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LMW-HEPARIN VERSUS HEPARIN-DHE IN ORTHOPAEDIC SURGERY  
H.-G. Breyer, R. Rahmzadeh, P. Bacher, B. Werner  
Dept. of Trauma and Reconstructive Surgery, Klinikum  
Steglitz, Free University, Berlin, West-Germany

The efficiency and the side effects of a LMW heparin (FRAGMIN<sup>R</sup>, KabiVitrum) and Heparin-DHE (Sandoz) have been compared in a randomized open prospective study of 120 patients (60/60) undergoing elective surgery on the lower limbs (total hip and knee replacement, corrective osteotomies). A radiofibrinogen uptake test (RFUT) was regularly done on all patients. Positive tests were controlled by ascending phlebography. The parameters, clinically obtained, included the intra- and postoperative blood loss, wound closure, and the incidence of haematoma. Hb, Hk, red and white blood cells, thrombocytes, total protein, aPTT, AT III, TT, and anti-Xy-activity were analyzed at the day before operation, the 2nd, 4th, and 6th day after operation.

There were three positive RFUT in the group of LMW heparin (5 per cent), and there were six (10 per cent) in the control group. No pulmonary embolism occurred. In no case an operative treatment of deep vein thrombosis was done. There were no statistically significant differences in intra- and postoperative blood loss, and in the laboratory data, except the anti-Xa-activity, which was significantly higher in the LMW heparin group.

The comparative study has shown, that a single daily injection of LMW heparin (FRAGMIN<sup>R</sup>) is more effective than the two daily injections of the combination of UF heparin and DHE in order to prevent postoperative thromboembolism.

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ENOXAPARINE (LOVENOX<sup>R</sup>), VERSUS STANDARD HEPARIN IN PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT) AFTER TOTAL HIP REPLACEMENT (THR).  
T. LE BALC'H\*, A. LANDAIS, J. BUTEL, D. WEILL, J.C. PASCARIELLO, A. PLANES. \*Department of Orthopedy (Pr. MAZAS), Hôpital Bicêtre, Paris, France.

THR is associated with a high risk of thromboembolic complications. Enoxaparine, Lovenox<sup>R</sup>, a low-molecular-weight-heparin, and standard heparin were compared in their abilities to prevent DVT in patients undergoing THR. The efficiency and the bleeding risk of each treatment were studied.

237 patients, with a non traumatic hip disease, requiring THR, were included in a multicentric, randomized, double blind trial. Mean age : 65.8 years  $\pm$  9.2 ; mean weight : 67.3 kg  $\pm$  1.3. 113 patients received standard heparin, 5000 UI/8 hrs, by subcutaneous (SC) injection. 124 patients received Enoxaparine, 40 mg/24 hrs, by SC injection. Administration of drugs was begun 2 hours before operation for standard heparin, 12 hours before operation for Enoxaparine. Patients were treated for 10-15 days, until bilateral ascending phlebography (BAP) had been completed.

Lower limbs BAP were performed in 228 patients. The incidence of DVT was significantly lower in the Enoxaparine group : a DVT was detected in 15 (12.5 %) of 120 patients who received Enoxaparine and in 27 (25 %) of 108 patients who received standard heparin ( $p = 0.014$ ). A pulmonary embolism occurred in 1 patient of the heparin group, in none of the Enoxaparine group.

The frequency of bleeding complications was significantly lower in the Enoxaparine group. A post operative wound hematoma occurred in 1 patient of the Enoxaparine group and in 3 patients of the heparin group. Red cell transfusions requirements were significantly lower in the Enoxaparine group (3.37 U  $\pm$  1.81) than in the heparin group (3.84 U  $\pm$  1.70) ( $p = 0.03$ ). The hemoglobin level was significantly higher, on the 3rd, 4th post operative day, in the Enoxaparine group.

Subcutaneous Enoxaparine (40 mg/24 hrs) was significantly more efficient than subcutaneous heparin (5000 UI/8 hrs) in preventing DVT, in patients undergoing THR. The incidence of bleeding complications was significantly lower in the Enoxaparine group.

Enoxaparine (LOVENOX<sup>R</sup>) - PHARMUKA S.F.

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PREVENTION OF DEEP VEIN THROMBOSIS (DVT) BY ENOXAPARINE (LOVENOX<sup>R</sup>) AFTER SURGERY FOR FRACTURE OF FEMORAL NECK. ONE DAILY INJECTION OF 40 MG VERSUS TWO DAILY INJECTIONS OF 20 MG. J. BARSOTTI, B. DABO, J. ANDREU, D. ALISON, J. LEROY, B. DELAHOUSSE Department of Orthopedy, C.H.R.U. Tours, France.

In a previous open study, a low-molecular-weight-heparin, Enoxaparine in a dose of 40 mg/24 hrs by subcutaneous (SC) injection, had been shown to be efficient and safe in preventing DVT after total hip replacement (THR), for a non traumatic hip disease. 103 patients (mean age : 82 years  $\pm$  10, mean weight : 52 kg  $\pm$  10) undergoing an orthopedic operation for fracture of femoral neck were included in a randomized, double blind study. These patients received SC Enoxaparine according to two different regimens : 54 patients received the treatment A (2 daily injections of 20 mg), 49 patients received the treatment B (1 daily injection of 40 mg). In both groups, administration of 40 mg of Enoxaparine was begun 12 hours before operation. Patients were treated for 10-15 days, until bilateral ascending phlebography (BAP) had been completed.

Lower limbs BAP were performed in 97 patients. The incidence of DVT is low and not significantly different between the two regimens : a proximal DVT was detected in 6 patients of the group A and in 2 patients of the group B. This difference is not significant ( $p = 0.28$ ). 3 patients of each group had a distal DVT. No clinical pulmonary embolism occurred.

There was no serious bleeding complication, and the two groups are not significantly different on this point ; 2 patients in each group had an important hematoma of the thigh. One hematoma, in a patient who received the treatment B, required a surgical treatment. Red cell transfusion requirements were 2.6 U  $\pm$  1.8 in the group A and 2.5 U  $\pm$  1.4 in the group B ( $p = 0.84$ ). There was no significant difference in the daily hemoglobin levels between the two groups.

This study shows that one daily SC injection of 40 mg of Enoxaparine is as efficient as two daily SC injections of 20 mg of Enoxaparine in preventing DVT, in very elderly patients undergoing orthopedic operation for fracture of the femoral neck. The frequencies of bleeding complications in each group were not significantly different.

Enoxaparine (LOVENOX<sup>R</sup>) - PHARMUKA S.F.

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DEEP VEIN THROMBOSIS PROPHYLAXIS IN SURGICALLY TREATED FRACTURED HIP PATIENTS. P.J.Powers, M.Gent, R.Jay, J.Hirsh, M.Levine, G.Turpie. St. Joseph's Hospital, McMaster Health Sciences Centre, Hamilton Civic Hospitals.

Deep vein thrombosis is a major complication in patients treated surgically for fractured hip. Methods employed to reduce the risk of thrombosis include dextran, ASA, warfarin, low or adjusted dose heparin and calf compression, but none has widespread acceptance. A randomized trial was carried out to assess the effectiveness of sodium warfarin and acetylsalicylic acid (aspirin) compared to placebo in the prevention of venous thrombosis in fractured hip patients. One hundred and ninety four patients were randomized to receive warfarin (65 patients), ASA (66 patients) or placebo (63 patients). Prophylaxis commenced post operatively and continued for 21 days or until discharge, if earlier. Warfarin patients received 10 mg sodium warfarin orally as soon as possible after surgery. Warfarin was then given daily according to the prothrombin time (PT), to obtain a PT of 16 seconds on the 5th post operative day. The PT was maintain at 16 to 18 seconds until the end of treatment. ASA and placebo patients received enteric coated tablets, 650 mg twice daily, in a double blind fashion beginning as soon as possible post operatively and continuing to the end of treatment. Surveillance testing and <sup>125</sup>I-fibrinogen leg scanning and impedance plethysmography was performed and venography was done if either test suggested thrombosis at the popliteal vein or above. Otherwise venography was performed at day 21 or prior to discharge, if earlier. Venous thrombosis occurred in 13 patients (20%) in the warfarin group, 27 patients (40.9%) in the ASA group, and 29 patients (46% in the placebo group ( $P=0.005$ ). Proximal vein thrombosis or pulmonary embolism occurred in 6 patients (9.2%) in the warfarin group, 7 patients (10.6%) in the ASA and 19 patients (30.2%) in the placebo group ( $P=0.002$ ). Two major hemorrhages occurred in the warfarin group, none in the ASA group, and 2 in the placebo group. The results of this study show sodium warfarin to be safe and effective in reducing thromboembolic complications in fractured hip patients and ASA to be effective in reducing thrombosis involving the proximal deep veins of the lower limbs in these patients.