

Doctor, I have clot in my lungs. Do I need a clot-buster?

In people with pulmonary embolism, anticoagulants are used to prevent the formation of new blood clots while the person's body breaks down the clots slowly over time. Drugs that dissolve blood clots may work faster, but they are not better than anticoagulants at reducing risk of death and they increase the risk of serious bleeding.

What's the evidence?

Understanding the problem

People with PE have an increased risk of death, but the risk varies from person to person. People with a new PE are usually treated with anticoagulants because they reduce the risk of forming new clots and allow the person's body to naturally break down the clot over time.

Another option is to give a fibrinolytic drug, or "clot-buster", that breaks down the clot. However, fibrinolytic drugs have a higher risk of major bleeding than anticoagulants. In particular, bleeding into the brain is more common with fibrinolytic drugs, and this can lead to symptoms similar to a stroke. For this reason, fibrinolytic drugs are usually reserved for patients who have large clots.

In this study, researchers looked at the benefit and harm of a fibrinolytic drug plus an anticoagulant given to people with moderate-size PE compared with people given anticoagulants alone.

The study

Who? The study included 1006 people who had a moderate-size PE within the past 15 days plus evidence (on imaging or with a blood test) that their heart was working hard to maintain blood flow.

What? The study compared fibrinolytic drug plus anticoagulant with placebo plus anticoagulant.

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|---|-----------|-----------------------------------|
| Fibrinolytic drug plus anticoagulant | vs | Placebo plus anticoagulant |
|---|-----------|-----------------------------------|

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|--|----|---|
| <p>Fibrinolytic drug (Tenecteplase): a clot-buster given by injection into a vein.</p> <p>Heparin: an anticoagulant given by injection into a vein (usual care).</p> | | <p>Placebo: a substance administered by vein injection that has no effect on the clot but has the same volume and appearance as Tenecteplase.</p> <p>Heparin: an anticoagulant given by injection into a vein (usual care).</p> |

What the researchers found

People who received a fibrinolytic drug plus an anticoagulant did not have a lower risk of death than people who received an anticoagulant alone.

3 fewer people out of 100 who received a fibrinolytic drug developed low blood pressure requiring urgent treatment.

9 more people out of 100 had serious bleeding, and 18 more people out of 1000 bled into their brain while taking a fibrinolytic drug.

Summary of findings

Fibrinolytic drug plus anticoagulant vs placebo plus anticoagulant in people who have a moderate-size pulmonary embolism plus evidence their heart is working hard

| Outcomes at 7 days | Rate of events with fibrinolytic drug | Rate of events with placebo | Results |
|---|---------------------------------------|-----------------------------|--|
| Death from any cause | About 1 out of 100 people | 2 out of 100 people | No difference* |
| Low blood pressure requiring urgent treatment | About 2 out of 100 people | 5 out of 100 people | About 3 fewer people out of 100 had low blood pressure requiring urgent treatment while taking the fibrinolytic drug |

| Outcomes at 7 days | Rate of events with fibrinolytic drug | Rate of events with placebo | Results |
|-------------------------------------|---------------------------------------|-----------------------------|--|
| Major bleeding | 11 out of 100 people | 2 out of 100 people | About 9 more people out of 100 had major bleeding while taking the fibrinolytic drug |
| Stroke (due to bleeding into brain) | 20 out of 1000 people | About 2 out of 1000 people | About 18 more people out of 1000 had a stroke while taking the fibrinolytic drug |

*Although the rates for the 2 groups look different, the differences were not statistically significant—this means that the difference could simply be due to chance rather than due to the different treatments.

This Evidence Summary is based on the following article:

Meyer G, Vicaut E, Danays T, et al. **Fibrinolysis for patients with intermediate-risk pulmonary embolism.** *N Engl J Med.* 2014 Apr 10;370(15):1402-11. doi: 10.1056/NEJMoa1302097. PubMed (<https://www.ncbi.nlm.nih.gov/pubmed/24716681?dopt=Abstract>)

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