Extending anti-clotting treatment after distal deep vein thrombosis could reduce further clot risk

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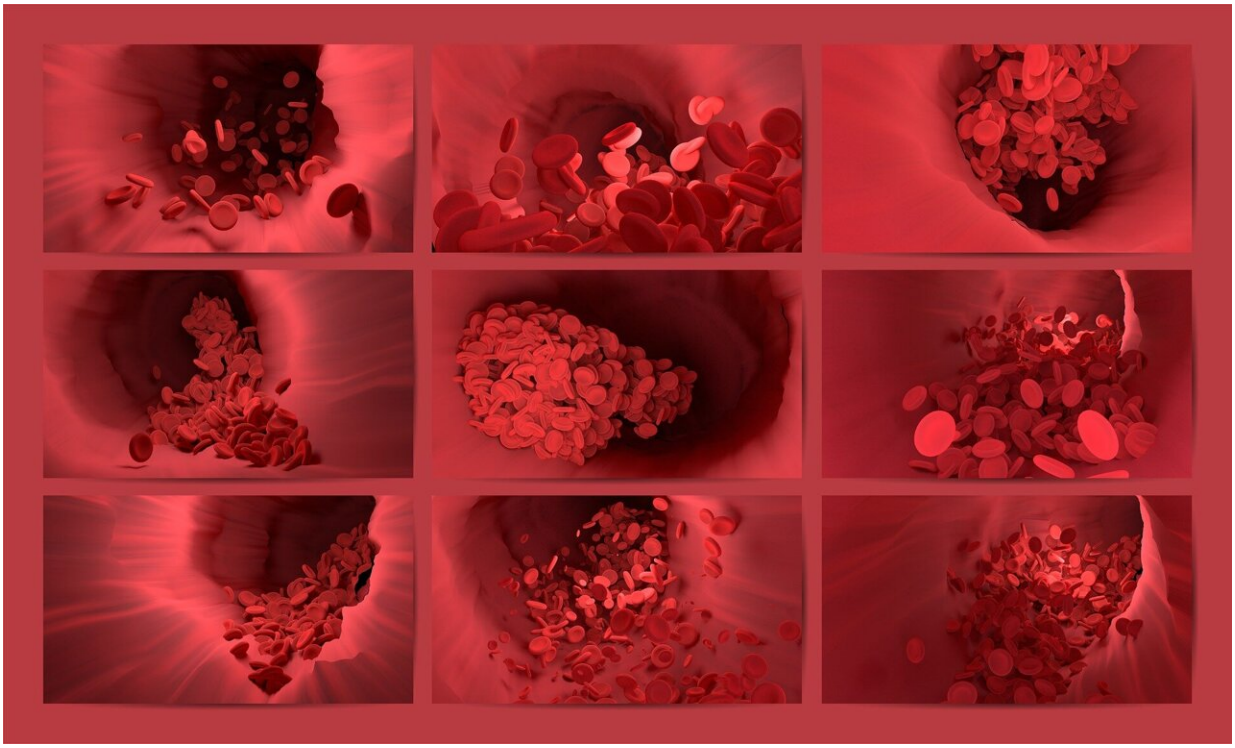

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Giving the anti-clotting drug rivaroxaban to patients for 12 weeks instead of the usual six after a blood clot in the lower leg reduces the risk of further clots developing up to two years after treatment, finds a trial

published by *The BMJ* today.

What's more, the additional six weeks of treatment did not result in increased bleeding risk, a common side effect of anti-clotting drugs.

Rivaroxaban is an anticoagulant drug. It's given to people at a high risk of getting dangerous blood clots to help their blood clot (thicken) more slowly.

Anticoagulation is known to prevent further clots developing in patients who have already had a blood clot in their leg, including those with isolated distal deep vein thrombosis (DVT). But doctors are still not sure whether all patients with distal DVT should receive anticoagulation, and for how long.

To address this uncertainty, researchers set out to compare two different treatment durations of rivaroxaban in 402 adults (average age 65; 58% women) diagnosed with isolated distal DVT at 28 specialist outpatient clinics across Italy.

None of the participants were pregnant or breastfeeding, had active cancer, kidney or liver problems, at high risk of bleeding, or unable to receive anticoagulant treatment due to an underlying condition.

After receiving standard dose rivaroxaban for six weeks, participants who had not developed any clotting or bleeding complications were randomly assigned to receive either rivaroxaban 20 mg or placebo once daily for an additional six weeks.

Participants were assessed for new clots or serious bleeding at three weeks, six weeks, three months, and 24 months, and were advised to seek medical advice if new signs or symptoms that potentially suggested recurrent events occurred.

The results show that after randomisation, 23 (11%) patients in the rivaroxaban group and 39 (19%) in the placebo group developed a further clot, either in the lower leg (isolated or recurrent distal DVT), the upper leg (proximal DVT), or the lung (pulmonary embolism).

Recurrent isolated distal DVT occurred in 16 (8%) patients in the rivaroxaban group and 31 (15%) in the placebo group, while proximal DVT or pulmonary embolism occurred in 7 (3%) patients in the rivaroxaban group and 8 (4%) in the placebo group.

No major bleeding events occurred during the two-year study period, and the researchers estimate that, for every 13 patients receiving additional rivaroxaban, one blood clot would be prevented.

The researchers point to some limitations, such as being unable to reach the ideal sample size of over 1000 patients owing to slow enrolment and the onset of the COVID-19 pandemic, and they can't rule out the possibility that diagnosis of isolated and recurrent distal DVT may have been overestimated.

However, this was a well-designed trial and results were consistent among patients with other types of clots, for example in the upper arm, suggesting that the findings are robust.

As such, the researchers conclude, "Rivaroxaban administered for three months effectively and safely reduces the risk of recurrent venous thromboembolism compared with rivaroxaban administered for six weeks in patients with isolated distal DVT."

These findings do not apply to patients with cancer-associated DVT and should not be extrapolated to other anticoagulant treatments, they add. "Additional investigation is still needed to identify low risk patients who may not require anticoagulant treatment."

More information: Rivaroxaban treatment for six weeks versus three months in patients with symptomatic isolated distal deep vein thrombosis: randomised controlled trial, *The BMJ* (2022). DOI: 10.1136/bmj-2022-072623