism and no major bleeding complications occurred.

Conclusion:
These findings show that there are no significant differences between short course and prolonged thromboprophylaxis therapy using Dalteparin with immobilization after ankle fracture surgery. The incidence of developing a DVT is higher when immobilized with plaster cast immobilization than with orthotic immobilization (28% vs. 8%) and that use of Dalteparin with plaster cast immobilization decreased the incidence of developing a DVT.