Drug study shows improvement in major orthopedic surgery care

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An ultra-low-molecular-weight heparin called semuloparin has been found to reduce the incidence of venous thromboembolism in orthopedic surgery patients in a large clinical program being lead by a steering committee chaired by McMaster University professor Dr. Alexander Turpie.

The follow-up analysis of three recently completed international clinical studies on short-term venous thromboembolism (VTE) protective medicine in patients undergoing major orthopedic surgery demonstrated that the ultra-low-molecular-weight heparin semuloparin reduced the incidence of VTE and all-cause death by 25 per cent compared to the commonly used therapy drug enoxaparin (a low-molecular-weight heparin).

Patients undergoing major orthopedic surgery are at increased risk of developing a dangerous blood clot that blocks veins, which is known as venous thromboembolism (VTE). Without treatment, the incidence of confirmed deep-vein thrombosis, blood clots within the veins of the legs and pelvis, is up to 40 to 60 per cent following major orthopedic surgery.

"This is a potential advance in orthopedic surgery compared to current VTE prophylaxis options," said Turpie, a professor of medicine at the Michael G. DeGroote School of Medicine at McMaster.

The favourable benefit-to-risk profile observed with semuloparin compared to enoxaparin in the classic major orthopedic surgery model

supports the further evaluation of semuloparin as VTE preventative therapy in other areas including oncology, as VTE is a known complication in patients with cancer. Patients suffering from cancer have a four to seven fold greater risk for VTE.

Turpie's meta-analysis study reports results from 4,479 patients recruited in three orthopedic surgery studies in hip replacement (SAVE HIP), hip fracture (SAVE HIP-FRA) and knee replacement (SAVE KNEE). The objective of the three studies was to assess once-daily preventative treatment with semuloparin (20 mg) compared to enoxaparin (40 mg daily in hip, and 30 mg twice-daily for knee) for seven to 10 days.

The results of the SAVE program in orthopedic surgery were presented today at the 21st International Congress of Thrombosis in Milan, Italy, and organized by the Mediterranean League Against Thromboembolic Diseases.

Turpie is chairing the steering committee for the SAVE program, an international series of studies. The SAVE program is supported by sanofi-aventis, producer of semuloparin.

Semuloparin's benefit-to-risk profile in cancer is currently being investigated in two ongoing phase three clinical studies. SAVE ONCO evaluates semuloparin in patients with cancer undergoing chemotherapy. SAVE ABDO assesses the benefits of semuloparin in major abdominal surgery, mainly cancer surgery.

Provided by McMaster University