Lessons learned from a 6-year clinical experience with superior vena cava Greenfield filters

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Purpose: **Therapy to prevent pulmonary embolism (PE) resulting from upper extremity deep venous thrombosis (UEDVT) remains controversial despite an increasing incidence of DVT of upper extremity origin. The purpose of this study was to evaluate the results of 72 superior vena cava Greenfield filters (SVC-GFs) placed in patients at risk for PE arising from UEDVT.**

Methods: **During the past 78 months, we placed SVC-GFs in 72 patients with UEDVT in whom anticoagulation was either deemed contraindicated (n = 67) or proved ineffective in preventing recurrent PE (n = 4) or extension of the thrombus (n = 1). There were 25 male (35%) and 47 (65%) female patients whose ages ranged from 25 to 99 years (mean, 74 years). Follow-up ranged from 10 days to 78 months (mean, 7.8 months). Sequential chest radiographs revealed no filter migration or displacement in 26 patients.**

Results: **Thirty-four patients died in the hospital of causes unrelated to the SVC filter or recurrent thromboembolism (mean time to death, 20 days). Follow-up of the surviving 38 patients ranged from 1 month to 78 months (mean, 22 months); none of these patients were seen with any evidence of PE. One SVC-GF was incorrectly discharged into the innominate vein and left in place. This vein remains patent 2 months after insertion without evidence of filter migration.**

Conclusions: **We think that insertion of SVC-GFs is a safe, efficacious, and feasible therapy and may prevent recurrent thromboembolism in patients with UEDVT who are resistant to anticoagulation or have contraindications to anticoagulation. (J Vasc Surg 2000;32:881-7.)**

Although therapy for upper extremity deep venous thrombosis (UEDVT) remains controversial, our group has chosen to treat UEDVT as aggressively as we treat lower extremity DVT (LEDVT). This approach is supported by the incidence of pulmonary embolism (PE) ranging from 4% to 28% in patients with UEDVT, which it makes it comparable to that of LEDVT.[1-8] Consequently, we have tried to systemically anticoagulate these patients with UEDVT by means of a full course of heparin and warfarin. However, treatment for those patients found to have an UEDVT who have contraindications to anticoagulation or who have a PE despite adequate anticoagulation has not well been addressed in the literature. We propose that these patients would benefit from the placement of a superior vena cava (SVC) filter.[9-13]

Our previously reported experience with SVC filters demonstrated the clinical feasibility of the placement of filters in the SVC. Nevertheless, there is scant follow-up in the literature examining a large series of patients undergoing placement of SVC filters. Issues concerning long-term efficacy, SVC thrombosis, migration of the filter, and perforation of the SVC have not been addressed. On the basis of our recent experience, we discuss the values and limitations of the placement of SVC filtration devices in the acute setting.

PATIENTS AND METHODS

From July 1993 to January 2000, there were 2232 upper extremity venous duplex scans performed to rule out UEDVT at our institution, which

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Competition of interest: nil.

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is accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories. We diagnosed UEDVT in 293 (8.6%) of these patients. During this time period, we placed SVC filters in 72 (24.5%) patients with UEDVT in whom anticoagulation was either deemed contraindicated (n = 67) or proved ineffective in preventing recurrent PE or extension of the thrombus (n = 5). Of the remaining 221 patients with UEDVT, 28 patients did not receive anticoagulation. Of these, eight (29%) died within 2 months of the diagnosis of DVT. None had clinical evidence of PE. During the same time period, 2107 (10%) of the 20,542 lower extremity duplex scans performed at our institution were positive for acute LEDVT. We placed 683 inferior vena cava (IVC) filters in these patients (30%).

Of the 72 patients with SVC filters, there were 25 (35%) men. The ages of these 72 patients ranged from 25 to 99 years (mean, 74 ± 1.7 years [SEM]). Nineteen (26%) patients had a malignancy, 20 (28%) had central venous catheters, and 1 (1%) patient had systemic lupus erythematosus. The remaining 25 patients had no identifiable risk factors. Nineteen (26%) patients had UEDVTs involving the left side, 48 (67%) UEDVTs were on the right side, and 5 (7%) were bilateral. The most proximal extent of the DVT was the subclavian vein in 44 (61%) patients, the axillary vein in 13 (18%), the brachial vein in 5 (7%), and the internal jugular vein in 10 (14%).

The duplex scan examinations included visualization of the innominate, subclavian, axillary, brachial, internal jugular, radial, and ulnar veins. The criteria for making the diagnosis of acute UEDVT were the absence of spontaneous flow with either respiration or augmentation maneuvers, inability to compress the vein whenever applicable, and hypoechoic signals within the vein lumen. All examinations were recorded on videotape and interpreted by attending vascular surgeons in conjunction with registered vascular technologists.

Indications for filter insertion included a contraindication to anticoagulation in 67 (94%) patients, PE despite adequate anticoagulation in 2 (3%) patients, and proximal extension of their DVT on repeat duplex scan examination in 3 (4%) patients. Contraindications to anticoagulation included gastrointestinal bleeding in 61 (86%) patients, severe thrombocytopenia after anticoagulation in 2 (3%) patients, thoracic aneurysm in 2 (3%) patients, brain metastases in 1 (1%) patient, and a cerebral aneurysm in 1 (1%) patient. All five patients with extension of DVT or recurrent PE despite anticoagulation were noted to have an activated partial thromboplastin time of more than 50 seconds after diagnosis of UEDVT. Two of these patients underwent workup for their recurrent DVTs and were found to have lupus anticoagulant. Two of these five patients died within 2 months of diagnosis of UEDVT.

Acute PE was diagnosed in five (7%) of the patients by means of high probability ventilation/perfusion scans or a computed tomographic scan of the chest before placement of the SVC filter. Fifteen patients underwent ventilation/perfusion scans that had negative (n = 10) or intermediate (n = 5) results. In addition, three (4%) of the 72 patients had already undergone previous insertion of an IVC filter, and 23 (32%) other patients underwent simultaneous insertion of both SVC and IVC filters because concomitant UEDVT and LEDVT.[10]

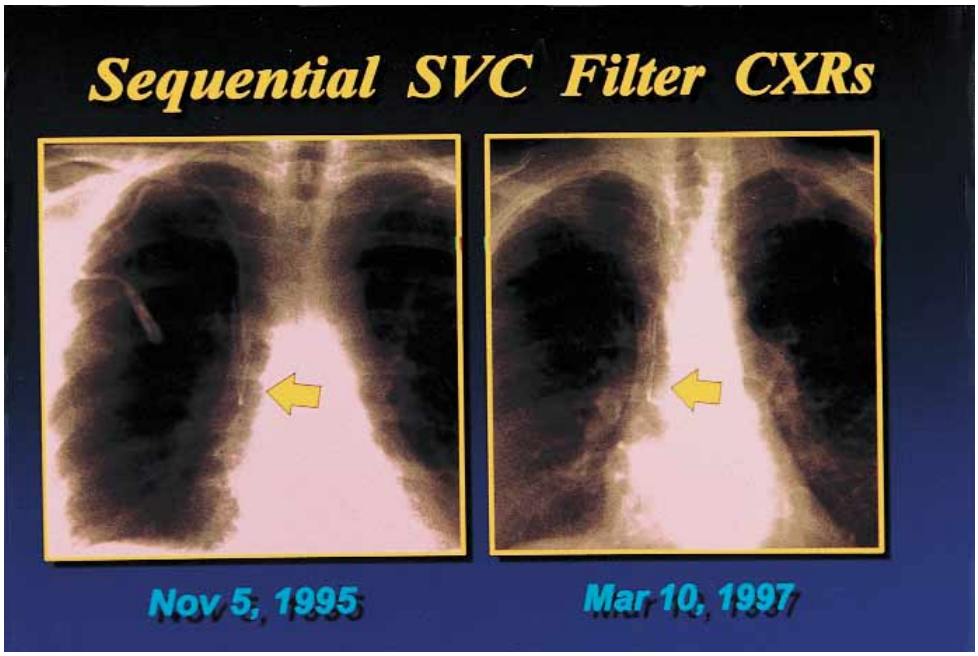
After venous access patency was determined by means of duplex scan examination, an intraoperative superior venacavogram was performed to ensure a caval diameter of less than 28 mm and to identify any venous anomalies. An SVC filter was percutaneously inserted in all patients by vascular surgeons in the operating room. Because it is our preference, we placed 60 of the filters using a femoral approach. Because LEDVT in the ipsilateral superficial femoral vein or popliteal vein or contralateral leg is not a contrainidication to placement of the filter through the femoral vein, most of the SVC filters could be placed from a femoral approach. The remaining 12 filters were placed through the right internal jugular vein.

These 72 patients with SVC filters were compared with 72 randomly selected age- and sex-matched patients who underwent placement of IVC filters during the same time period. Indications for placement of the IVC filter included gastrointestinal bleeding in 57 (79%) patients, failure of anticoagulation to prevent PE or DVT in 7 (10%) patients, metastatic carcinoma in 4 (6%) patients, recent hemorrhagic cerebral vascular accident in 3 (4%) patients, and recent surgery in 1 (1%) patient.

Data were reviewed for all patients from medical records, office charts, databases from the hospital radiology department, the Social Security Administration Death Index, the New York City Department of Vital Statistics, telephone interviews and clinical examination. Statistical analysis was performed with χ^2 analysis and the Student t test with the Texas Soft WinKS4.21 program (Cedar, Tex) and Graphpad Instat 2.05a program (San Diego, Calif).

RESULTS

Seventy-two SVC Greenfield filters were inserted into 72 patients with UEDVT. Follow-up ranged



Example of SVC filter. Chest x-ray film in November 1995. *Arrow* marks SVC filter. Same patient's chest x-ray film in March 1997. Note no apparent change in location of filter despite three interval placements of long-term venous catheters.

from 10 days to 78 months (mean, 7.8 months). Thirty-four patients (47%) died in the hospital of causes unrelated to the SVC filter or recurrent thromboembolism. The cause of death in these patients appeared to be multisystem organ dysfunction including sepsis, respiratory failure, and acute renal failure. These patients underwent prolonged ventilatory support, dialysis, and administration of multiple pressor agents and antibiotics. However, no autopsies were performed on these patients. Four additional patients died during the follow-up. Thirteen patients had follow-up of more than 1 year.

The average interval between filter placement and date of in-hospital death was 20 ± 6.1 (SEM) days. Follow-up of the surviving patients ranged from 1 month to 78 months (mean, 22 ± 2.8 [SEM] months); none of these patients were seen with any clinical evidence of PE or SVC thrombosis. One SVC filter was incorrectly discharged into the innominate vein and left in place. This vein remains patent 2 months after insertion without evidence of filter migration. The other 71 (99%) procedures were performed without complications. Specifically, there was no evidence of procedure-related pneumothorax, hemothorax, or arrhythmias, as documented by postoperative chest radiograph and intraoperative electrocardiogram monitoring. Postoperatively, there were no episodes suggestive of PE, SVC thrombosis, or perforation of the SVC or myocardium after the SVC filter placement in any patient. Sequential chest radiographs taken for reasons other than for follow-up of the SVC filter placement revealed no filter migration or displacement in the 26 patients, with a mean of 2 months after SVC filter placement (Figure). Postoperatively, one filter was dislodged during placement of a central line with the J-wire. The filter remained in the innominate vein without further sequalae. Fluoroscopy was not used during this procedure.

Using the Fisher exact or χ^2 test, we found no significant differences in age, sex, or comorbid medical problems (including diabetes mellitus, hypertension, history of tobacco use, intensive care unit [ICU] admission, localized or metastatic neoplasm, history of LEDVT, and in-hospital treatment for infection) between patients who were discharged from the hospital alive and those who had died (Table I). Presence of a central line did reach statistical significance between the two groups. Table II demonstrates the various factors present in the subgroups of patients who died. The patients who have SVC filters are compared with the age- and sex-matched patients with IVC filters in Table

Table I. Differences between in-hospital deaths and patients alive at discharge

	Nonsurvivors (%)	*Survivors (%)*	P *value*
Average age (y)	77 ± 4	72 ± 2.5	.14
Males/females	15/19 (44)	11/27 (29)	.22
Diabetes mellitus	2/34 (6)	8/38 (21)	.09
Hypertension	8/34 (23)	11/38 (29)	.79
History of tobacco use	4/34 (13)	10/38 (26)	.38
History of neoplasm	9/34 (26)	10/38 (26)	.60
Presence of central venous line	19/34 (56)	10/38 (26)	.02
History of LEDVT	6/34 (18)	11/38 (29)	.28
Concomitant LEDVT	13/34 (38)	11/38 (29)	.46
Admission to ICU	9/34 (26)	7/38 (18)	.57
In-hospital treatment for infection	9/34 (26)	10/38 (26)	.60

III. None of the patients had an SVC more than 28 mm in diameter.

DISCUSSION

Examination of the history of therapy for lower extremity venous thromboembolism reveals an evolution that has included various types of anticoagulation and different techniques of caval interruption. This has progressed with the basic appreciation of the natural history of the disease process and the effects of the interventions that may be made. Recent data also indicate that UEDVT may be associated with PE.[8,14] Extrapolation of the data for LEDVT has led us to the hypothesis that anticoagulation may be able to prevent PE in patients with UEDVT. However, because some of these patients will be unable to undergo anticoagulation, alternate treatment options need to be explored. The successful clinical use of IVC filters, experimental data on the use of SVC filters in animals, and case reports of SVC filters placed in humans have allowed us to report our initial experience on the safety and efficacy of SVC filters in patients unable to undergo anticoagulation.[6,8,9,15,16] These preliminary data now need additional refinement on the basis of information gleaned from further experience.

Thirty-two percent of the patients in this series had LEDVT. Often these cases were silent, clinically. In a separate series of 41 patients, 39% of patients undergoing placement of an SVC filter were found to have an LEDVT.[17] When we screened patients with UEDVT for LEDVT, we had found that 10 (38%) of the 26 patients with UEDVT had asymptomatic LEDVT.[10] Because of the high association of UEDVT with LEDVT, we suggest that lower extremity venous duplex scans be obtained preoperatively to assess the extent of thrombosis and to assess the lower extremity venous system as an access route for potential placement of an SVC/IVC filter. Furthermore, we suggest that systemic factors may play a role in the pathogenesis of DVT in a significant percentage of these patients because a significant portion of patients with UEDVT has been found to have a hypercoagulable state.[18,19]

One of the most striking features of this series was the extremely high mortality rate in these patients. Similarly, an earlier report found a survival rate of only 48% at 6 months.[14] Although it is difficult to analyze the factors contributing to the high mortality rate associated with UEDVT, in an earlier review of patients with UEDVT,[11] we concluded that clinically evident PE did not seem to contribute to this high mortality rate, whereas the underlying severity of the comorbid medical problems (eg, multiorgan system dysfunction, sepsis, metastatic carcinoma) may play a role in these findings.

Analysis of this mortality rate suggested that the patients with central lines did have the highest mortality rates. This may have been partially due to the underlying comorbidities that necessitated the placement of the central line. However, this analysis failed to identify a subset of the population with a limited life expectancy in whom the SVC filter placement would have little benefit. This may have been a result of the relatively small number of patients in each subgroup. Because of the difficulty in justifying placement of an SVC filter in a moribund patient and appreciating the high mortality rate associated with UEDVT, we have attempted to limit the use of SVC filters to patients with an expected life expectancy greater than 1 month, fully realizing that prediction of life expectancy by any measure can be extremely inaccurate. These retrospective data suggest that the elderly patients with multiple comorbid factors with multiorgan system dysfunction (eg, acute respiratory failure, cardiogenic shock, fulminant sepsis, and acute renal failure) at the end of a protracted intensive care stay would be the type of

Table II. In-hospital death rate of various subgroups

	Risk factor present (%)	*Risk factor absent (%)*	P *value*
Age > 75 y	20/40 (50)	14/32 (44)	.6
Female sex	19/46 (41)	15/26 (58)	.18
Diabetes mellitus	2/10 (20)	32/62 (51)	.06
Hypertension	8/19 (42)	26/53 (49)	.6
History of tobacco use	4/14 (29)	30/58 (52)	.12
History of neoplasm	9/19 (47)	25/53 (47)	.6
Presence of central venous line	19/29 (66)	15/43 (35)	.01
History of LEDVT	6/17 (35)	28/55 (51)	.26
Concomitant LEDVT	13/24	21/48	.06
Admission to ICU	9/16	25/56	.4
In-hospital treatment for infection	9/19	25/53	1.0

Table III. Comparison of SVC and IVC filters

	SVC filter (n = 72)	*IVC filter (n = 72)*	P *value*
Mean follow-up ± SEM (mo)	7.8 ± 2	10 ± 1.9	.25
In-hospital death (%)	47	12.5	< .001
Posthospital death (%)	6	43	< .001
Mean time to death ± SEM (mo)	0.7 ± 0.2	4.6 ± 0.8	< .001

patient in whom limiting the placement of an SVC filter because of minimal expected benefit might be considered. On the other hand, the incidence of PE (about 8% in our experience) does not seem to correlate with the site of UEDVT, placement of central line, pacemaker, history of carcinoma, and age of the patient. Therefore, these criteria do not seem to suggest which UEDVT would be less likely to cause PE and may not need placement of a SVC filter.[8,14]

When comparing these results to that of IVC filters, we noted several differences and similarities. The higher in-hospital mortality rate of the patients with SVC filters as compared with the patients with IVC filters suggests that the underlying comorbid conditions of these patients may vary. The rate of SVC thrombosis after SVC filter placement seems to be quite low; only two cases have been reported.[20,21] Whether this is due to the higher flow rates in the SVC as compared with the IVC is unknown. Because the SVC is a shorter vessel as compared with the infrarenal IVC, more attention to detail is needed for correct filter placement. A superior venacavogram is crucial to identify the SVC and the junction of the innominate veins to prevent placement of the filter into the innominate veins. One might expect a higher incidence of filter migration with SVC placement because of the cardiac activity. However, no data appear to support this hypothesis. Nevertheless, because the follow-up for SVC filters is much shorter and has fewer patients as compared with historical controls for IVC filters, further confirmation from other institutions with prospective data is needed.

Filters have now been placed for therapeutic occlusion of anomalous venous connections.[22,23] After placement of the filter, coils have been embolized to the filter to thrombose the duplicated SVC. Although not identical to the situation of thromboembolism, these cases do attest to the efficacy of the SVC filter to trap large emboli.

Another concern has been the future cannulation of the right heart. Although there have been reports of dislodging an IVC filter with cannulation, we have noted multiple cases of the passage of central venous catheters, pacemakers, hemodialysis catheters, and Swan-Ganz catheters through these SVC filters without dislodging the filter. Fluoroscopy for placement of these catheters to prevent dislodging the filter is suggested because one case of dislodgment occurred when fluoroscopy was not used.[14,24]

Insertion of an SVC filter is safe therapy to prevent recurrent thromboembolism in patients with UEDVT who are resistant to anticoagulation or who have contraindications to anticoagulation. There have been no major complications related to the procedure, and a similar rate of complications to IVC filter placement can be expected.[25] On intermediate follow-up, there remains no clinical evidence of recurrent PE or SVC thrombosis after SVC filter placement in our cohort of patients. Of course, certain precautions need to be taken to avoid the

pitfalls of SVC filter placement, and further data need to be collected to properly assess which patients are candidates for the procedure. However, the overall efficacy and safety of filters placed in the SVC seem to justify further investigation.

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DISCUSSION

Dr Patricia Thorpe (Omaha, Neb). Thank you, Dr Harris, and good morning. This study represents a very large series of patients who underwent SVC filter placement, perhaps the largest in the world. In fact, until last year in 1999, the number of SVC filters placed in people was equal to that placed in dogs in the experimental study by Dr Greenfield, which was published in 1985. The series from the Cleveland Clinic was published in 1999, just last year, where they had 41 patients and also demonstrated effectiveness and safety of placing an SVC filter. They only had follow-up of 15 weeks, and therefore, the present study with median follow-up of 22 months, for patients who survived the hospitalization, represents an important contribution to better understanding this area of increasing clinical concern because of the increase in the amount of upper extremity thrombosis associated with central line placement. The paper emphasizes that we must not disregard this upper extremity thrombosis. I think a lot of us have thought it was relatively benign because of collateralization, but particularly in patients who are not anticoagulated, maybe there is a risk of pulmonary embolus. Although pulmonary embolus may occur between 12% and 18% in some of the literature studies, absolute fatal embolization from subclavian thrombosis is relatively rare, probably 1% to 2% of all patients with upper extremity thrombosis. Although your study clearly demonstrates the technical safety of filter placement and points out the anatomical concerns pertinent to placing an upside-down

filter in a relatively limited space, I think that your report begs several questions, especially in the analysis, so I would like to ask these right now.

The first question does indeed deal with patient selection. You placed SVC filters in 10% of the patients you diagnosed with upper extremity DVT. I know that you did preinsertion cavograms to assess the size of the cava, but did you in fact do extremity phlebography to identify patients who had subclavian stenoses or mediastinal compression related to tumor compression, both of which might be contraindications to filter placement? In the first group they might be less likely to embolize with the stenosis in the subclavian and therefore not need a filter. In the second group, if you already have mediastinal compression, it may be a setup for SVC thrombosis.

You did point out that an SVC thrombosis has only been reported twice in the literature associated with filter placement in the SVC, and in fact, that represents almost 20% of those first 11 cases. That in itself is not benign.

The other thing associated with phlebography is, do you think that minimal nonocclusive thrombus requires a filter placement in the absence of anticoagulation?

You did point out that a significant number of patients died within 20 days. In fact, a large percentage of your patients did not survive the hospitalization. This compares with the Cleveland study that showed almost a similar mortality rate at 1 year. There was a study in 1994 presented by the Swedish group led by Bergqvist that showed that very few elderly patients with moribund conditions benefit from filter placement so the group cautioned that we should be very selective in whom we put filters and about patients who are ICU bound at that time in their lives.

So although your clinical follow-up appears excellent, the study does in fact lack objective patient follow-up, which is true of the other large study as well. We do not know how many patients have actually had a PE or superior vena cava perforation or occlusion, so it would be ideal to have this information perhaps with CT scanning or echocardiography. I understand the limitations of doing that kind of study, but do you have any data like this or do you plan to do this in the future, because if not I encourage you to do so.

Lastly, given your extensive experience compared with all the rest of us in this room, would you suggest any design modifications to make a better filter for the superior vena cava when it is indeed indicated?

I compliment you on your impressive series. I want to thank you for giving me your manuscript in advance. It is a privilege to be asked to be a discussant for this paper. Thank you.

Dr Enrico Ascher. Thank you very much, Dr Thorpe. Yes, the patient selection of these patients undergoing this type of therapy is a very thorny issue. Initially, we really were placing them in just about any patient with an upper extremity DVT and contraindication to anticoagulation, but as we accumulated the data from the upper extremity DVT patients and from the SVC filter patients, we realized that we need to be more selective, just because the mortality rate was ridiculous and it did not make sense to be placing this type of filter in patients who really did not have a 1-month survival.

As I said, we tried to limit, being more selective in placement of these types of filter in a moribund who is really not going to make it out of the hospital; however, that is a very subjective criteria. When we tried to analyze some of these things, again as we tried to look at APACHE scores or injury severity scores, trying to predict which patients—when you really look at those papers there is always going to be a patient who has a high expectation who does not make it out of the ICU—the 90-year-old who is in septic shock with multiorgan system dysfunction is going to make it. They always end up making the studies much more difficult in trying to predict which patients are not going to make it, so while we have tried to be more selective and we do agree that you do have to be selective in this type of patient population, it can be a very thorny issue.

We do perform vena cavograms on all of the patients, but we do not perform upper extremity phlebography. The only time that we usually would try to do that would be if a patient clinically had a history of thoracic outlet syndrome. We have only had two patients who fit into that category who underwent thoracic outlet decompression in our prior series, which covered about 6 years. That I think has to be treated very differently. Most of these types of patients who presented for the SVC filters seem to be a different type of patient. They seem to be much older, and most of them were quite sick and in the intensive care unit.

The issue of nonocclusive DVTs with the upper extremity is very difficult. There is really very little literature suggesting what the incidence of PEs is with even lower extremity nonocclusive and what the natural history of nonocclusive lower extremity or upper extremity DVTs is. Because of the lack of data, we have really been treating them with full anticoagulation and placement of an SVC filter if indicated.

With regard to some of the changes that we would suggest in design modification. The Cleveland Clinic has also suggested that there need to be some changes made in terms of smaller foot size, and perhaps a smaller length of the filter. However, while these issues are being looked into, we are still talking about a relatively small number of patients. When we had 72 patients, we had almost 10 times that number of patients who had placement of an IVC filter. So the number of patients who are going to be undergoing this type of procedure also needs to be taken into consideration.

Thank you.