

Extended use of anti-clotting drug helps some bedridden patients

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A treatment plan used to prevent potentially dangerous blood clots in recovering surgical patients can also benefit some patients immobilized by acute medical illness, doctors have found in a multi-institutional study.

In women, patients age 75 or older, and patients strictly confined to 24-hour bed rest, a month of extended treatment with a blood thinner significantly reduced the chances of blood clots while only slightly increasing the risk of bleeding.

Researchers at Washington University School of Medicine in St. Louis and several other institutions report the results online this week in Annals of Internal Medicine. The double-blind, placebo-controlled trial was funded by Sanofi-Aventis, the manufacturer of enoxaparin, a form of the blood thinner heparin that was used in the study.

Causes of decreased mobility of patients in the study varied and included <u>heart failure</u>, infections and chronic respiratory disease.

"We currently treat acutely ill medical patients with a week or two of blood thinners to prevent clots," says co-author Roger D. Yusen, MD, associate professor of medicine at Washington University. "These results suggest that, depending on the patient, physicians may want to consider extending that treatment for an additional month."

Extended treatment with a blood thinner is already standard in such



contexts as recovery from knee and hip replacement surgery and abdominal cancer surgery.

Yusen is a member of the steering committee for the study, known as the EXCLAIM, or Extended Prophylaxis for Venous ThromboEmbolism (VTE) in Acutely Ill Medical Patients With Prolonged Immobilization trial.

To be eligible for the trial, patients had to be 40 years or older, have had decreased mobility within the three days prior to admission and have been likely to have decreased mobility for at least three more days after admission. Patients were given the conventional six to 14 days of enoxaparin and then randomized into two groups that received either enoxaparin or a placebo for an additional 28 days.

Researchers initially enrolled both patients who were on 24-hour bed rest and patients who were on bed rest except for the ability to use the bathroom. However, when monitoring during the early stages of the trial suggested an unfavorable risk to benefit ratio in the second group, the participation criteria for that group were adjusted to require the presence of at least one of three additional blood clot risk factors: age greater than 75 years, female gender or a previous history of a blood clot.

At the end of the treatment period, patients were scanned using an ultrasound for blood clots known as deep vein thromboses in the large veins in their upper legs.

"Clots in these areas tend to be bigger and have a greater chance of breaking away and traveling to the lungs, where they can cause a potentially fatal pulmonary embolism," Yusen says.

Researchers also followed up on patients six months after their participation in the trial began.



Their final analysis, which included results from more than 5,000 patients, showed that the rate of blood clots was 2.5 percent in the group that received extended treatment and 4 percent in the group that only received the conventional treatment, a statistically significant reduction in blood clots of 1.5 percent. Major bleeding risk was 0.8 percent in the treatment group and 0.3 percent in the placebo group, a statistically significant increase in bleeding of 0.5 percent. There was no difference in survival between the two groups.

"The benefits of extended treatment were restricted to three groups: patients who were in bed all day at the beginning of the trial, patients who were 75 years or older and female patients," Yusen says.

Yusen and his colleagues plan to further examine the results to see if they can fine-tune their recommendations for when extended-duration blood clot prevention can be beneficial.

More information: Hull RD, Schellong SM, Tapson VF, Monreal M, Samama M-M, Nicol P, Vicaut E, Turpie AGG, Yusen RD. Extended-duration venous thromboembolism prophylaxis in acutely ill medical patients with recently reduced mobility. Annals of Internal Medicine, published online.

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