Vena caval filters for the prevention of pulmonary embolism (Review)

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Background
Pulmonary emboli (PE) can have potentially fatal consequences. Inferior vena caval filters (VCFs) are metal alloy devices that mechanically trap fragmented thromboemboli from the deep leg veins en route to the pulmonary circulation. Filters are designed to be introduced (and in the case of retrievable filters, removed) percutaneously. Although their deployment seems of theoretical benefit, their clinical efficacy and adverse event profile is unclear.

This is an update of a Cochrane review first published in 2007.

Objectives
To examine evidence for the effectiveness of VCFs in preventing pulmonary embolism (PE). Secondary outcomes were mortality, distal (to filter) thrombosis, and filter-related complications.

Search methods
The Cochrane Peripheral Vascular Diseases Group searched their Specialised Register (last searched October 2009) and the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library 2009, Issue 4 for randomised or controlled clinical trials of VCFs for the prevention of PE. The authors contacted filter manufacturers for information.

Selection criteria
Controlled clinical trials (CCTs) and randomised controlled trials (RCTs) that examined the efficacy of filters in preventing PE.

Data collection and analysis
Two authors independently extracted information.

Main results
Two studies were included involving a total of 529 people. One open quasi-randomised trial of 129 participants with traumatic hip fractures showed a reduction in PE but not mortality over a 34 day period in the filter group. The PREPIC (Prévention du Risque d’Embolie Pulmonaire par Interruption Cave) trial, was an open RCT of 400 participants with documented proximal deep vein thrombosis (DVT) or PE who received concurrent anticoagulation. Permanent VCFs prevented PE at eight years. No reduction in mortality was seen, but this reflected an older study population; the majority of deaths were due to cancer or cardiovascular causes. There was an increased incidence of (DVT) in the filter group. Adverse events were not reported.
Authors’ conclusions

No recommendations can be drawn from the two studies. One study showed a reduction in PE rates but not mortality, but was subject to significant biases. The PREPIC study lacked statistical power to detect a reduction in PE over shorter and more clinically significant time periods. However, the trial demonstrated that permanent VCFs were associated with an increased risk of long term lower limb DVT.

There is a paucity of VCFs outcome evidence when used within currently approved indications and a lack of trials on retrievable filters. Further trials are needed to assess vena caval filter safety and effectiveness.

Plain Language Summary

Vena caval filters for the prevention of pulmonary embolism

Blood clots in the lungs are called pulmonary emboli. They originate in the legs, fragment and travel to the lungs via the inferior vena cava. Vena caval filters are metal alloy devices inserted within the inferior vena cava to trap blood clots and thus prevent pulmonary emboli. Further emboli are usually prevented by blood thinning medications (anticoagulants).

In some instances (approximately 4% of cases), anticoagulation alone is insufficient to prevent more emboli or it is too dangerous for anticoagulation to be given because the person has a high risk of bleeding. Blood clots are known to occur as a result of certain types of surgery or injuries, and are more likely to fragment if they extend into the thigh or pelvis.

Vena caval filters have been in use since the 1970s and were designed to be left permanently within the inferior vena cava. The latest generation of filters are temporary or ‘retrievable’. They can be removed at the manufacturer’s recommendation between two to 12 weeks, if their use is no longer required. However, despite being called retrievable, a number of retrievable filters cannot be removed because of complications. The long-term safety profile of these devices left inside the body remains to be seen. The authors looked for articles comparing permanent and temporary (or retrievable) filters and comparisons between the different filter designs.

Two trials were included in the review involving a total of 529 people. No recommendations can be made regarding filter efficacy in preventing pulmonary embolism. One trial which was conducted in 1972 showed a reduction in pulmonary embolism rates but not deaths in a group of people who suffered traumatic hip fractures and who had a filter inserted. No preventive DVT treatment was given as this was controversial at the time. Outcomes were given at 34 days. The trial participants were inadequately randomised, had a higher proportion of people who were not able to undergo surgical fixation in the control group, and outcome assessors were not blinded.

In the PREPIC trial, caval filters were associated with an increased risk of blood clot formation in the legs following their insertion. This study did not demonstrate any difference in the death rates between the two groups; the participants were older (average age 73 years) with co-existing medical conditions and the majority of people died from cancer-related causes or heart problems. No details were recorded of adverse events of filters, but the numbers in this trial were not of sufficient size to detect them.

There is a lack of information on the effectiveness of caval filters in other clinical scenarios, especially in the two situations where they are used most frequently and thought to be the most advantageous. These are when patients cannot be anticoagulated, or when pulmonary embolism occurs despite adequate anticoagulation. Vena caval filter use is increasing and more trials are needed to confirm their benefit and accurately assess their safety.