When to implant a permanent or retrievable filter in the vena cava? *Quand poser un filtre cave temporaire ou définitif?*

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> Conflict of interest: None declared

Is DVT a benign disease?



Flinterman LE, van Hylckama Vlieg A, Cannegieter SC, Rosendaal FR (2012) Long-Term Survival in a Large Cohort of Patients with Venous Thrombosis: Incidence and Predictors. PLoS Med 9(1): e1001155. doi:10.1371/journal.pmed.1001155

Rudolf Ludwig Karl Virchow (1821-1902)

"The detachment of larger or smaller fragments from the end of the softening thrombus which are carried along by the current of blood and driven into remote vessels. This gives rise to the very frequent process on which I have bestowed the name of Embolia." 1856

How PE occurs?

- Thrombus formation in a vein is a biological phenomenom imbalance toward fibrin formation and/or weakness of physiological fibrinolysis
- Thrombus detachment a less known phenomenom and migration to the lungs is a pure hemodynamic sequence with also the risk of paradoxical emboli
- Size of the thrombi and frequency of migration events determine symptoms

Present Pulmonary embolism prevalence and mortality

- The proportion of deaths caused by pulmonary embolism appears to be considerably lower than the widely published rate, and of this small number, few have a pre-mortem diagnosis of DVT or pulmonary embolism.
- There is little scope for further reduction of pulmonary embolism mortality through use of caval filters according to guidelines.
- Current policy on pulmonary embolism risk prevention appears to be based on an overestimate of the level of risk.

Caval interruption Devices

- Thread Ligature of femoral veins and vena cava
- Caval clip
- Umbrella Mobin Udin
- The Greenfield filter (introduction of the Greenfield IVCF in 1973)
 - Acier
 - Titane
 - Titane percutané
- Other types of VC filters

Numerous publications and only 2 RCTs!



Year



Rational of filter placement

Trapping clots Avoiding major PE Allowing physiological thrombolysis in the filter



Technique

- Measure the caval diameter
- Prefer the Jugular or the brachial routes
- Always Percutaneously
- Always in the Angiosuite
- Always under Local anesthesia
- Obtain a Good renal carrefour cavogram
- Pitfalls: Avoid too low implantation or intrarenal leg anchoring or tilting filter

Complications of permanent caval filters

- The main complication of caval filters is DVT
- Patients with CF do have more DVT in the follow up than patients without filters
- Other complications are
 - Tilting
 - Perforations
 - Caval perforation
 - Aortic perforation with pseudoaneuvrism
 - Fracture and Migrations even in the right ventricle
 - Caval thrombosis

KAPLAN-MEIER SURVIVAL CURVE, DEMONSTRATING A PREDICTED FRACTURE RISK OF 40% AT 5.5 YEARS



Complications of IVCF (1):Thrombosis



Complications of IVCF (2):Thrombosis





Aortic pseudoaneurism due to perforation of the two walls by a VCF

st Med Fr Rate Med ZD Opt:Gen

Col 61%, Map 5 WF Low PRF 2500 Hz Flow Opt Med V



Potential indications of filter placement

- Patients with no DVT and or PE and at risk of thrombosis and CI for AC
- So called prophylactic use
- Patients with DVT and/or PE and CI to AC
- Often used to bridge the period when AC will be less risky

Observational and retrospective studies

• What do they teach to us?

Graph shows numbers of patients with a caval filter (*) or surgical caval interruption (•) over time.



Radiology

Four-year trend in the age of patients with caval filters.



Athanasoulis C A et al. Radiology 2000;216:54-66

Radiology

Sex of patients with caval filters.



Radiology

Graph shows types of clinical thromboembolic events that led to filter placement over time: ♦ = PE; □ = deep venous thrombosis; and ▲ = no event, filter for prophylaxis.



Athanasoulis C A et al. Radiology 2000;216:54-66

Radiology

Graph shows types of imaging examinations used to confirm venous thromboembolism: ♦ = pulmonary angiography, □ = venous US, △ = conventional venography, and • = ventilationperfusion lung scans.



Athanasoulis C A et al. Radiology 2000;216:54-66

Radiology

Pie chart shows percentages of caval filters implanted according to the day of the week.



Athanasoulis C A et al. Radiology 2000;216:54-66

Radiology

Graph shows numbers and types of filters implanted over time: BN = Bird's Nest, yellow; GF = Greenfield 24-F standard, dark orange; GP = Greenfield 24-F standard introduced percutaneously light blue: GS - Greenfield slim, gray: GT - Greenfield titanium, li...



Athanasoulis C A et al. Radiology 2000;216:54-66

Radiology

Kaplan-Meier survival curve for 65 patients who developed fatal postfilter PE.



Kaplan-Meier survival curve for fatal postfilter PE in 1,731 patients.



Inferior vena caval thrombosis after filter placement.



Kaplan-Meier estimates of survival for patients with neoplasms and patients without neoplasms.



Radiology

Kaplan-Meier estimates of survival free of caval thrombosis in 1,731 patients.



Clinical trials and meta-analysis

• The Cochrane review

Young T, Tang H, Hughes R



Figure I. Flow diagram of search results

Search results flow diagram



Methodological quality summary: review authors' judgements about each methodological quality



Adequate sequence generation?

Allocation concealment?

Blinding? (Mortality)

Blinding? (Pulmonary embolism)

Incomplete outcome data addressed? (Mortality)

Incomplete outcome data addressed? (Pulmonary embolism).

Free of selective reporting?

PREPIC 1

PREPIC study group,10 2005 Randomized trial Permanent filters (VenTech, titanium GF, Cardinal, bird's nest)

- 400 patients: indications were DVT with or without PE, randomized to receive filter or not in addition to anticoagulation therapy for at least 3 mo
- 8 years
- Symptomatic PE in 9 patients with filters (6.2%) and 24 patients without filters (15.1%); DVT in 57 with filters (35.7%) and 41 without filters (27.5%), post-thrombotic syndrome in 109 (70.3%) with filters and 107 (69.7%) without filters
- At 8 years, 103 patients with filters had died (2 from PE), and 98 without filters had died (5 from PE);
- Conclusion is that IVC filters reduce risk of PE but increase risk of DVT and have no effect on overall survival or major bleeding events

TABLE 2. PRINCIPAL END POINTS WITHIN THE FIRST 12 DAYS AFTER RANDOMIZATION TO THE FILTER OR NO-FILTER GROUP.

NEJM

END POINT	FILTER	No Filter	Odds Ratio (95% CI)*	P Value
	number (p	ercent)		
Pulmonary embolism				
Symptomatic†	2	5		
Asymptomatic	0	4		
All‡	2 (1.1)	9 (4.8)	0.22 (0.05-0.90)	0.03
Major bleeding	9 (4.5)	6 (3.0)	1.49	0.44
Death	5 (2.5)	5 (2.5)	(0.53-4.20) 0.99 (0.29-3.42)	0.99

*CI denotes confidence interval.

[†]The category includes certain or highly probable fatal pulmonary embolism.

‡Information about the primary end point was missing for 28 patients. Percentages were based on the 372 patients who were evaluated.
 TABLE 3. PRINCIPAL END POINTS DURING THE TWO-YEAR

 FOLLOW-UP PERIOD IN THE FILTER AND NO-FILTER GROUPS.*

EVENT AND TIME OF OCCURRENCE	FILTER	No Filter	Odds Ratio (95% CI)	P Value
	number	(percent)		
Symptomatic pulmonary				
Enrollment 2 mg	2	4		
Enrollment-3 mo	2	0		
>3 mo-1 yr	0	4		
>1-2 yr	4	12 ((2)	0.50	0.17
All	6 (3.4)	12 (6.3)	(0.19 - 1.33)	0.16
Recurrent deep-vein thrombosis				
Enrollment-3 mo	9	6		
>3 mo-1 vr	8	7		
>1-2 vr	20	8		
All	37 (20.8)	21 (11.6)	1.87	0.02
	, ,	· · · ·	(1.10 - 3.20)	
Major bleeding			(,	
Eprollment_3 mo	11	10		
$>3 \text{ mo}_{-1} \text{ yr}$	5	8		
>1_2 yr	1	4		
>1-2 yi	17 (8 8)	22 (11.8)	0.77	0.41
All	17 (0.0)	22 (11.0)	(0.41 1.45)	0.41
			(0.41-1.45)	
Death				
Enrollment-3 mo	15	10		
>3 mo-1 yr	12	12		
>1-2 yr	16	18		
All	43 (21.6)	40 (20.1)	1.10 (0.72-1.70)	0.65

*Estimates of incidence were derived from Kaplan–Meier survival analysis. CI denotes confidence interval.

†The category includes certain or highly probable fatal pulmonary embolism.

Results (1)

Référence

Kaplan-Meier analysis of time to pulmonary embolism



Kaplan-Meier analysis of time to deep vein thrombosis



Kaplan Meyer analysis of survival



Cochrane data base review (2010)

- 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 1 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.

Future of caval interruption (1): Retrievable Filters

- Retrievable Filters (RF) should be tested in RCTs
- Long term complications can be avoided with retrievable filters but
 - Is there at the price of less efficacy?
 - Are RF truly retrieved? In fact 70 80 % of RF stay in the vena cava...

Future of caval interruption (2a):

New devices with new design and better synergy of prevention



Future of caval interruption (2b):

New devices with new design and better synergy of prevention

- Stent Filter
 - The filter is transformed in a kind of stent with a balloon and stays open in the caval wall
- Crux filter
 - Completely new device presently in the process of FDA approval
- Combination of mechanical compression and active muscular contraction of the calf to lower the DVT rate in patients with a filter because anticoagulants cannot be used
- Better synergy in the bridge before AC can be used especially in trauma or neurosurgical patients



Future of caval interruption (3): new RCT(s)

Clinical Trials gov				Home	Search	Study Topics	<u>Glossary</u>
A	service of the U.S. National Inst	itutes of Health					Search
-							
2.5	Full Text View	Tabular View	No Study Results Poster	1	Relate	ed Studies	

PREPIC 2 : Prevention of Recurrent Pulmonary Embolism by Vena Cava Interruption (PREPIC2)

This study is currently recruiting participants.

Verified November 2011 by Centre Hospitalier Universitaire de Saint Etienne

First Received on April 4, 2007. Last Updated on November 10, 2011 History of Changes

Sponsor:	Centre Hospitalier Universitaire de Saint Etienne		
Collaborators:	Ministry of Health, France Fondation de France Fondation de l'Avenir ALN Implants Company Agence Nationale de Recherche sur le SIDA (ANRS), France		
Information provided by (Responsible Party):	Centre Hospitalier Universitaire de Saint Etienne		
ClinicalTrials.gov Identifier:	NCT00457158		

PREPIC 2 study

- Purpose: The purpose of this study is to assess efficacy and safety of optional vena cava filter implanted 3 months in prevention of recurrent pulmonary embolism in patients presenting with acute pulmonary embolism associated with thrombotic risk factors
- <u>Condition</u> Pulmonary Embolism/Venous Thrombosis
- Intervention Device: ALN optional filter versus
 Device: No ALN optional filter
- **<u>Phase</u>** Phase IV

If you decide to implant a filter which is the best ?

PE prevention



Figure 2 The cumulative incidence of PE after placement of various vena caval filter models or treatment with anticoagulation (data on anticoagulation derived from the meta-analysis of Douketis et al.⁶³).

DVT after placement



Figure 3 The cumulative incidence of DVT after placement of various vena caval filter models or treatment with anticoagulation (data on anticoagulation derived from the meta-analysis of Douketis et al.⁶³).

VC Thrombosis after placement



The trauma patient

Cohort studies reporting PE in trauma patients (observational studies)

	Experim	ental	Contr	lor		Odds Ratio		Odds Ratio			
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	8	M-H	Fixed, 95%	6 Cl	
Gorman 2009	1	54	0	58	1.3%	3.28 [0.13, 82.27]	line -				
Gosin 1997	0	99	12	249	19.3%	0.10 (0.01, 1.63)		*			
Khansannia 1995	0	108	13	216	24.3%	0.07 [0.00, 1.18]			-		
Rodriguez 1996	1	40	14	80	24.7%	0.12 (0.02, 0.96)	-				
Rogers 1995	3	- 83	23	692	10.2%	0.47 (0.06, 3.53)				-	
Rogers 1997	1	35	6	83	9.4%	0.38 [0.04, 3.26]				8	
Rosenthal 1994	0	29	9	94	10.9%	0.17 (0.01, 3.08)	+			-	
Total (95% CI)		428		1472	100.0%	0.21 [0.09, 0.49]		-	6		
Total events			76								
Heterogeneity: Chi? =	4.87. df=	6 (P = 0	56); (*=)	0%			dia.				
Test for overall effect	Z = 3.59 (P = 0.00	03)	0563			0.01	0.1	1	10	100
								Favours experi	mental F	avours contre	ol.

Cohort studies reporting DVT (observational studies)



Indications for IVC filter placement

Appropriate Indication

- Contraindication to anticoagulation

Potential Indications

- Failure of adequate anticoagulation
- Pulmonary thromboembolectomy patients
- Prophylaxis in high-risk trauma patients
- Extensive free-floating iliofemoral thrombus
- Thrombolysis of ilio-caval thrombus

Unsubstantiated indications

- Treatment of VTE in
 - Cancer patients
 - COPD patients
 - Patients with poor cardiopulmonary reserve
 - Pregnant patients
 - Organ transplant patients
 - Patients with history of GI bleed
- Prophylaxis in burn patients
- Prophylaxis in bariatric surgery patients



Conclusion (1): non trauma patients

Risk: Overtreatment because of overdiagnosis and fear of PE in recent era?

There has been a substantial reduction in the proportion of deaths of hospital inpatients due to pulmonary embolism in the last 30 years from around 10% to 1% of deaths and from around 1% to 0.01% of admissions. Current NHS prioritization of VTE appears to be based on outdated estimates of the magnitude of the problem.

J R Soc Med 2011: 104: 327–331. DOI 10.1258/jrsm.2011.100395

Accepted indications for percutaneous IVC filter placement

- Evidence of pulmonary embolism, IVC, iliac, femoral-popliteal DVT and one/more of the following:
 - 1. Contraindication to anticoagulation
 - 2. Complication of anticoagulation
 - 3. Failure of anticoagulation
- 2. Massive pulmonary embolism with residual DVT in a patient at risk for further pulmonary embolism.
- 3. Free floating iliofemoral or IVC thrombus
- 4. Severe cardiopulmonary disease and DVT

Conclusion (2): trauma patients

Risk: underutilisation because of rare indications or overuse in large prophylactic indications

In trauma patients VTE occur in 7% of critically injured trauma patients who cannot receive chemical prophylaxis. Aggressive screening and/or prophylactic IVCF placement may be considered in patients with a PMH of DVT or extremity fractures when anticoagulation is prohibited.

If you have understood the problem of caval filters would you like to share it?

Where should you post your status?



Look at my preferred social network!

Rechercher dans le sit 👂



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- Groupes de travail 1 à 7 »
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Merci de votre attention



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