

INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

# Cost-benefit analysis of establishing an inferior vena cava filter clinic

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#### PURPOSE

Adverse events associated with retrievable inferior vena cava filters (IVCFs) have generated an increased interest in improving IVCF retrieval rates to improve patient safety and quality care. This study aims to demonstrate the cost-benefit of implementing an IVCF clinic to improve patient care in an institution in the United States.

#### METHODS

An IVCF clinic was established at a single institution in September 2012 and for ten months referring physicians were contacted to facilitate retrieval when appropriate. Additionally, a retrospective review was conducted on filter placements over the eight preclinic months. Cost-benefit analysis was conducted by creating a model, which incorporated the average cost and reimbursement for permanent and retrievable IVCFs.

#### RESULTS

A total of 190 IVCFs (152 retrievable IVCFs and 38 permanent IVCFs) were implanted during the IVCF clinic period. Twenty-nine percent of the retrievable IVCFs were successfully retrieved compared to 10 of 119 retrievable IVCFs placed during the preclinic period (8.4%). Cost-benefit analysis, using the average of the institution's six most common reimbursement schedules, demonstrated an average net financial loss per permanent or retrievable IVCF not removed. However, a net financial gain was realized for each retrievable IVCF removed. The additional hospital cost to maintain the IVCF clinic was offset by removing an additional 3.1 IVCFs per year.

#### CONCLUSION

An IVCF clinic significantly increases retrieval rates, promotes patient safety, and is economically feasible. Given the adverse event profile of retrievable IVCFs, strategic efforts such as these ultimately can improve quality care for patients with in-dwelling IVCFs.

he use of retrievable inferior vena cava filters (IVCFs) for mechanical prevention of pulmonary embolism resulting from deep vein thrombosis has been steadily increasing over the last decade (1–3). However, this increased utilization of retrievable IVCFs has coincided with an increased awareness of their potential long-term adverse effects. These effects include caval penetration, strut fracture, occlusion, or migration (4). As these events may carry significant morbidity, the FDA, first in 2010 and then most recently in 2014, recommends prompt filter retrieval when no longer clinically indicated (5).

Given the adverse event profile of retrievable IVCFs, these filters should be removed once no longer clinically indicated to avoid the complications of long-dwelling filters. The initiation of an IVCF clinic along with prospective consultation with an interventional radiologist by the referring physician has been shown to significantly improve IVCF retrieval rates and lower dwell time (6, 7). Further, preplacement discussions with referring physicians have been shown to improve decision making on permanent versus retrievable filter placement (7). Despite these efforts, the rates of IVCF retrieval demonstrate great variance between 3.7% and 58% in the literature (8). A large portion of filters placed for temporary indications are therefore being placed permanently, whether intentionally or unintentionally, with the potential for these adverse effects.

In addition to improving quality in patient management, filter retrieval may be a practice building effort. Indeed, healthcare delivery is executed differently in each country and reimbursement schedules, although reflecting the procedure performed, are dependent upon the healthcare system of that country. In the United States, state and federally administered

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Published online 11 November 2016. DOI 10.5152/dir.2016.16007 insurance programs are available dependent upon financial need (Medicaid) and advanced age (Medicare), although many patients receive health insurance through private insurance companies. Further, the recently enacted Affordable Care Act extends an opportunity for health insurance to those previously uninsured. From a financial perspective, reimbursement is similar for permanent and retrievable IVCFs. However, given the significant risks associated with long-dwelling filters and the technical challenges of retrieval, filter retrieval is supported by third-party payers when clinically indicated. Previously, D'Othee et al. (9) demonstrated that, given the variable cost of retrievable IVCFs compared with permanent filters in 2008, the retrieval rate would have to exceed 41% for retrievable IVCF placement to be cost-effective. However, the competition amongst the now numerous commercially available retrievable IVCFs as well as changes in technology and the reimbursement structure in the United States have significantly impacted clinical practice. Permanent and retrievable IVCFs are now similar in cost. Each filter retrieved is a benefit to the patient in avoiding the long-term sequelae associated with filter placement assuming that risk is greater than the procedural risk; however, managing and building an IVCF clinic comes as an organizational challenge and expense. This study aims to demonstrate the cost-benefit of implementing an IVCF clinic through improved communication with patients and referring physicians to improve patient care.

# **Methods**

#### Design

Under institutional review board approval, we retrospectively identified and

## Main points

- Adverse events from inferior vena cava filters (IVCFs) have increased interest in their prompt retrieval.
- An IVCF clinic was established to facilitate IVCF retrieval as coordinated with referring physicians.
- Cost-benefit analysis was performed incorporating average costs and reimbursements for permanent and retrievable IVCFs.
- The IVCF clinic increased retrieval rates and promoted patient safety.
- The cost of maintaining the IVCF clinic was offset by removing an additional 3.1 IVCFs per year.

reviewed all consecutive patients who underwent IVCF placement and/or removal from January 1st, 2012 to June 30th, 2013 in the interventional radiology section of a tertiary academic medical center. For this type of study, formal consent is not required. All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. A dedicated IVCF clinic was established in September 2012 with a comprehensive database of prospectively added information for all consecutive patients receiving IVCFs. Cases were chronologically classified into the preclinic group (January 2012 to August 2012) and postclinic group (September 2012 to June 2013). Additionally, the preclinic group was retrospectively evaluated by the clinic initiative to identify patients eligible for filter retrieval. For each case, clinical data were extracted from the patients' electronic medical record and imaging records. Indications for and placements of filters were in accordance with the Society of Interventional Radiology guidelines (10). Retrievable filters were placed in those patients with the intent of their retrieval when clinically appropriate and mechanical pulmonary embolism protection was no longer needed.

## **IVCF device information**

Retrievable filters were placed in patients with the intent of their retrieval once mechanical prophylaxis was no longer required. All filters reviewed were FDA-approved retrievable IVCFs and were placed via fluoroscopic guidance. Those retrievable filters placed during the time period of the study included Gunther Tulip (Cook Medical), Celect (Cook Medical), Option (Argon Medical), ALN (ALN Inc.), and Denali (Bard Medical). Permanent filters included either the Greenfield (Boston Scientific) or Vena Tech (B Braun Medical, Inc.). The type of filter placed was at the discretion of the interventional radiologist performing the procedure.

#### **IVCF placement and retrieval**

Patients were prepared for the procedure according to previously described protocol (11), and all implant procedures were performed according to the instructions for use. Only retrievable filters, rather than permanent filters, were retrieved during the study dates. Briefly, after local anesthesia with lidocaine, the right internal iugular vein or common femoral vein was accessed under real-time ultrasound guidance. Following an inferior vena cavagram, the IVCF was typically deployed in an infrarenal position within the IVC. Filter retrieval was conducted when deemed clinically appropriate by the interventional radiologist and referring physician. The filter was captured and removed through a vascular sheath as previously described under fluoroscopic quidance (11). Patients were discharged or transferred to their hospital room if inpatient after one hour of observation according to conscious sedation protocol at our institution. After filter retrieval, no patients during the study dates required repeat IVC filter placement.

#### **Patient follow-up**

Prior to the implementation of the IVCF clinic, referring physicians would typically contact an interventional radiologist to schedule retrieval when clinically appropriate and patients were candidates for retrieval. An IVCF virtual clinic paradigm was established in September 2012 including a comprehensive database of acquired information at time of filter placement for patients managed by a nurse coordinator (6). After filter placement, the nurse coordinator and IVCF placement interventional radiologist would monitor and coordinate filter retrieval with the patient's physicians when clinically indicated. Communication via messaging through the electronic medical record system and phone calls with the patient's physician initiated four weeks following placement (6) and continued until the filter was removed or considered permanent.

#### **Retrospective review**

Alongside the IVCF clinic initiation, a retrospective review was conducted on filter placements over the eight preclinic months (January 2012 to August 2012) immediately prior to the IVCF clinic. A separate database was created for these IVCFs at time of clinic initiation, and referring physicians were contacted electronically or by phone to educate them on the IVCF clinic, IVCF types, indications, and coordinate for possible retrieval. The number of IVCFs referred for retrieval before and after the implementation of the filter clinic or retrospective review was recorded as well as procedural date and indication. For each case, patient demographic data including age and sex were extracted from the medical record. The type of filter, date of filter removal and each patient's status as an inpatient or outpatient was also recorded.

## **Cost-analysis model**

Cost-analysis was conducted by creating a model, which examined average cost and average reimbursement for each IVCF placement and retrieval. For this cost-analysis model, average costs were calculated as described previously (9) and then subtracted from average reimbursements (i.e., weighted average of the allowable amounts from the six major third-party payers at our institution) to provide the average financial benefit per case. Given the differential price in permanent versus retrievable filters as well as the reimbursement benefit of filter retrieval, the cost benefit was then calculated following a retrospective evaluation of the preclinic period as well as following the implementation of the IVCF clinic relative to the control preclinic period. Average cost calculations were based on the type of filter used and included a fixed cost for additional supplies and a fixed cost of labor based on procedure duration derived from the medical record as procedural time-out to sign-out from nursing intraprocedural documentation, which was calculated to be 37.5±17 minutes for filter placement and 50.3±28 minutes for filter removal, similar to a previously conducted study in which the average placement was estimated as 30 minutes and the average retrieval was estimated as 45 minutes (9). Additional laboratory tests, such as blood work, were not included in the cost calculation given the variability in patient needs in the inpatient or outpatient setting for these additional tests. Labor costs include the salaries of interventional radiology residents and fellows, nurses, and technologists as well as interventional radiology attending physicians. Labor costs are considered dependent upon average procedure time for IVCF placement and retrieval, whereas other supply costs are considered constant and independent of time. IVCF placement and retrieval procedure times were calculated as an average for these procedures from the included study population. Complicated filter retrievals occurred at a low rate in both the preclinic and postclinic period (6/67, 9%); however, the additional time required for these complicated retrievals were considered in the average retrieval procedure

time for weight cost estimates. After costs were calculated for each filter type and procedure, a weighted average cost was calculated according to the case mix (i.e., relative utilization of each filter type and inpatient/ outpatient status of the procedure) observed in the study population.

Weighted average reimbursement calculations used in the cost-analysis model utilized data from actual outpatient payments from the six most commonly encountered payers over the prior six months for both IVCF placement and retrievals. These reimbursement amounts included technical and professional components as obtained from the institution's financial services to reflect actual payments. Reimbursement is dependent upon the Current Procedural Terminology (CPT) code(s) for that specific procedure. CPT codes for IVCF placement include 36010, 76942, 37620 and 75940 prior to August 2012 and 37191 and 37192 afterwards. Retrieval procedures utilize CPT codes 37203, 36010, 75825, and 75961 prior to August 2012 and 37193 afterwards. Reimbursement was not directly impacted by the changes in these CPT codes over time. Because inpatient reimbursements are part of a global envelope based on a diagnosis-related group, inpatient procedures are not generally reimbursed at the same rate as outpatient procedures. Filter placements were performed on an inpatient basis in 85% of our cases, whereas removals were performed on an outpatient basis in 86% of cases. Inpatient filter placement was for urgent indications and therefore placed in the inpatient setting, whereas outpatient filter placement was for elective indications. In consideration of the reimbursements received for the procedures included, inpatient procedures were reimbursed at approximately 30% the rate of that of outpatient procedures. Therefore, a 30% reimbursement rate for IVCF placements and 86% reimbursement rate for IVCF retrievals was assumed, similar to the rates suggested by literature (9) and institutional experience. An 86% reimbursement collection rate was chosen for IVCF retrievals as this

correlated with the percent of procedures performed in the outpatient setting (86% of retrievals were completed as outpatient). Overall, 9% of placements and no retrievals were completed after working hours. The rate of reimbursement denials by third-party payers was equivalent for all payers and did not vary depending on the filter chosen, placement or retrieval procedure, or during the preclinic or postclinic period.

Average cost and reimbursement were calculated separately for permanent IVCFs, retrievable IVCFs that were eventually removed, and retrievable IVCF that were not removed. Weighted average reimbursements were subtracted from calculated weighted average costs for each procedure type to provide an estimate of the average net benefit for the hospital. The outcomes were expressed in terms of retrieval rates for the preclinic and postclinic period as well as the financial benefit to the hospital for each of the periods.

## **Statistical analysis**

Two-sample t-tests and Chi-square tests were used to compare the differences of continuous and categorical data, respectively, in patient demographics and retrieval rates between the preclinic phase and postclinic phase.

# Results

The mean and median age of the 335 included patients in our study population was 59 and 60 years, respectively, with slightly more females (n=176, 53%) than males (n=159, 48%) (Table 1). The age and sex distribution was not significantly different in the preclinic patient population compared with the postclinic population (P =0.466 and 0.533, respectively). According to IVCF placement indication guidelines (10), 63% of the included IVCFs were placed for absolute indications (n=211), 7% IVCFs for relative indications (n=24), and 30% IVCFs for prophylactic indications (n=100). A total of 335 IVCFs (64 permanent and 271 retrievable filter types) were implanted during the 18 months of this study (Table 2), with 145

Table 1. Demographics				
	Preclinic	Postclinic	Total	Р
Age at placement, mean±	ESD 59.8±12.7	58.7±15.0	59.2±14.1	0.466
Gender (M/F), n (%)	66 (46)/ 79 (54)	93 (49)/ 97 (51)	159 (48)/ 176 (53)	0.533
SD, standard deviation; M, male; F, female.				

Table 2. Inferior vena cava filter placements and retrievals				
	Preclinic	Postclinic	Total	Р
Total number of filters	145	190	335	
Retrievable filters	119 (82)	152 (80)	271 (81)	0.633
Total permanent filters	26 (18)	38 (20)	64 (19)	
Filter retrievals	10 (8.4)	44 (28.9)	67 (24.7)	<0.001
Data are presented as n (%).				

Table 3. Inferior vena cava filter type				
Type of filter	Preclinic	Postclinic	Total	Number removed
Tulip	1 (0.7)	0	1 (0.3)	0
Celect	53 (36.6)	19 (10.0)	72 (21.5)	13 (3.9)
Option	40 (27.6)	123 (64.7)	163 (48.7)	40 (11.9)
ALN	25 (17.2)	10 (5.3)	35 (10.5)	14 (4.2)
Greenfield	26 (17.9)	26 (13.7)	52 (15.5)	-
VenaTech	0	12 (6.3)	12 (3.6)	-
Data are presented as n (%).				

Table 4. Average cost associated with filter placement and retrieval					
	Filter Other supplies Labor Total				
Placement procedure	\$1,030.12	\$171.57	\$97.46	\$1,299.15	
Retrieval procedure	\$0.00	\$460.07	\$146.18	\$606.25	

Table 5. Average allowable reimbursement			
	Technical	Professional	Total
Allowable placement reimbursement*	\$2,243.94	\$360.51	\$2,604.45
Allowable removal reimbursement*	\$1,706.89	\$441.86	\$2,148.75
*From the top six payers at our institution.			

filters placed during the preclinic period (26 permanent [18%] and 119 retrievable [82%]) and 190 filters placed in the postclinic period (38 permanent [20%] and 152 retrievable [80%]). Eighty-one percent of all filters (271/355) were retrievable. The proportion of retrievable filters implanted was not significantly changed at postclinic with 82% and 80% of filters representing retrievable types during the pre- and postclinic months, respectively (P = 0.633). There was also a similar rate of filter placements in the eight preclinic months (18 filters per month) as the 10 postclinic months (19 filters per month) reflecting similar referral patterns during both time periods. The types and distribution of filters placed in the preclinic and postclinic periods are represented in Table 3.

During the eight-month preclinic period, 10 of 119 retrievable IVCFs (8.4%) were re-

ferred and successfully removed. After implementation of the clinic, the preclinic data were reviewed as an opportunity to contact referring physicians and educate them on the clinic initiative and offer retrieval for eligible preclinic patients. The remaining preclinic 109 retrievable IVCF patients were at that time individually contacted and 13 additional patients (19.3%) were referred and retrieved. The retrospective review resulted in more than a two-fold increase in the initial preclinic removal rate. As referring physicians were contacted as part of the IVCF clinic initiative from September 2012 through June 2013 (postclinic), 28.9% of IVCFs (44/152) were referred for retrieval and were successfully removed, which is significantly improved from the 8.4% in the preclinic period (P < 0.0001, Table 2). Technical failure of IVCF retrieval was experienced during three attempted retrievals in

the preclinic period (87% technical success rate) and during one attempted retrieval in the postclinic period (98% technical success rate). No complications were reported during filter retrieval in either the preclinic or postclinic period.

Table 4 and 5 show the average costs of placing IVCFs at our institution and the average allowable reimbursement from the top six payers for placing and retrieving IVCFs, respectively. The calculated average cost was \$1,264, \$1,317, and \$1,281 (reported here and throughout in US dollars) for permanent IVCFs, retrievable IVCFs that were not removed, and retrievable IVCFs that were removed, respectively, as shown in Table 6. The difference in placement cost of retrievable IVCFs not removed and retrievable IVCFs removed was due to the differences in costs of specific types of IVCFs. The cost of a permanent filter and retrievable filter was more similar in our study compared with historical prices, which were significantly higher for retrievable filters (9). The calculated average total reimbursement was \$781 for both permanent IVCFs and retrievable IVCFs that were not removed and \$2,629 for retrievable IVCFs that were removed. This resulted in an average net financial loss of \$483 and \$535 for each permanent IVCF and retrievable IVCF that was not removed, respectively, and a net financial gain of \$742 for each retrievable IVCF that was removed. For each additional IVCF that was removed, an additional \$1,278 in revenue was generated on average, compared with an IVCF that was not removed.

Table 7 summarizes the net revenue generated from IVCF removals during the study period extrapolated over a one-year period. Retrospectively contacting the referring physicians for those patients having filters placed during the preclinic period and eligible for filter retrieval would yield an additional \$31,102.53 in actual revenue. Assuming a continued retrieval rate of 8.4% as that realized during the preclinic period, a total of 18 filters would be retrieved during a one-year period. However, the implementation of the IVCF clinic would yield an additional 46 IVCF retrievals for a total of 64 filter retrievals. Therefore, the IVCF clinic implementation would yield an additional \$54,311.85 in revenue over one year above that generated by the baseline model.

The virtual IVCF clinic was managed by a nurse coordinator and an average of two hours of dedicated time per week were

Table 6. Average cost and reimbursement per filter				
	Permanent IVCF	Retrievable IVCF not removed	Retrievable IVCF removed	
Cost				
Placement cost	\$1,263.71	\$1,316.68	\$1,280.67	
Retrieval cost	-	-	\$606.25	
Reimbursement				
Placement reimbursement*	\$781.34	\$781.34	\$781.34	
Retrieval reimbursement*	-	-	\$1,847.93	
Net revenue	-\$482.37	-\$535.34	\$742.34	

\*Average reimbursement reflects a 30% reimbursement rate for placements and 86% reimbursement rate for retrievals.

IVCF, inferior vena cava filter.

#### Table 7. Inferior vena cava filter clinic

	Preclinic 12-month estimate	After retrospective review 12-month estimate	Postclinic 12-month estimate	
Revenue from removals	\$23,968.92	\$55,071.44	\$82,464.50	
Additional revenue compared with preclinic retrieval rate	-	\$31,102.53	\$58,495.58	
Cost of RN to manage IVCF clinic	-	-	\$4,183.73	
Net gain	-	\$31,102.53	\$54,311.85	
IVCF, inferior vena cava filter; RN, registered nurse.				

necessary to facilitate database management and referring physician communication. This time allocation was calculated to be \$3,973 per year. Therefore, to offset the additional time required by the nurse coordinator, an additional 3.1 IVCF retrievals per year were necessary. However, during the 10-month postclinic period an additional 31 filters were retrieved by use of the virtual IVCF clinic.

# Discussion

Our analysis demonstrates that IVCF clinic implementation results in significantly improved retrieval rates, in agreement with previous reports (6, 13). Our model for an IVCF clinic involving a database managed by a nurse has a low overall cost, which can easily be recuperated with the resultant additional IVCF retrievals per year. More robust clinic models (14) may yield higher retrieval rates: however, the offset of the additional costs to maintain these clinic models would need to be evaluated to elucidate the actual financial benefit. Retrospective review of IVCF patients prior to implementing an IVCF clinic at our institution was also beneficial as a way to educate referring physicians on

the clinic initiative, while simultaneously improving retrieval rates during that time period.

Given the lower consumable supply costs for filter retrieval relative to those of filter placement in light of similar procedural reimbursement, the methods and findings provided in our study are generalizable. While these cost analysis estimates are specific to our institution, the overall financial benefit endured from increasing IVCF retrieval rates is therefore generalizable to other institutions. Although this study represents an evaluation on the impact of insurance status on reimbursement at an institution in the United States, the results may be applicable to nations with other healthcare models as well. Indeed, the high retrieval rate of 83% recorded by the British Society of Interventional Radiology filter registry (15) may support the role of insurance status in a patient's decision to pursue retrieval given the more universal healthcare model in the United Kingdom as well as the associated hospital reimbursement for the increased IVCF retrieval rate. These results may also have important implications in the United States with the recent adoption and implementation of the Affordable Care Act. Although not investigated in our study, more expensive IVCF clinic paradigms may be offset with improved retrieval rates and referrals. Social and demographic differences in patient populations served by an institution, procedural indication, and hospital setting may impact the utility of a filter clinic as well as retrieval rates (11). Additionally, geographic and financial barriers may present obstacles to care for patients, which may ultimately affect filter retrieval rates (11). Our population consists of a large level I trauma and referral center in an urban location. The urban location may also suggest access to more interventional radiology physicians willing to retrieve these filters.

The net financial loss demonstrated for permanent IVCFs and retrievable IVCFs that were not removed is similar to that identified in a prior study (9). Further, the percent of IVCFs placed and removed in an outpatient versus inpatient setting was similar (9). Unlike prior studies, our study showed a similar cost of placing a permanent versus a retrievable IVCF due to the decreasing costs of retrievable IVCFs and increased market competition. Further, reimbursement rates in our study were higher than a prior study from 2008, which may reflect regional differences or may partially reflect increases secondary to inflation.

The changing economy of healthcare delivery in the United States indicates an added importance on cost-analysis of procedures in interventional radiology. Healthcare outcome metrics emphasizing quality and patient management also make it important for following patients and optimizing IVCF retrieval rates. Minimizing potential long-term complications with tactics such as these will improve quality of care by improving IVCF retrieval rates and have the potential to decrease the overall financial costs to the healthcare system. Improving quality of care and minimizing complications will only continue to increase in importance as medicine moves toward more value-centered care. As advocated by the FDA recommendations (5), increased efforts to retrieve IVCFs when no longer clinically indicated are essential to promote patient safety. Although influenced by the filter type, potential long-term effects including strut fracture, IVC thrombosis, caval perforation or filter migration can all be minimized by efforts toward prompt IVCF removal when appropriate. Previous studies have shown that approximately 40% of retrievable filters eventually perforate the IVC (8, 15). Improving the filter retrieval rate by 20%, as was accomplished in this study, would result in a three-fold increase in retrievals for patients with strut perforation for every 100 retrievable filters placed. As strut perforation is progressive over time (15), efforts to decrease dwell time through clinic initiatives further benefits patients by reducing dwell time and preventing additional perforations. Further, the risk for severe bleeding in patients eligible for anticoagulation treatment for venous thromboembolic disease is approximately four events per 100 patient-years (16), which is significantly less than the risks associated with long-dwelling retrievable IVCFs (17).

This study is limited as it only evaluates the costs and reimbursements associated with the IVCF placement and retrieval procedures and should be considered within the context of its design and assumptions. Other costs including additional laboratory costs as well as long-term medical costs associated with altered morbidity or mortality are not considered. Additional indirect costs such as overhead and transfer costs are also not included, as they are similar for all procedures examined in this study. Further, the assumptions made in our cost-analysis model regarding reimbursement rates may vary at other institutions, regionally, or with different patient populations. Nevertheless, the methodology and implementation strategy described here is applicable across institutions and centers to improve filter retrieval rates, patient care, and hospital revenue.

In conclusion, given the known risks associated with prolonged filter placement, filter retrieval and improving filter retrieval rates are also of benefit to the patient. Therefore, establishing an IVCF clinic is beneficial for both patients and for practice building. The retrieval rate of IVCFs at our institution was significantly increased by the retrospective review of previously placed filters and by implementation of a virtual IVCF clinic paradigm. These efforts resulted in a financial benefit exceeding the cost of maintaining the virtual clinic. Additional efforts, including improving patient education and inpatient rounding, may further impact filter retrieval rates. Coordinated efforts such as these can ultimately improve retrieval rates and increase patient safety by reducing long-term complications associated with in-dwelling retrievable IVCFs.

## **Conflict of interest disclosure**

The authors declared no conflicts of interest.

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