Prevention of fatal pulmonary embolism and mortality in surgical patients: a randomized double-blind comparison of LMWH with unfractionated heparin.

Abstract:

The incidences of fatal pulmonary embolism and death in surgical patients receiving low-molecular-weight heparin thromboprophylaxis have not been previously determined in large, adequately designed clinical trials and information on the relative efficacy and safety of unfractionated and low-molecular-weight heparin in preventing these clinical endpoints is not available. In a double-blind study, 23078 surgical patients randomly received the low-molecular-weight heparin, certoparin (3000 anti Xa IU) subcutaneously once-daily, or unfractionated heparin (5000 IU) subcutaneously three-times daily, for a minimum of 5 days. The primary outcome measure, autopsy-proven fatal pulmonary embolism recorded up to 14 days after the end of prophylaxis, occurred in 0.152% (95% confidence interval (CI) 0.10, 0.20%; 35 of 23078 patients) of cases, with no significant difference between the certoparin-treated patients (0.147% (95% CI 0.077, 0.217%; 17 of 11542 patients) and patients treated with unfractionated heparin (0.156% (95% CI 0.084, 0.228%; 18 of 11,536 patients, P=0.868). The autopsy rate was 70.2%. Comparing mortality, there was no significant difference between the groups (1.44% [166 of 11542 certoparin patients] versus 1.27% [146 of 11536 unfractionated heparin patients]; P=0.279). The safety profiles of both treatment
groups were similar. Once-daily certoparin and three-times daily unfractionated heparin are equally effective and safe in reducing fatal pulmonary embolism and death to low levels in surgical patients and mirror the findings of comparative efficacy studies using surrogate endpoints.