Long-term complications of inferior vena cava filters

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ABSTRACT

Objective: Some inferior vena cava filter (IVCF) complications only manifest after prolonged dwell time (IVCF fracture, inferior vena cava [IVC] occlusion, and IVC perforation). Incidence of these complications is often based on mathematical projections given the lack of long-term imaging follow-up. The aim of this study was to assess the incidence of long-term complications of IVCFs using ideal imaging, contrast-enhanced computed tomography (CT).

Methods: From 2007 to 2009, 3303 IVCFs were placed across a large healthcare region. Only patients with contrast enhanced CTs of the abdomen at a minimum of 4 years post-IVCF implantation were selected. A retrospective observational study was performed in 96 patients. Primary outcomes were prevalence and predictive factors for IVCF fracture, IVC thrombosis, and IVC perforation.

Results: Of 96 patients, 39 had permanent IVCFs and 57 had retrievable IVCFs. Mean dwell time at most recent CT scan was 61 months. Overall rate of fracture was 14% with the majority (92%) in Cordis OptEase and TrapEase filters (Cordis, Fremont, Calif; $P < .0001$). Overall rate of partial/complete IVC occlusion was 13% (7.3% total and 5.2% partial). IVC perforation rates were higher among retrievable devices (70%) compared with permanent devices (15%; $P < .0001$). Perforation involving retroperitoneal structures was 68% among conical retrievable devices and 5% among permanent devices ($P < .0001$).

Conclusions: Long-term complications related to chronic IVCFs are relatively common, and the incidence of fracture and IVC perforation varies with device type. Higher rates of fracture were seen with the Cordis OptEase and TrapEase filters, whereas higher rate and degree of IVC perforation were seen with retrievable conical type devices. (J Vasc Surg: Venous and Lym Dis 2016;■:1-8.)

Inferior vena cava filters (IVCFs) have been used for over 40 years to reduce the risk of pulmonary emboli.[1] Utilization of these devices has increased over the last 2 decades with the advent of retrievable IVCF devices and emerging primary prophylactic indications for IVCF.[2,3] Most devices are newer, retrievable designs[4]; however, rates of retrieval vary significantly and many are lost to follow-up, thereby remaining in place as permanent devices.[5-7]

Increasing reports of retrievable IVCF complications including filter fracture,[8] fracture embolization,[9-11] cava thrombosis,[12] and inferior vena cava [IVC] perforation[13,14] have been published and an advisory was issued by the United States Food and Drug Administration in 2010.[15] A recent systematic review of 37 IVCF studies showed an overall mean follow-up duration of only 7.3 months using variable imaging modalities.[16] Several studies have shown that filter fracture and degree of IVC perforation appear to be a function of dwell time.[13,14] Considering that filter fracture is typically reported at 2 to 4 years of dwell time,[9-11] and cava thrombosis and perforation are difficult to diagnose reliably without contrast-enhanced computed tomography (CT), the true prevalence of long-term complications of IVC filters remains poorly characterized.

We hypothesize that long-term complications of IVCFs have been under-reported. The purpose of this study was to characterize long-term (>4 years dwell time) complications of both retrievable and permanent IVCFs using contrast-enhanced CT. Four years dwell time was chosen based on prior reports of high fracture rates at 4 years based on mathematical models.[9-11]

METHODS

This retrospective study protocol was approved by Inter-regional Institutional Review Boards for both Kaiser Permanente (KP) Northern California and KP Southern California with a waiver of informed consent.

Primary outcomes were prevalence and predictive factors for IVCF fracture, IVC thrombosis, and IVC perforation.

Patients. Patient selection algorithms were tested and used by the Kaiser IVC Filter Registry. Using electronic

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medical record data, current procedural terminology codes, and inventory tracking data; all patients who underwent IVCF placement at a KP Hospital in the Northern California and Southern California regions between January 1, 2007 and December 31, 2009 were identified. A total of 3303 IVCFs were placed during this period. Additional selection criterion was added to select only patients who had at least one intravenous contrast-enhanced CT of the abdomen at a minimum of 4 years from the date of filter placement (search algorithms based on imaging reports were used and 46 months dwell time was used for patient selection criteria to allow for variations in transcription time and report addendums); 121 patients who met all these criteria were identified. Of these 121 patients, 25 were eliminated because of either current procedural terminology coding error or interval retrieval of filter. The final study group contained 96 patients.

Table I. Demographics of selected subgroup compared with all patients with inferior vena cava filter (*IVCF*) 2007-2009

Variables	All IVCFs (N = 3303)	Selected patients with 4- year post-CT scan (n = 96)
Mean age, years (SD)	64.8 (16.9)	63.4 (14.3)
Mean BMI (SD)	29.1 (8.67)	30.4 (8.57)
Male sex, %	48.6	42.7
Female sex, %	51.4	57.3
Caucasian race, %	61.8	67.7
African American race, %	17.2	12.5
Hispanic race, %	14.4	13.5
Asian race, %	4.9	5.2

BMI, Body mass index; *CT*, computed tomography; *SD*, standard deviation.

Demographics. Patient demographics and clinical histories were obtained from our institutional electronic medical record. Filter placement indication and presence or absence of hypercoagulable states were recorded from individual chart review.

Indication for the filter placement was recorded based on clinical notes, as reviewed by board certified vascular and interventional radiologists (S.L.W. or E.R.).

Imaging. All contrast enhanced CTs of the abdomen and pelvis with maximum slice thickness of 5 mm were reviewed by board certified vascular and interventional radiologists (S.L.W. or E.R.), using picture archiving and communication system workstations. Presence or absence of coronal and sagittal reformatted images was recorded. In the event of numerous CTs (>3), representative time points were chosen at the discretion of the reviewing radiologist. If a filter fracture was detected by CT, all prior CTs, as well as plain films of the abdomen or lumbar spine were reviewed to determine the first observation of fracture. All fractures were characterized by the number of struts fractured and any fracture embolization or migration was noted.

Cava thrombus was recorded as either partial cava thrombosis (defined as filling defect in the IVC and either separate from the filter or extending beyond the filter) or complete cava thrombosis (defined as no filling of the IVC ± chronic findings including retraction of the IVC or iliac vein[s]). If cava thrombus was detected by CT, all prior CTs were reviewed to determine the first observation of cava thrombus.

IVC perforation was defined as a filter leg extending greater than 3 mm beyond the IVC wall.[17] The number of perforating struts and maximum amount of perforation was recorded for each CT. If there was direct extension to or within a retroperitoneal structure, the structure was recorded. If IVC perforation was detected by CT, all prior CTs were reviewed to determine the first occurrence of perforation.

Chart review was also performed to evaluate CT scan indications and categorized as follows: postsurgical follow-up, routine cancer follow-up, routine follow-up other, trauma, abdominal pain, or other. For patients who had CTs ordered for abdominal pain, this was further subdivided into abdominal pain with non-IVCF etiology for pain identified on CT scan (diverticulitis, abscess, bowel obstruction, appendicitis, etc), abdominal pain with clinical history or findings attributable to IVCF, or abdominal pain with no definitive findings on CT scan to account for abdominal pain.

Data analysis. Frequencies and percentages were reported for categorical variables and means/medians were reported for continuous variables. Statistical significance for IVC perforation and fractures were calculated using Fisher exact test. All data analysis was performed using SAS v 9.2 (SAS Institute, Cary, NC), and P value of $<.05$ was considered statistically significant.

RESULTS

Demographics and imaging. The distribution of patient age, sex, race, and body mass index was similar among all patients who had an IVCF placed (n = 3303) and the subset of patients who had an IVCF and a contrast enhanced CT at 4 years dwell time (n = 96) (Table I). Most common indications for filter placement in our group of filter patients (Table II) were for (1) pulmonary embolism (PE) and a contraindication to anticoagulation (36%); (2) deep vein thrombosis (DVT) and a contraindication to anticoagulation (30%); (3) Primary prophylaxis in a high-risk patient (14%); and (4) PE despite adequate anticoagulation (9.4%).

Of the 96 patients included in this study, 39 had permanent filters placed (10 B Braun Venatech LP [B Braun, Bethlehem, Pa], 2 Boston Scientific Greenfield