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Decision analysis of retrievable inferior vena cava filters in patients without pulmonary embolism

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Background: **Retrievable filters are increasingly implanted for prophylaxis in patients without pulmonary embolism (PE) but who may be at transient risk. These devices are often not removed after the risk of PE has diminished. This study employs decision analysis to weigh the risks and benefits of retrievable filter use as a function of the filter's time in situ.**
Methods: **Medical literature on patients with inferior vena cava (IVC) filters and a transient risk of PE were reviewed. Weights reflecting relative severity were assigned to each adverse event. The risk score was defined as weight × occurrence rate and combines the frequency and severity for each type of adverse event. The value function in the decision model combines the following risks: (1) risk in situ; (2) risk of removal, and (3) relative risk without filters. A decreasing net risk score represents a net expected benefit, and an increasing net risk score indicates the expected harm outweighs the expected benefit.**
Results: **The net risk score reaches its minimum between day 29 and 54 postimplantation. This is consistent with an increasing net risk associated with continued use of retrievable IVC filters in patients with transient, reversible risk of PE. The results were insensitive to reasonable variations in the assessed weights and adverse event occurrence rates.**
Conclusions: **For patients with retrievable IVC filters in whom the transient risk of PE has passed, quantitative decision analysis suggests the benefit/risk profile begins to favor filter removal between 29 and 54 days after implantation. (J Vasc Surg: Venous and Lym Dis 2013;1:376-84.)**

The use of inferior vena cava (IVC) filters in patients without a history of pulmonary embolism (PE), commonly referred to as *prophylactic use*, is considered off-label use of the device because it lies outside of the indications for use that the U.S. Food and Drug Administration (FDA) have cleared for these devices. Currently, all IVC filters on the market in the United States have the following indications for use, which the FDA believes are appropriate based on the clinical data supporting their use: "for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism when anticoagulant therapy has failed or is contraindicated."

In addition, some filters are able to be retrieved when filtration is no longer necessary. These filters contain the following statement in the indications "The filter may be retrieved in patients who no longer require a filter." Importantly, all retrievable filters are cleared as permanent devices as well. Any use outside the above-mentioned FDA-labeled indications is considered off-label use of the device.

Multiple factors have contributed to the rise in such use of these devices, including the introduction of retrievable filters, improved interventional skills by physicians, medico-legal factors, and continued development of new devices. It is unknown how many retrievable filters are placed for permanent or retrievable use. The use of retrievable IVC filters is particularly attractive for clinicians in patients who are considered to have a high risk for PE but have a temporary contraindication to anticoagulant therapy. However, because there are significant limitations in the studies of patients with this indication, the benefit/risk balance over time of off-label IVC filter implantation in a patient without a history of PE is unclear.

The most common adverse events associated with IVC filters include IVC thrombosis, deep vein thrombosis (DVT), access site thrombosis, filter migration, caval

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penetration, and filter fracture. Postmarket adverse event reports suggest that the number of these filter-related events has risen over the past decade. The increase in prophylactic use of the devices[1,2] and the number of reported adverse events led the FDA to release an initial communication on August 9, 2010, which recommended that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.[3] Increased retrieval rates of retrievable filters in patients who no longer require filtration might reduce the associated long-term complications.

Given that a well-controlled clinical study has not been conducted to address how device-related adverse events vary with time and the clinical impact of retrieval vs continued implant duration, quantitative decision analysis is an alternative tool to investigate these issues based on the information currently available. Decision analysis has been previously used in the area of PE treatment and IVC filters.[4-6]

In this article, we describe the materials, methods, and results of a mathematical model that was developed using data publicly available in the medical literature to determine whether there is a time period during which the risk of having the device in situ is expected to outweigh the benefits.

METHODS

Decision analysis. To address the issues of risks related to implant duration and retrieval, a quantitative decision analysis model was developed to analyze how the relative risks of implant, retrieval, or continued implantation vary as a function of time for patients without PE, but who were considered at high risk of developing it. Such patients would include trauma victims and bariatric and orthopedic surgery patients. Quantitative decision analysis is a mathematical tool used to describe, inform and analyze decision making in the presence of uncertainty. This method of analysis provides insight by explicating the values that drive decisions, such as treatment objectives or preferences.[7-9] The analysis combines values and data, accounting for differences in preferences and uncertain information.

Data. Data were collected from the literature to assess rates of adverse events at different times after implantation. A search of the medical literature from 2000 to 2009 using PubMed and including the search terms *vena cava filter*, *IVC filter*, *IVCF*, *caval interruption*, and *caval filtration* was performed. Publications without abstracts, review articles, non-English language articles, clinical studies with fewer than 20 patients, and duplicates were all excluded. Original publications from randomized controlled studies, regardless of indication, were included.[10] A total of 188 studies met the inclusion criteria. From those, we identified 30 publications involving patients with transient risk of PE who commonly have short-term need for IVC filtration (eg, trauma, bariatric surgery, and orthopedic surgery). Of these, 12 publications were excluded because they either did not provide quantitative results or did not specify follow-up time frames or the study sample size. The remaining 18 publications,[11-28] in addition to the original publication from the Prévention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) study, which is the only randomized controlled trial comparing filter vs nonfilter, were selected for the decision analysis (Fig 1; Table I).[10] Data from the FDA's Manufacturer and User Facility Device Experience Database (MAUDE) were not included in this analysis since that information does not provide adverse event rates.

Patients. Patients described in the literature with the short-term need for filtration were heterogeneous and encompassed different comorbidities, demographics, and anticoagulation regimens. Because patient-level data were lacking, patients were assumed to have similar risk profiles and prognostic characteristics (ie, patient subgroups were assumed to be exchangeable), although we recognize that the risks and benefits for individual patients may vary.

Weight of adverse events. Adverse events associated with IVC filters were assigned numerical weights based on a scale developed from independent rankings by three physicians: two vascular surgeons and one interventional radiologist (Table II). To validate the results, we later consulted six additional physicians (three vascular surgeons, two interventional radiologists, and one cardiologist). The scale ranges from 0 (least severe) to 10 (most severe [ie, death]). Uncertainty about weights and variability in clinical significance of individual adverse events was reflected by the range of assigned values. When a range of values was given, sensitivity analysis of the model was performed for the whole range.

Definition and classification of risk score. Risk score at time t for a specific adverse event (AE) is defined as the cumulative occurrence rate from time *0* to *t*.

$$RS_{AE}(t) = Weight_{AE} \int_{s=0}^{t} OR_{AE}(s)\mathrm{d}s,$$

where $Weight_{AE}$ is the weight for AE and $OR_{AE}(s)$ is the density function of the occurrence rate for AE. The risk score combines the frequency and severity for each type of adverse event. The risk score is unitless and is relative because the weights are measured on a relative scale that compares the severity of different adverse events. The weight ranges from 0 (no harm) to 10 (most severe [ie, death]). The occurrence rate is the proportion of patients who experienced the given adverse event per unit of time (day).

A decision tree of the decision analysis model shows the relationships among benefits, adverse events, and risks (Fig 2).

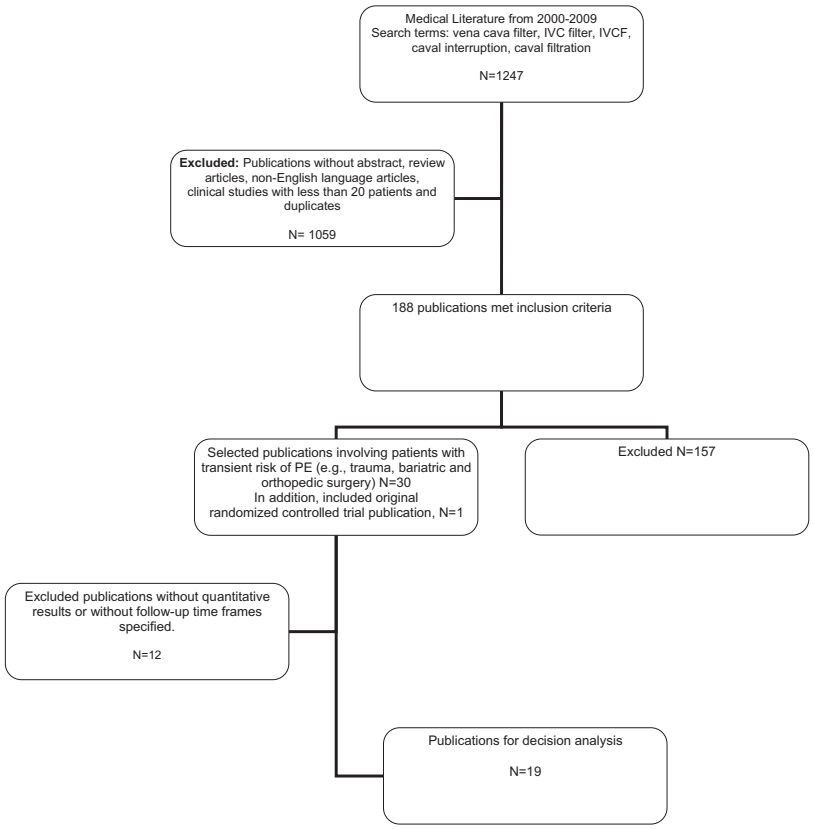

Fig 1. Quorum diagram summarizing the steps involved in the literature search and the selection of publications to develop the mathematical decision analysis. *IVC*, Inferior vena cava; *IVCF*, inferior vena cava filter; *PE*, pulmonary embolism.

The value function of this decision model gives the overall risk score at the time *t*. It combines the following risks:

1) Risk score in situ (t) = risk score from occlusion, filter emboli, migration, penetration, fracture, and DVT;

$$RS_{in-situ}(t) = RS_{Occlusion}(t) + RS_{emboli}(t) + RS_{migration}(t) + RS_{penetration}(t) + RS_{fracture}(t) + RS_{DVT}(t)$$

2) Risk score of removal (t)

$$RS_{removal}(t) = \begin{cases} 0 & t \neq t_{removal} \\ RR(t) & t = t_{removal} \end{cases}$$

where $t_{removal}$ is the time of removal and $RR(t)$ is the one-time removal risk at time t; and

3) Relative risk score without the filter (death and PE).

$$RS_{no-filter}(t) = RS_{death}(t) + RS_{PE}(t)$$

"Risk without filter" is the benefit gained by having the filter in place. For a filter that has been implanted, the net risk score for keeping the filter in the body is defined as the risk score in situ minus the risk score without the filter, minus the risk score of removal.

$$NRS(t) = RS_{in-situ}(t) - RS_{no-filter}(t) - RS_{removal}(t)$$

An increasing trend of the net risk score indicates the expected harm of keeping the filter in place outweighs the expected benefits. The turning point, that is, the time when the risk of having the filter in place starts to outweigh the benefit, is the day when the net risk score reaches its minimum (ie, the cumulative net risk stops to decrease and starts to increase). The turning point is the earliest day when removal of the filter should be considered.

Software and analysis. Commercially available decision analysis software (DPL 7, Syncopation Software, Inc,

Table I. References used for the decision analysis

Reference	*Author*	*Follow-up time*	*Sample size*
10	Decousus et al	12 days and 2 years	200
11	Antevil et al	2 months	216
12	Bovyn et al	3 months	103
13	Cherry et al	2 years	244
14	Gargiulo III et al	2 years	58
15	Greenfield et al	1 year	385
16	Hoppe et al	3 months	41
17	Imberti et al	2 years	30
18	Johnson III et al	12 months	72
19	Kardys et al	12 months	27
20	Karmy-Jones et al	6 months	446
21	Oliva et al	45 days	27
22	Overby et al	6 months	160:170[a]
23	Piano et al	6 months	59
24	Rosenthal et al	1 year	117
25	Schuster et al	2 years	24
26	Toro et al	4 years	102
27	Vaziri et al	NG	30
28	Velmahos et al	NG	321:2889[a]

NG, Not given.
[a]With filter:without filter.

Concord, Mass and a free statistical software, R) was used to perform the analysis based on the weights assigned to each adverse event and its occurrence rate over time. To assess the impact of variability in obtaining the weights and uncertainty on the occurrence rates, sensitivity analyses were performed for a range of weights and for a range of occurrence rates for each adverse event. Resulting uncertainty associated with the net risk was reported via the 95% confidence intervals of turning points.

Adverse events and models for their occurrence rates. Cumulative adverse event rates were estimated based on the literature available for the following intervals after filter implantation: 0 to 30 days, 31 days to 6 months, and 6 months to 2 years. These time intervals were chosen as they were the most common intervals used in the literature for reporting adverse events for IVC filters. Rates for death, PE, and DVT are relative differences comparing the "filter" group with a "no-filter" group. For PE, the event rate was higher in the "no-filter" group, resulting in a negative point estimate. Since the model focuses on the prophylactic use of filters, that is, filters to be used in patients with a temporary (up to 6 months) need, the rate of PE after 6 months was assumed to be zero.[29-31] Retrieval complication was considered a one-time risk that occurs at the time of retrieval and includes any associated access site complications. Table II provides point estimates of occurrence rates used in calculating the risk scores. We used the time-adjusted average method to estimate the occurrence rates.

We assume continuous density functions for the occurrence rates of all adverse events except for "retrieval complication," which can occur only at the time of the retrieval procedure. Specifically, we assume that the PE occurrence rate follows gamma and triangular density functions (Fig 3) in which the accumulated PE occurrence rate in 180 days is equal to 5%, the total PE occurrence rate based on observed data. For the occurrence rates, we used 95% confidence intervals since they were estimated through meta-analysis. The occurrence rates for occlusion, embolization, migration, penetration, fracture, and DVT were assumed to follow three different functions: constant, slightly increasing, and slightly decreasing over time. These functions were chosen in a way that each adverse event has the same cumulative rate at day 180 estimated from literature, as shown in Table II. We believe these assumptions encompass a wide range of plausible variations on the adverse event rates, including the unlikely possibility that

Table II. Weights of severity (range) and occurrence rates of adverse events (estimates from literature)

Adverse event	*Weight*	*Risk classification*	*0 to 30 days*	*1 to 6 months*	*6 months to 2 years*	*Estimating method*
Death	10	Risk without filters	0%	0%	0%	Relative differences comparing with the no-filter group (that is why some rates are negative)
PE	8 7-9		−4%	−1%	0%	
DVT	5 4-6	Risk in situ	0.27%	1.35%	4.86%	
IVC occlusion	5 4-6		0.15%	0.75%	2.70%	A constant monthly rate was assumed
Filter emboli[a]	8 7-9		0.11%	0.55%	1.98%	
IVC penetration	6 5-7		0.06%	0.30%	1.08%	
Filter migration	3 2-4		0.15%	0.75%	2.70%	
Filter fracture	4 3-5		0.02%	0.1%	0.36%	
Retrieval complications	3 2-4	Risk of removal	3%	3%	4%	One-time risk, which increases slightly over time

DVT, Deep vein thrombosis; *IVC,* inferior vena cava; *PE,* pulmonary embolism.
[a]Refers to embolization of the filter and/or its components.

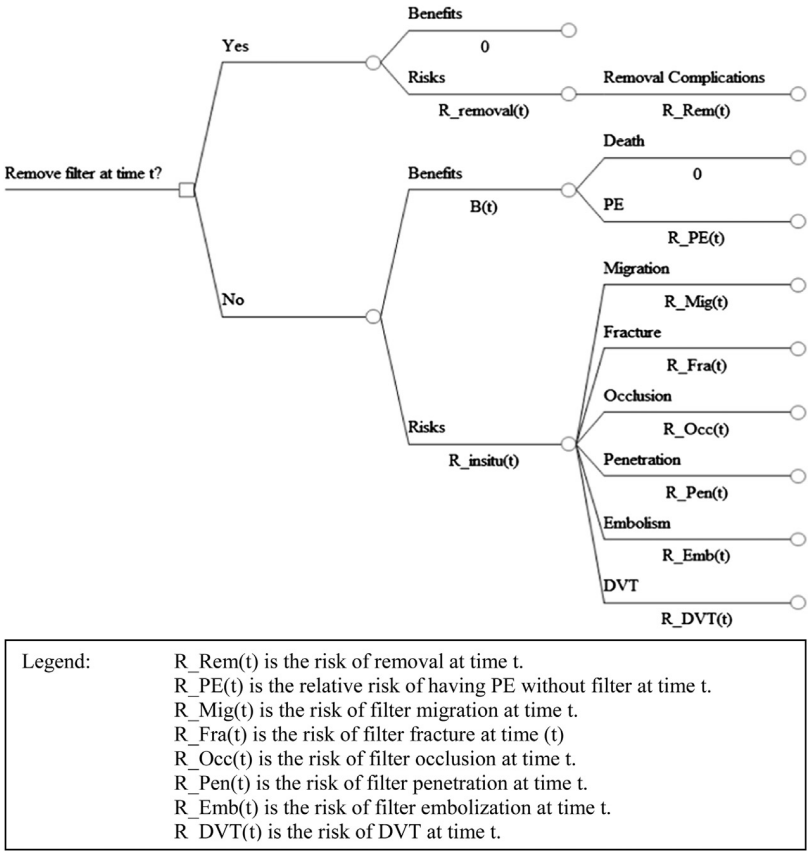

Fig 2. Decision tree (at time *t*) of the decision analysis model showing the connections among adverse events and the risks. *DVT*, Deep vein thrombosis; *PE*, pulmonary embolism.

they may decrease with time. With these assumptions, we calculated the net risk score functions and the turning points.

RESULTS

Fig 3 presents the net risk score curves under six different scenarios. The net risk score decreases at the beginning and starts to increase after 5 to 8 weeks. Table III presents the turning points calculated under different assumptions. If a gamma occurrence rate is assumed for the PE and constant rates are assumed for other filter-related adverse events, the model shows that the risks of complications start to outweigh the protective benefits of the filter at day 35 postimplantation (Fig 4).

Sensitivity analyses were performed to assess the variability of the calculated net risk score when the weights and the adverse event occurrence rates vary, as shown in Table IV.

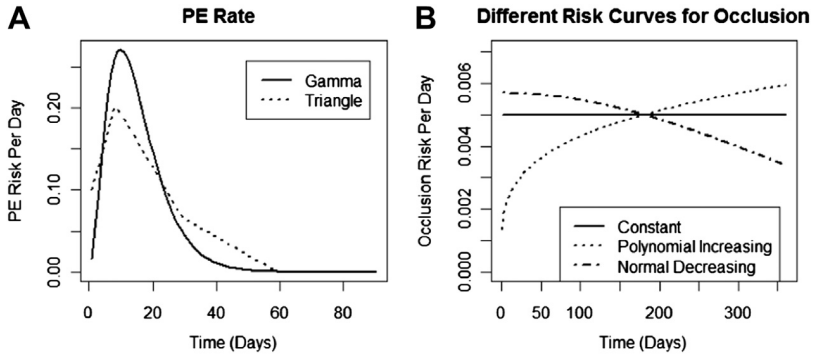

Fig 3. Assumed occurrence rate functions for pulmonary embolism (*PE*) **(A)** and other adverse events **(B)**.

Originally, the weights were assessed by three physicians. Subsequently, we validated the results, adding six physicians. Among those, two physicians assigned different weights than their colleagues, being in opposite extremes (Table V). These differing opinions are reflected in wide ranges and were taken into account in the sensitivity analysis.

Sensitivity analyses show that the range of turning points is relatively robust, for example, from 30 to 40 days under the first scenario. These sensitivity analyses support the robustness of the result that the net risk score reaches its minimum within the 2nd month.

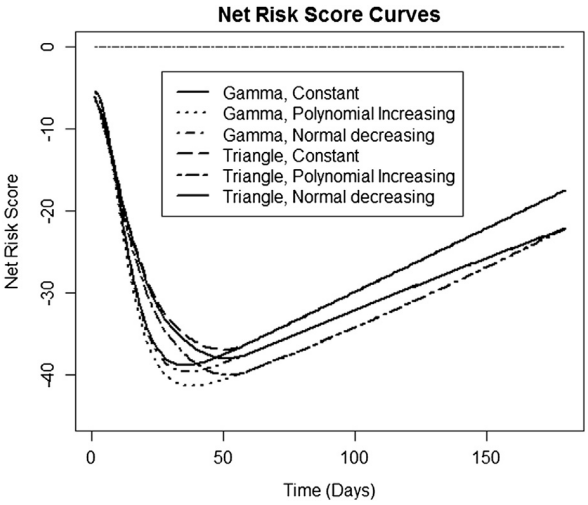

Fig 4. Net risk score curves under various assumptions. Here gamma and triangular mean that the pulmonary embolism (PE) occurrence rate follows either gamma or triangular density functions as shown in Fig 3.

DISCUSSION

IVC filters play an important role in the prevention of recurrent PE in patients for whom anticoagulation therapy is contraindicated, has failed, or poses complications. Practice patterns vary significantly by institution and practitioner, and many physicians in the United States are increasingly using IVC filters prophylactically, despite the lack of level 1 evidence to support such use.[32] Few studies have evaluated the off-label use of IVC filters; absent robust clinical data, the benefit/risk balance over time of off-label IVC filter implantation in a patient without a history of PE remains unclear.

The widespread off-label use of IVC filters outside of FDA-cleared indications is believed to account for more than 50% of IVC filters implanted in the United States,[1] and this percentage is likely to increase.[33] According to the most recent IVC filter consensus panel, 50% or fewer of retrievable IVC filters are ever removed, although it is unknown whether they were implanted for transient high risk of PE or for the management of chronic venous thromboembolism.[1] Although the true risk of developing a complication after successful placement of an IVC filter is unknown, the risk would be expected to increase with the duration of implantation, as with any chronic implant.[34] This raises safety concerns for patients who received IVC filters with the expectation that implantation would be temporary but whose filters are not removed when the need for filtration has subsided.

While some retrievable filters remain in place because of the continued need for filtration, others that could be retrieved are not. The practice of leaving retrievable IVC filters in situ that could be removed could be due to a lack of data identifying appropriate retrieval times, loss of follow-up of patients, or lack of physician initiative to consider device retrieval. To better understand the time course of risks related to implant duration and retrieval, a decision analysis model that utilizes data publicly available in the medical literature for IVC filters was formulated. Decision analysis is a methodology in which the component parts of a complex decision are separated and analyzed in a mathematical model. Decision models often compare different therapeutic strategies for clinical dilemmas using existing literature. The ultimate goal of such decision analysis is to provide insight and transparency to enable clinicians to reach an optimal and coherent clinical decision.[35,36] Quantitative decision analysis affords new possibilities for regulatory decision making by weighting risks and benefits distilled from disparate sources of information to form a cohesive picture that can be used, in this case, to decide whether recommendations should be

Table III. Turning points and sensitivity analyses under different function assumptions

Function for occurrence rate of PE	*Function for occurrence rate of other AEs*	*Turning point and 95% confidence intervals (in days)*		
		Original raters	*Conservative rater*	*Anticonservative rater*
Gamma	Constant	35 (30-40)	38 (33-42)	30 (22-36)
	Polynomial increasing	39 (33-40)	42 (35-42)	34 (27-35)
	Normal decreasing	36 (29-37)	38 (33-41)	30 (25-33)
Triangle	Constant	50 (41-54)	52 (45-55)	39 (22-51)
	Polynomial increasing	53 (40-53)	55 (48-55)	47 (31-48)
	Normal decreasing	50 (40-52)	53 (47-55)	40 (27-46)
Total range from sensitivity analysis		(29-54)	(33-55)	(22-51)

AE, Adverse event; *PE,* pulmonary embolism.
The turning point is the day the cumulative risk stops decreasing and starts to increase. The ranges in Table III were used in the sensitivity analysis.

Table IV. Ranges of weights and 95% confidence intervals of occurrence rates of adverse events for sensitivity analyses

Adverse event	*Weight*	*0-30 days*	*1-6 months*
Death	10	0.00% (−1.0%-1.0%)	0.00% (−1.0%-1.0%)
PE	8 (7-9)	−4.00% (−7.00%- −1.00%)	−1.00% (−2.00%-0.00%)
DVT	5 (4-6)	0.27% (0.00%-0.55%)	1.35% (0.00%-2.70%)
IVC occlusion	5 (4-6)	0.15% (0.01%-0.48%)	0.75% (0.40%-1.30%)
Filter emboli[a]	8 (7-9)	0.11% (0.0%-0.59%)	0.55% (0.20%-1.20%)
IVC penetration	6 (5-7)	0.06% (0.0%-0.54%)	0.30% (0.10%-0.80%)
Filter migration	3 (2-4)	0.15% (0.0%-0.51%)	0.75% (0.40%-1.40%)
Filter fracture	4 (3-5)	0.02% (0.0%-0.45%)	0.10% (0.01%-0.65%)
Retrieval complications	3 (2-4)	3% (2.20%-4.10%)	3.00% (2.20%-4.10%)

DVT, Deep vein thrombosis; *IVC,* inferior vena cava; *PE,* pulmonary embolism.
[a]Refers to embolization of the filter and/or its components.

made to clinicians involved with the care of patients with retrievable IVC filters. Since it is beyond the FDA's mission to regulate the practice of medicine, including the prophylactic use of IVC filters, the main focus of the decision analysis model was to assess the risk/benefit profile of IVC filter use over the potential life of the implant. Emphasis was placed on the off-label prophylactic use of these devices once they had already been implanted as per clinician judgement (eg, as part of trauma care or bariatric and orthopedic surgery).

Given that data from a high-quality clinical trial for prophylactic implantation of IVC filters, including identification of the optimal time for retrieval, are not available, decision analysis provides a method to evaluate available information and to gain insight about the relative risks and benefits of IVC filter retrieval. The analysis presented in this article was intended for a population-level decision and is not appropriate or sufficient for individual patient-level decisions. Although the results of this analysis may provide general guidelines for physicians, individual patient decisions should be made on a case-by-case basis, using not only the insight provided by the model but also the particular circumstances regarding each patient. Once the filter is implanted, our model suggests that the net risk tends to increase with time. If the patient's transient risk for PE has passed, the risk-benefit profile resulting from the analysis begins to favor filter removal between 1 and 2 months, assuming retrieval is possible. However, because this analysis was not designed to evaluate the use of IVC filters in patients without PE, the results cannot be extrapolated to support prophylactic implantation of IVC filters. Such an indication should be assessed in a well-controlled clinical study.

As with any model, there are limitations in the decision analysis presented here. First, the data used for the analysis were primarily obtained from single-center experiences of patients with IVC filters. Second, to estimate the occurrence rates of adverse events, we used meta-analysis and literature review, which bear intrinsic limitations, such as pooling data from different populations, inability to control the quality of the data, and the potential for underlying selection bias of the studies chosen for the analysis. Importantly, estimates of occurrence rates of all adverse events could not be determined at all time points, with the 0- to 30-day time frame being most deficient. To mitigate this deficiency, assumptions of increasing, decreasing, and constant adverse event density functions were made. Third, the weights presented in the analysis were elicited from three physicians and are subjective, although sensitivity analysis showed that, even with variations in the assumed weights and adverse event rates, the trend of increasing net risk with time persisted. Fourth, data used for this analysis of prophylactic IVC filter implantation were leveraged, in some cases, from studies of IVC filters in other patient populations. In particular, the inclusion of patients with pre-existing venous thromboembolism including PE in estimating event rates may lead to an inflation of the benefits of filtration in the first month. However, the

Table V. Validation of the original results using six additional physicians

		Turning point						
Function for occurrence rate of PE	*Function for occurrence rate of other AEs*	*Original*	*Ph 1*	*Ph 2*	*Ph 3*	*Ph 4*	*Ph 5*	*Ph 6*
Gamma	Constant	35	**38**	33	35	34	**30**	36
	Polynomial increasing	39	**42**	36	38	38	**34**	39
	Normal decreasing	36	**38**	33	35	34	**30**	36
Triangle	Constant	50	**52**	45	49	48	**39**	50
	Polynomial increasing	53	**55**	50	52	52	**47**	53
	Normal decreasing	50	**53**	46	49	48	**40**	50

AE, Adverse event; *PE,* pulmonary embolism; *Ph,* physician.
Bold values indicate weights at the opposite extremes.

fundamental device performance with respect to PE prevention and device-related complications was assumed to be similar across all populations. In addition, we recognize that among patients with short-term need of filtration, there were different subgroups of patients (ie, trauma, bariatric, and orthopedic surgery) that have different comorbidities, demographics, and pathophysiological circumstances. Nevertheless, due to the lack of data to perform individual group analysis, those subgroups were assumed to be exchangeable, as they all had transient risk of PE. Finally, despite differences between IVC filter designs and their failure modes, a device class approach was deemed appropriate for the purpose of this analysis since device-specific data were not available. The limitations of the available data underscore the need for additional development of high-level clinical evidence involving IVC filter implantation and retrieval. When available, such data can be used to further refine the decision analysis model and increase the precision of the resulting risk/benefit considerations.

In summary, quantitative decision analysis suggests that if the patient's transient risk for PE has passed, the risk-benefit profile begins to favor removal between 1 and 2 months. While there are limitations in the analysis, particularly related to the paucity of patient data for prophylactic use, the analysis supports the recommendations of the FDA[3] and the clinical community[37]: filter removal should be considered for individual patients whose transient increased risk of PE has diminished.

AUTHOR CONTRIBUTIONS

Conception and design: JM, XL, TI, NI, MM, KC
Analysis and interpretation: JM, XL, TI, MM
Data collection: JM, NI
Writing the article: JM, XL, TI, NI, MM, KC
Critical revision of the article: JM, TI, NI, MM, KC
Final approval of the article: JM, KC
Statistical analysis: XL, TI
Obtained funding: Not applicable
Overall responsibility: JM

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