Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration

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PURPOSE: To report on the evaluation and management of Bard Recovery filter limb perforation, fracture, and migration.

MATERIALS AND METHODS: In 2007, all patients who received a Bard Recovery filter at a single institution were contacted for consultation and evaluation by noncontrast computed tomography. Rates of limb perforation, fracture, and migration were evaluated on early (<180 days) and final images. Retrieval success and complications were evaluated.

RESULTS: Fourteen of 16 patients with Bard Recovery filters were evaluated. The early images in nine patients (mean, 30 days; range, 0–126 d ± 40) demonstrated arm perforations in 56% (n = 5), leg perforation in 11% (n = 1), and no early fractures or migrations. Final images (mean, 899 days; range, 119–1,218 d ± 320) demonstrated filter arm perforations in all 14 patients. Leg perforations were seen in 36% of patients (n = 5), and there were a total of four fractures with migration in 21% of patients (n = 3). All fractures occurred in arms that had perforated the vena cava on early images. Two patients had already had their filters retrieved at 119 and 302 days, respectively; the remaining 12 patients elected to have their filters retrieved after evaluation. All 12 filters were retrieved at a mean of 1,021 days (range, 119–1,242 d ± 134). Leg hook fractures occurred during eight of 12 filter retrieval procedures (67%).

CONCLUSIONS: Recovery filter limb perforation of the vena cava increases over time and is associated with a 21% incidence of filter arm fracture and migration. Follow-up imaging is recommended. Filter retrieval has a high success rate and is the authors’ preferred management strategy.

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Abbreviation: IVC = inferior vena cava

THE Recovery filter (Bard Peripheral Vascular, Tempe, Arizona) was developed as a permanent and retrievable filter and was commercially available from April 2003 to October 2005. Reports on the early experience with the Recovery filter noted problems with arm fracture and migration (1). In 2005 the G2 filter (Bard Peripheral Vascular) replaced the Recovery filter. The new G2 filter was modified to reduce filter tilt, fracture, and migration (2). Despite the initial concerns, there is little information published in the literature on long-term outcomes with the Recovery filter.

A patient presented to our institution with symptomatic filter arm fracture and migration 2 years after placement of a Recovery filter. This patient was having chest pain and nonsustained ventricular tachycardia. The filter fragments were removed from the heart and the remaining filter was removed from the vena cava (3). A separate case report (4) describes a patient with Recovery filter arm migration to the right ventricle resulting in right ventricle perforation and cardiac tamponade. As a result, we reviewed the records and available images in patients treated with the original Recovery filter to evaluate the incidence of inferior vena cava (IVC) arm perforation, arm fracture, and migration. All known patients were subsequently contacted for consultation and further evaluation with noncontrast computed tomography (CT). This report details the imaging findings and the resulting patient management.

MATERIALS AND METHODS

The institutional review board approved this study. Retrospective review of procedure logs, picture archiving and
communication system images, and purchasing and billing records was performed to identify patients treated with the Recovery filter. These records revealed 16 patients with the Recovery filter. Fifteen filters were placed with intention for retrieval; one filter was placed as a permanent filter. The mean age of patients was 45 years ± 11 (SD; range, 26–68 y). Seven filters (44%) were placed in male patients and nine (56%) were placed in female patients. Indications for filter placement are listed in the Table. All available images were reviewed for filter limb perforation, fracture, and migration. The number of limbs perforating the vena cava, fractured, or migrated was recorded for each examination. Subsequently, all patients were contacted by telephone and scheduled for consultation and follow-up abdominal CT. The number of final limb perforations, fractures, and migrations were obtained from follow-up CT or IVC images before filter removal. The patients’ medical records were reviewed for age, sex, indication for filter placement, and symptoms related to filter fracture or migration. At follow-up consultation, the patient’s current need for an IVC filter was assessed. They were advised that the Recovery filter was designed for removal, that their filter was placed with the intention of retrieval, and that the Recovery filter had been found to have arm fracture and migration in as many as 10%–20% of patients with arm perforation. Patients were then notified if they had arm perforation, fracture, or migration. In patients with filter fracture, removal was recommended. Patients with arm perforation were given the option of filter removal or regular imaging follow-up. Filter retrievals were performed in the angiography suite from the jugular approach with use of the Recovery Cone catheter (Bard Peripheral Vascular). All filters retrieved were examined with a dissecting microscope (magnification ×50) to evaluate the location of fracture. If present, fracture surfaces were evaluated at high magnification with a scanning electron microscope to determine the fracture mechanism.

### Definitions

**IVC limb perforation.**—A filter limb was considered to have perforated the IVC when the inferior tip of a limb was clearly outside the circumference of the vena cava on abdominal CT or an inferior vena cavoogram (Fig 1).

**Indication for filter placement.**—The six indications for filter placement described by the Vena Cava Filter Consensus Committee (5) are listed in the Table.

**Early images.**—Early images are abdominal CT scans or inferior cavo grams of the filter obtained less than 180 days after filter placement.

**Final images.**—Final images are abdominal CT scans or inferior cavo grams obtained at the time of follow-up consultation or filter removal.

**Spontaneous filter retrieval.**—Filters removed from patients without concern for perforation, fracture, or migration were considered to have been removed spontaneously.

**Complications.**—Complications included pulmonary embolus, deep vein thrombosis, whole filter migration, limb perforation of IVC, limb fracture and migration, IVC thrombosis, filter tilting, IVC perforation after removal, and incomplete retrieval of the filter.

**Extreme filter tilting.**—Filter tilting to such an extent that the cap of the filter was in contact with the wall of the IVC was considered to constitute extreme filter tilting.

**Distal attachment hook fracture.**—Distal attachment hook fracture is simply fracture of the distal leg hook from the filter during filter retrieval.

### Data Collection and Analysis

Data were collected as described, and quantitative analysis comparing the number of patients with perforation, fracture, and migration was performed, along with the total numbers of each. Whole filter migration, filter tilting, and IVC thrombosis rates were obtained from final images. A best estimate of time to fracture was obtained by evaluation of images between filter placement and fracture identification. Images reviewed were those available on our picture archiving and communications system. Rates of spontaneous filter retrieval and retrieval for arm perforation or fracture were calculated. Success rate, complications, fluoroscopy time, and contrast agent use during retrieval were obtained from reports. History of previous and ongoing thromboembolic disease was determined from follow-up consultation (ie, history and physical examination), available medical records on the hospital information system, and available imaging. Statistical comparisons of arm and leg perforation and fracture rates between early and final imaging was performed with use of a paired Student t test.

### RESULTS

On initial review, nine of 16 patients had early images (range, 0–126 days ± 40; mean, 30 d), including one patient presenting with arm fracture and migration to the right ventricle. All these patients had CT examinations of the abdomen. All filters appeared to be centered within the IVC without filter tilting. The early images demonstrated arm perforations in 56% of patients (n = 5), leg perforation in 11% (n = 1), and no early fractures or migrations. There were 12 arm perforations in five patients and one leg perforation in one patient.

At time of initial review, four patients had final images. Two patients had spontaneous removal of intact filters at 119 and 302 days, respectively, and their final images were IVC images before filter removal. Two other patients had recent abdominal CT examinations demonstrating filter arm fracture with migration and under-
Figure 1. Appearance of perforated arms on CT and inferior vena cavogram. The Recovery filter has six arms and six legs. (a) Intact top of the filter with six arms. On images (b), note that all the arms are outside the IVC. Several of the arms are completely surrounded by fat. The arm at 7 o’clock (white arrow) appears to be in a small vein. The six legs are in the center of IVC and none of the legs have perforated the IVC. (c) On an image taken caudal to b, the tips of only four arms are noted. Arms at 5 and 7 o’clock are adjacent to but outside the IVC (note acute angle between arm and IVC wall), and these were counted as perforations. (d) Anteroposterior view of the IVC shows the arms on either side to be well outside the IVC.
went filter retrieval. Therefore, in our initial review, we found a 22% prevalence (n = 2) of filter arm fracture and migration.

Follow-up Examination

Two of 16 patients were completely lost to follow-up. Two patients had undergone spontaneous filter removal. Twelve patients were seen in consultation, and all 12 requested filter retrieval. Two patients had symptoms related to filter fracture and migration. No patients had a history of pulmonary embolus. One patient had recurrent deep vein thrombosis.

Final images (range, 119–1,218 days; mean, 899 ± 320) were available in 88% of patients (14 of 16). Of these patients, filter arm perforation was found in all 14, leg perforation in five (36%), and fracture with migration in three (21%). A total of 61 arm perforations, 10 leg perforations, four arm fractures, and four migrations were noted. Final images were abdominal CT in 12 patients and inferior vena cavaograms in two. Filter arms migrated into the right ventricle, into the right upper-lobe pulmonary artery, among the legs of the filter, and into the retroperitoneum. There were no whole-filter migrations or tilted filters. One patient had evidence of IVC thrombosis and recanalization (Fig 2).

No acute thrombus was noted in the IVC. All filters were successfully retrieved without significant complications. Procedure time ranged from 9 to 24 minutes (mean, 14 min ± 5). Fluoroscopy time ranged from 2 to 7.5 minutes (mean, 4.0 min ± 1.7) and contrast agent dose ranged from 20 to 80 mL (mean, 30 mL ± 21). Half the migrated arms (n = 2) were retrieved, one from the right ventricle and one from the IVC. Two migrated filter arms were not retrieved; one was left in the right upper-lobe pulmonary artery where it had been for 18 months and one was left in the retroperitoneum. One filter was retrieved via the external jugular vein because of right internal jugular vein thrombosis. One filter was retrieved from a vena cava deformed at the filter site from earlier occlusion. There was no apparent trend in the initiation site of the fatigue-fractured arms. Indeed, two fractures initiated at the outer part of the nitinol wire arm whereas the other two initiated toward the medial position of the device. However, the mechanism of fatigue fracture was evident in each fractured arm and suggested a slow fracture process resulting from the cumulative effect of cyclic deformations.

Figure 2. Narrowed and irregular IVC is seen below the Recovery filter. There is a prominent collateral vessel to the left.

Statistical comparison of early and final images with a paired Student t test demonstrated significant increases in arm perforation rate over time, and a tendency—but not a statistically significant one—toward increased leg perforation and arm fractures. Early imaging (range, 0–126 days; mean, 30 d ± 40) showed average per-patient rates of arm perforation of 1.33 (12 arms in nine patients), leg perforation of 0.11 (one in nine patients), and arm fracture with migration of zero. Final imaging (range, 119–1,218 days; mean, 899 ± 319) in 14 patients demonstrated higher average per-person rates of arm perforation of 4.36 (61 in 14 patients; P = .002), leg perforation of 0.71 (10 in 14 patients; P = .10), and arm fracture with migration of 0.29 (four in 14 patients; P = .20).

Microscopic evaluation of all four arm fractures revealed fracture just below the filter cap. Furthermore, eight of the 12 retrieved filters (66%) contained fractures through the device leg’s distal attachment hooks (11 total fractures). Examination of the fracture surfaces by scanning electron microscopy revealed classical signs of high-cycle metal fatigue in the fractured arms, whereas the hook fractures exhibited ductile overload fracture features with a possible low-cycle (ie, high-stress) fatigue component (6). Representative arm and hook fracture surfaces are presented in Figures 3b and c, respectively.

There was no significant extravasation of contrast medium seen on angiograms obtained after filter retrieval. Examination of the extracted filters demonstrated 11 distal attachment hook fractures in eight of the 12 extracted filters.
witnessed by the device in vivo (ie, breathing). Conversely, all hook fractures were similar. They exhibited pure overload bending fractures that initiated on the concave surface of the hook. In addition, the fracture initiation sites were surrounded by rough (ie, high-energy) low-cycle fatigue features, and contained little to no tissue on the surface. It is therefore most likely that the hook fractures occurred during device removal procedure, as the long indwell time likely promoted endothelialization of the hooks, thereby requiring significant forces to extract the devices.

DISCUSSION

Our initial review of picture archiving and communication system images of patients treated with a Recovery filter demonstrated three arm fractures and migrations in two of nine patients with images. We believed this exceeded the previously noted fracture rate of 2%-10% outlined in the Society of Interventional Radiology consensus statement on IVC filters (7), and thus felt compelled to review our records and contact patients in whom we had placed a Recovery filter.

All the Recovery filters inserted at our institution were placed with the intention of retrieval; one patient from an outside institution had a filter placed as a permanent filter (Table). The Recovery filter was placed in a small, highly selected group of patients for whom the referring physician specifically requested a removable filter. Despite this strong bias in favor of retrieval, we found that only 13% of our patients (n = 2) had returned for filter removal. This low rate of retrieval is similar to the 13% reported by Grande et al (8) in 105 patients who had filters placed with the intention of retrieval. However, we found our patient population was receptive to returning for follow-up consultation and examination of their filters. All counseled patients elected to have their filter removed in part because there was a preexisting expectation that the filter would be removed and in part because they were informed that there was a potential for fracture and migration.

According to the Society of Interventional Radiology quality improvement guidelines (7), vena cava perforation is a trackable event with reported rates as high as 40%. In the current study, the incidence of Recovery filter arm perforation progressed from 56% of patients on early images (mean, 30 days ± 40) to 100% of patients on final images (mean, 899 days ± 320). In the same interval, fractures progressed from an incidence of
zero to 21% (four arms in three of 14 patients).

One published report (1) showed 28% of patients (11 of 40) with arm perforation at 80 days. Conversely, Binkert et al (9) reported only two limb perforations and no fractures in 13 patients at an average of 254 days. However, these authors described arms of the filter extending outside the wall of the IVC in 12 of 13 patients (92%) on inferior vena cavograms at the time of removal. The authors described this finding as “tenting the vena cava” (9). In our experience, arms extending outside the IVC wall on venograms had clearly perforated the IVC on CT images when both studies were available (Fig 1). Therefore, we considered arm extension beyond the IVC wall a perforation. Our study further finds a significant increase in the rate of arm perforation from early to final images.

In the present study, all fractures occurred in arms that had previously shown perforation of the IVC. Three of our 14 patients (21%) exhibited device fracture and migration. The association of fracture with previous arm perforations has been noted in a case report and an earlier study (1,3). Kalva et al (1) described 11 arm perforations with three fractures. Fractures have been reported to occur in as many as 7.5% of patients in previous studies (1,8,9), which evaluated filters at 80–254 days. The average estimated time to fracture in our study was 668 days. The current study finding of a 21% fracture prevalence may be related to longer follow-up interval.

All fractured arms migrated. Two migrations were local: one migrated into the adjacent retroperitoneum and one moved into the legs of the filter. These local migrations were thought to be asymptomatic. Two of our patients were symptomatic; one had persistent symptoms of chest pain and nonsustained ventricular tachycardia to the extent that we were obliged to uncover the underlying source. The other patient had transient symptoms after right pulmonary artery migration. This patient came to the hospital with atypical chest pain; the patient was evaluated and discharged after negative findings on a workup that included chest radiography (Fig 4). The migrated filter arm was discovered 18 months later when we contacted the patient for follow-up.

The fractures were seen to have occurred just below the filter cap on CT images as well as on microscopic examination (Fig 3a). Scanning electron microscopy of the fractured arm surfaces demonstrated changes characteristic of bending fatigue fractures (Fig 3b). Arm fractures are apparent on abdominal CT studies (Fig 5), but the migrated fragments were more difficult to detect. The conspicuity of migrated arms on plain radiographs was poor, and migrated arms were difficult to find even when an arm was known to be absent from its proper location on the filter. In one case, an arm that migrated to the right upper lobe was repeatedly missed on plain radiography and CT of the chest. The difficulty in identifying the fragment on plain radiographs most likely arose from the fact that there were surgical clips nearby (Figs 4, 6). On CT, the arm was difficult to see on axial noncontrast images. Contrast-enhanced images obscured the arm on most standard window and level settings (Fig 6). Assuming that our data do not represent a statistical aberration, we suggest there are many other patients with Recovery filters with arm fractures and migrations in whom it is conceivable that these migrated fragments have gone undetected.

The purpose of the retrievable filter is to reduce risk to the patient. The retrievable filter concept is built on the idea that a long-term venous foreign body is undesirable, as is demonstrated in the often-cited article by Decousus et al (10). In addition, the Recovery filter is associated with a high rate of IVC arm perforation and structural weakness, as initially reported by Kalva et al (1) in a multicenter study. The current study is in agreement with the findings of Kalva et al (1) that arm perforation and structural weakness leads to fracture. In addition, we have shown high incidences and statistically significant progression of filter arm IVC perforation rates between early and final images, suggesting that fracture rates may progress as well. A

Figure 4. Chest radiograph obtained in a patient with a Recovery filter who was seen in the emergency room for atypical chest pain.
significant increase in fracture rates was not demonstrated in the present small series, but an arm fracture and migration rate of 21% was found. Serious clinical events associated with filter fracture and migration have been reported rarely (3,4). The overall risk of leaving the Recovery filter in place is defined by the risk of increased thromboembolic disease inherent in all filters and the risk that the high rate of arm perforation will lead to increasing numbers of fractures, migrations, and clinical events. Fortunately, the retrieval side of this analysis is better defined.

The current report demonstrated a 100% success rate for late filter retrieval at a mean of 1,014 days ± 137. Similarly high success rates of 82%–100% for retrieval of the Recovery filter have been reported in small series of 13–24 patients (1,8,9,11,12). The range of average indwell times for these series was 33–254 days. In the series with the longest reported dwell time of 254 days in 13 patients (9), 100% of retrievals were successful. In all reports, retrievals were performed without major complication. Failed retrievals were related to residual thrombus or tilted filters (1,8,12). It appears the indwell time before retrieval of the Recovery filter is indefinite. The relative ease, high success rate, and low complication rate of retrieving the Recovery filter makes the decision for removal less complicated.

Based on the clinically successful filter retrieval in the limited patient population of the present study, there appears to be justification for late-stage removal of these devices. The most clinically significant reason is the potential risk of migration of a fractured arm into the heart or lungs, which could result in a negative clinical sequela; or that leaving the devices implanted exposes them to additional deformation cycles, thereby increasing the risk of arm fatigue fracture. In addition, fracture of the device exposes fresh (ie, non-passivated) metal to the blood stream, which could result in an inflammatory response in patients with nickel allergies, and/or corrosion of the device itself. However, retrieval is not without its risks. Indeed, removal of the Recovery filter resulted in leg hook fracture in 66% of patients (eight of 12). Although it is most likely that the fractured leg hook remnants stay contained within the IVC walls, there is the possibility of migration of these small (approximately 1 mm long) fragments through the circulatory system, which poses a potential risk of embolization.

The patients with the Recovery filter did not have clinical evidence of recurrent pulmonary embolus. One patient had problems with bilateral leg swelling and recurrent deep vein thrombosis. This patient was found to have a narrowing and irregularity of the IVC at the level of the filter and a prominent collateral vein, suggesting thrombosis and recanalization of the IVC at the filter placement site (Fig 2). This patient receives permanent long-term anticoagulation. His filter was removed without complication. No other thromboembolic complications were noted in our patients. None of the filters were tilted into the wall of the IVC or exhibited significant displacement. These complications are in keeping with expected outcomes for a permanent or retrievable filter (7).

Figure 5. Abdominal CT findings of fracture. (a) At the top of the filter, the cap is in the center of the IVC. Only five arms are present (compare with Fig 1a). The arm at nine o’clock is absent. (b) The most caudal image demonstrates the tips of the remaining arms: three arms have perforated the IVC, extending beyond the IVC wall. Arms at 3 and 6 o’clock were not counted as perforations because of a lack of a clear acute angle of tissue between the arm and the IVC wall.
Figure 6. (a) Magnified view of right upper lobe (same as Fig 4). Migrated arm (open arrow) was missed on numerous chest radiographs and chest CT examinations over a period of 18 months. (b) Fragment in right upper lobe is seen on contrast-enhanced chest CT scan (white arrow). (c) Axial images with and without contrast medium windowed and leveled for mediastinum, lung, and bone, respectively. White arrow points to the hard-to-see filter fragment on the contrast images.
The present study has profound implications for patients with Recovery filters, suggesting that these patients require more intensive imaging and clinical follow-up; however, the patient cohort is too small to allow definitive recommendations. The study does define an important clinical problem with the Recovery filter and describes some of the clinical and imaging findings associated with filter fracture and migration. The site and type of the arm and distal attachment hook fractures has been identified, but the overall mechanism for the more clinically relevant arm fractures is still uncertain. In situ motion analysis could give insight into the forces causing the arms to fracture. The present study does not evaluate the risk and benefits of leaving the Recovery filter in place versus removal, as all patients underwent filter retrieval. Study of a larger number of patients with the Recovery filter is necessary to clarify the best course of action for these patients.

The Bard Recovery filter was found to be associated with increasing rates of limb perforation, arm fracture, and migration in our small study population. IVC wall perforations of the upper arm of the Recovery filter progress over time and are associated with filter arm fracture and migration. The Recovery filter has otherwise functioned well as an IVC filter. The Recovery filter appears to have an indefinite indwell time before retrieval. We are recommending imaging with abdominal CT to screen for perforation, fracture, and migration in patients with a Recovery filter in place. In our experience, fractured filters can be removed successfully with high success rates and a low incidence of complications. Removal may be considered if the clinical risks associated with leaving the fractured device in place outweigh the risks attributed to the removal procedure.

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References