

Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

Medwave2017;17(Suppl2):e6935 doi: 10.5867/medwave.2017.6935

Is it worth adding an inferior vena cava filter to anticoagulation in thromboembolic disease?

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Citation: Yunes A, Aizman A. Is it worth adding an inferior vena cava filter to anticoagulation in thromboembolic disease?. *Medwave*2017;17(Suppl2):e6935 doi: 10.5867/medwave.2017.6935

Submission date: 23/3/2017

Acceptance date: 30/3/2017

Publication date: 28/4/2017

Abstract

Some patients who have presented a thromboembolic event persist with a high risk of recurrence despite anticoagulant treatment. It has been suggested that adding an inferior vena cava filter may reduce this risk, but the clinical effects of this measure are not clear. To answer this question we searched in Epistemonikos database, which is maintained by screening multiple information sources. We identified three systematic reviews including four randomized trials answering this question. We extracted data, conducted a meta-analysis and generated a summary of findings table using the GRADE approach. We concluded there might be little or no difference on the occurrence of deep venous thrombosis by adding an inferior vena cava filter in anticoagulated patients, and it is not clear whether there are differences in the occurrence of pulmonary embolism or mortality because the certainty of evidence is very low.

Problem

Patients with thromboembolic disease have a variable risk of developing recurrent thrombi that might be detached and travel intravascularly in favor of circulation. After a first episode, this risk persists in spite of anticoagulant treatment, so it has been proposed that the placement of an inferior vena cava filter in patients with high risk of developing pulmonary embolism might be beneficial.

Inferior vena cava filters are intraluminal devices that mechanically trap fragmented thrombi from deep veins of the leg, thus preventing their passage into the lung. They are designed to be introduced percutaneously, through jugular, subclavian or femoral veins depending on the filter model. Although its use for prevention of pulmonary

embolism appears to be beneficial in theory, its clinical efficacy and adverse events profile are not clear.

Methods

We used Epistemonikos database, which is maintained by screening multiple information sources, to identify systematic reviews and their included primary studies. With this information we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages

- There might be little or no difference in the occurrence of deep venous thrombosis when an inferior vena cava filter is added in anticoagulated patients.
- It is unclear whether there are differences in the occurrence of pulmonary embolism or mortality by adding an inferior vena cava filter in anticoagulated patients because the certainty of the evidence is very low.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found three systematic reviews [1],[2],[3] including four primary studies answering the question of interest, reported in six references [4],[5],[6],[7],[8],[9]. All of the studies correspond to randomized controlled trials.</p>
<p>What types of patients were included*</p>	<p>All of the trials included patients at high risk for pulmonary embolism [4],[7],[8],[9]. One trial (PREPIC) included patients with documented proximal deep vein thrombosis or pulmonary embolism [4], another trial included patients with documented deep vein thrombosis and cancer [7], another trial (FILTER-PEVI) included patients with symptomatic proximal deep venous thrombosis [8], and the remaining trial included inpatients with symptomatic acute pulmonary embolism with pre-existing deep venous thrombosis presenting a high risk of recurrence [9].</p>
<p>What types of interventions were included*</p>	<p>All of the trials evaluated the addition of an inferior vena cava filter to anticoagulant treatment for the prevention of pulmonary embolism. Two trials used a permanent filter; one used Vena Tech LGM, B. Braun; Titanium Greenfield, Boston Scientific; Cardial, Bard; Bird's Nest, Cook Group [4], and the other trial used Vena Tech Vena TMLP, B. Braun [7]. One trial used a removable vena cava filter (ALN filter, ALN Implants Chirurgicaux) [9]. One trial used several filters (Celect, Tulip [Cook Medical, Bloomington, IN], Optease [Cordis, Miami, FL]; Eclipse [Bard, Tempe, AZ]) ** [8]. All trials compared against anticoagulant treatment; one trial used low molecular weight heparin (enoxaparin), unfractionated heparin or vitamin K antagonists [4]; one trial used fondaparinux [7]; another trial used tinzaparin, enoxaparin, fondaparinux, unfractionated heparin or vitamin K antagonists; the remaining trial used enoxaparin or unfractionated heparin in those with renal insufficiency, followed by warfarin ** [8].</p>
<p>What types of outcomes were measured</p>	<p>The different systematic reviews grouped the outcomes as follows:</p> <ul style="list-style-type: none"> • New pulmonary embolism • Recurrent pulmonary embolism • New deep venous thrombosis • Recurrent deep venous thrombosis • Mortality (all-cause) • Major bleeding • Thrombosis distal to the inferior vena cava filter • Complications related to the inferior vena cava filter

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

** Information extracted from the full text of the primary study.

Summary of findings

The information on the effects of the addition of an inferior vena cava filter to anticoagulation in patients with thromboembolic disease is based on four randomized trials involving 1004 participants in total [4],[7],[8],[9]. All of the trials reported the outcomes pulmonary embolism, deep venous thrombosis and mortality. The summary of findings is as follows:

- It is not clear whether there are differences in the occurrence of pulmonary embolism when adding an inferior vena cava filter in anticoagulated patients because the certainty of the evidence is very low.
- There may be little or no difference in the occurrence of deep venous thrombosis when an inferior vena cava filter is added in anticoagulated patients. The certainty of the evidence is low.
- It is not clear whether there are differences in mortality when adding an inferior vena cava filter in anticoagulated patients because the certainty of the evidence is very low.

Inferior vena cava filter plus anticoagulation in thromboembolic disease				
Patients	High-risk thromboembolic disease			
Intervention	inferior vena cava filter (IVCF) plus anticoagulation			
Comparison	anticoagulation			
Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITH anticoagulation	WITH IVCF + anticoagulation		
	Difference: patients per 1000			
Pulmonary embolism	26 per 1000	25 per 1000	RR 0.96 (0.42 to 2.2)	⊕○○○ ^{1,2} Very low
	Difference: 1 patient less per 1000 (Margin of error: 15 less to 31 more)			
Deep venous thrombosis	78 per 1000	76 per 1000	RR 0.98 (0.69 to 1.39)	⊕⊕○○ ^{1,3} Low
	Difference: 2 patients less per 1000 (Margin of error: 24 less to 30 more)			
Mortality	76 per 1000	100 per 1000	RR 1.32 (0.89 to 1.97)	⊕○○○ ^{1,2} Very low
	Difference: 24 patients more per 1000 (Margin of error: 8 less to 73 more)			

RR = Risk ratio.
Margin of error = 95% confidence interval (CI).
GRADE: evidence grades of the GRADE Working Group (see later in this article)

* The risk **WITH anticoagulation** is based on the risk in the control group of the trials. The risk **WITH IVCF + anticoagulation** (and its margin of error) is calculated from relative effect (and its margin of error)

¹ We downgraded the certainty of the evidence in one level for risk of bias.
² We downgraded the certainty of the evidence in two levels for imprecision, since the confidence interval is very wide.
³ We downgraded the certainty of the evidence in one level for imprecision, since the confidence interval is wide.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision.

Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented in this summary applies to patients at high risk of developing pulmonary embolism with demonstrated thromboembolic disease.
 - It does not apply to patients who have a formal contraindication for anticoagulation, which is one of the most common situations in which the use of vena cava filters is proposed in the medical practice.
-

About the outcomes included in this summary

- The outcomes included in the summary of findings table are those considered critical for decision-making by the authors of this summary. These generally coincide with those evaluated in the systematic reviews identified and in the main clinical guidelines.
 - It should be noted that in many of these trials, pulmonary embolism and deep venous thrombosis were screened even in the absence of symptoms, which could overestimate the incidence of events and show differences of arguable clinical value.
-

Balance between benefits and risks, and certainty of the evidence

- Given the uncertainty derived from the available evidence, it is not possible to make an adequate balance on the risk/benefit of this intervention.
-

Resource considerations

- Adding an inferior vena cava filter to anticoagulation leads to increased costs.
 - It is not possible to make an adequate balance between costs and benefits due to the existing uncertainty.
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What would patients and their doctors think about this intervention

- With the evidence presented in this summary most patients and clinicians should lean against the use of the intervention.
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Differences between this summary and other sources

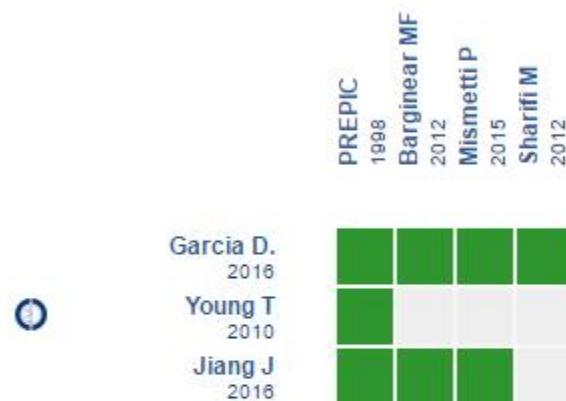
- The conclusions of this summary are consistent with those of two reviews identified [2],[3]. Another review [1] concluded that there is a decrease in the risk of pulmonary embolism with the addition of an inferior vena cava filter.
 - Our summary agrees with the conclusions of the American College of Chest Physicians 2016 clinical guideline [10] that recommends against the use of an inferior vena cava filter in patients with acute events of deep venous thrombosis or pulmonary embolism who can receive anticoagulant treatment.
-

Could this evidence change in the future?

- The probability that the conclusions of this summary would change in the future is high, due to the existing uncertainty.
 - However, we did not identify any ongoing trial evaluating this question in the International Clinical Trials Registry Platform of the World Health Organization.
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How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The *rows* represent systematic reviews that share at least one primary study, and *columns* display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: [Vena cava filters plus anticoagulation versus anticoagulation for patients with thromboembolic disease.](#)

Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here <http://dx.doi.org/10.5867/medwave.2014.06.5997>.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-

makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org).

These summaries follow a rigorous process of internal peer review.

Conflicts of interest

The authors do not have relevant interests to declare.

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