

INTERMITTENT PNEUMATIC COMPRESSION IN THE PREVENTION OF POSTOPERATIVE VENOUS THROMBOEMBOLISM IN PATIENTS AT EXTREMELY HIGH RISK: THE RESULTS OF IPC SUPER STUDY

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Aim: To assess the efficacy and safety of intermittent pneumatic compression (IPC) in the prevention of postoperative venous thromboembolism (VTE) in surgical patients with high VTE risk.

Methods: This study was a two-center open randomized clinical trial with a blinded outcome assessor (NCT03044574); the enrolled patients were at extremely high risk for postoperative VTE (≥ 11 Caprini scores). Participants were randomized into two groups: a control group that received standard prophylaxis with above-knee anti-embolic elastic compression stockings and subcutaneous low-molecular-weight heparin (enoxaparin 40 mg), and an experimental group that utilized additional IPC (Cardinal Health™ Kendall SCD™ 700 system) for the period of immobility. Patients were followed throughout their hospital stay and observed at one and six months after surgery. Duplex ultrasound to detect asymptomatic deep vein thrombosis (DVT) was performed at baseline and every 3-5 days after surgery during inpatient treatment. PECT/CT or CTPA to exclude pulmonary embolism (PE) was performed in cases of clinical suspicion. Autopsy was performed on all deceased patients. The primary endpoint of the study was occurrence of asymptomatic DVT during hospital stay. The main secondary endpoints included symptomatic and asymptomatic VTEs during inpatient treatment and at one and six months after surgery, leg skin injury, and major or clinically relevant non-major bleeding.

Results: In total, 407 patients were randomized to the experimental and control groups (204 and 203 respectively). There were 160 men and 247 women with a mean age of 68.8 ± 9.8 , who underwent major abdominal (68.3%), thoracic and neck (7.9%), gynecological (8.6%), urological (7.3%) or cranial (7.9%) surgery with the mean duration of 165.3 ± 77.7 min. Mean Caprini score was 11.4 ± 1.9 . Groups had similar baseline Caprini scores. The presence of a malignant tumor was the indication for surgery in 83% of patients.

The median hospital length-of-stay was 10 days in both groups. Primary endpoint was observed in 1 of 204 patients (0.5%; 95% CI: 0.1-2.7%) in the experimental group and 34 of 203 patients (16.7%; 95% CI: 12.2-22.4%) in the control group ($p < 0.0001$). PE incidence was 0% vs. 2.5% ($p = 0.030$) and fatal PE was 0% vs. 1.5% ($p > 0.05$). The 30-day incidence of VTE was 0.5% and 18% ($p < 0.0001$). At six months 80% of patients were followed-up, and no new VTE events occurred. Leg skin injury was detected in 12.3% vs. 7.4% and bleeding in 3.4% vs 5.4% patients in the experimental and control groups, respectively ($p > 0.05$).

Conclusion: Combination IPC and standard prophylaxis reduced the incidence of postoperative VTE in patients at extremely high risk without increasing rates of leg skin injury or bleeding.