Successful Retrieval of 29 ALN Inferior Vena Cava Filters at a Mean of 25.6 Months after Placement

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ABSTRACT

Purpose: To prospectively evaluate the outcomes of ALN inferior vena cava (IVC) filter extractions after long-term implantation (ie, > 1 y).

Materials and Methods: Between November 2004 and January 2011, 503 retrievable ALN IVC filters were implanted, but only 188 (37%) were addressed for removal. Because it was suspected that a subset of patients had not been referred for IVC filter retrievals, between November 2008 and January 2011, all patients who still had an ALN filter that had been implanted at least 1 year previously were systematically recalled. For those patients, the relative benefits and risks of filter removal were evaluated by a multidisciplinary conference. If deemed necessary by the conference, filter removals were performed. The endpoints were the feasibility and safety of filter retrieval, which were based on an evaluation of the success rates, pre- and postprocedure complications, and dosimetric assessments.

Results: Twenty-nine patients still retained their filters at least 1 year following implantation. The mean interval between implantation and retrieval was 25.6 months (range, 14.8–40.8 mo), and extractions were performed on eight patients who had received a filter at least 2 years earlier. The longest dwell time was 40 months. All filters were extracted successfully without complications.

Conclusions: Optional ALN filter retrievals can be performed safely after more than 1 year following implantation.

ABBREVIATIONS

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism

The field of inferior vena cava (IVC) filtration is a very active and creative branch of endovascular techniques. However, high-level clinical evidence has remained poor despite numerous publications. In fact, only two randomized trials have been published in the past 30 years, both of which examined the use of definitive IVC filters plus anticoagulation versus anticoagulation alone (1–3). The data from these published studies suggest that permanent filters decrease the risk of symptomatic pulmonary embolism (PE) but increase the risk of deep vein thrombosis (DVT) at 8 years (1). Retrievable IVC filter devices have been developed to overcome the long-term complications of permanent filters while maintaining the benefits of filtration (4). However, in clinical practice, filter retrieval times are often delayed because of a prolonged need for IVC filtration or because contact with patients is lost during the follow-up period (5). Nonetheless, successful filter retrievals have been described for a variety of IVC filters after extended dwell times (6–9). A direct relationship exists between extended implantation times and the success of filter retrieval. In addition, additional maneuvers are often used to increase the extraction success rate (10,11). The ALN filter (ALN Implants Chirurgicaux, Ghisonaccia, France) is one of the filters currently in use. Its extractability has been examined after an average implantation time of 93 days (12–14). Therefore, it is of interest to evaluate how safely the delayed retrieval of ALN filters can be performed.

The purpose of the present study was to evaluate the feasibility and safety of percutaneous removal of ALN filters more than 1 year following implantation.

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MATERIALS AND METHODS

The present single-institution prospective registry was approved by our institutional review board as an observational study of regular practice and was compliant with the Health Insurance Portability and Accountability Act. From November 2008 to January 2011, a systematic recall was conducted of all consecutive patients who had received an ALN filter at least 1 year previously. We suspected that a subset of patients had not been referred by their primary physician for IVC filter retrievals because of a lack of awareness of the potential long-term complications. All patients underwent clinical examinations, and abdominal radiography was performed to screen for filter migration or damage. Recommendations for filter extractions were based on a meticulous review of each patient's medical history. Decisions regarding extractions were discussed on a case-by-case basis in our PE and DVT multidisciplinary conference (which includes a pulmonologist and an interventional radiologist). Patient characteristics, indications for IVC filtration, and possible complications were registered according to the Society of Interventional Radiology (SIR) guidelines, as were the reasons why the extraction was delayed (15).

The ALN IVC filter is made of 316 L nonferromagnetic stainless steel and is described as having a "cone" or "umbrella" shape. It is placed with the apex of the filter in the cephalic position. Removal procedures were attempted with the use of a dedicated extraction kit. In case of major tilting (ie, filter tilt $> 15^{\circ}$), additional manipulations were used as described previously by Pellerin et al (12). Retrieval procedures were performed under local anesthesia, usually on an outpatient basis, but occasionally during the course of a short hospital stay (< 2 d), depending on clinical presentation. According to our institutional protocols, patients with ongoing oral anticoagulation therapy were switched to low molecular weight heparin 5 days before the extraction attempt to minimize the occurrence of bleeding. Low molecular weight heparin injections were not performed on the morning of the day of filter removal and were postponed until the day after the extraction. Following removal, a final vena cavogram was obtained through the retrieval sheath to assess IVC patency.

For the purpose of standardized reporting, SIR reporting standards were used (15). Adverse clinical events were those occurring during the retrieval of the device or within the first month following extraction. Major complications were defined as those requiring additional procedures or prolonged hospitalization or resulting in death. Filter migration was assessed by comparing the postinsertion and preretrieval cavograms. Any migration in excess of 2 cm was reported. Tilting was assessed by comparing the long axis of the filter after implantation and before the retrieval procedure by using cavography. Tilting was defined as moderate if the deviation from the IVC axis was less than 15° and severe if the deviation was greater than 15°. Deviations from the IVC axis were assessed by comparing the cavogram taken immediately after filter insertion versus the preextraction cavogram. Filter fracture was defined as any loss in the structural integrity of the filter that could be documented by imaging. IVC penetration was defined as an instance in which the filter strut or anchor extended more than 3 mm outside of the contrast agent column on venography. Dosimetric data were retrieved from our institution's electronic patient records (DxCare; Medasys, Gif-sur-Yvette, France).

The objective of the study was to determine the safety and feasibility of filter retrieval, which were based on an evaluation of the success rates, peri- and postprocedure complications, and dosimetric assessments. Statistical analyses were performed by using XLSTAT 2011.4.02 (Addinsoft, Paris, France). Values are reported as means (or medians), standard deviations, and ranges.

RESULTS

Between November 2004 and January 2011, 503 retrievable ALN IVC filters were consecutively implanted with the intent to be removed when possible. Of the 503 patients implanted with a retrievable filter, only 188 (37%) had their filter removed during the first year following implantation. Forty-nine (10%) had been implanted with a filter within the previous year. Those 49 patients were closely followed, and the removal of their IVC filters was scheduled as needed. Of the 266 patients (53%) in whom filter retrievals were not attempted, 52 (10%) did not respond to phone calls or mailings and were considered lost during the follow-up period, 159 (32%) were deceased (115 of cancer, 27 of cardiovascular disease, and 17 as a result of multiple trauma), and 26 (5%) had a filter that was left in place because the treating physician had considered the indication to be permanent (as a result of ongoing cancer and/or age > 80 y). The 29 remaining patients (6%) still had a filter in place without any indication for long-term vena cava interruption. A flowchart of study patient disposition is shown in **Figure 1**. In the group of 29 patients (6%) examined in the present report, indications for filter placement included the following: PE or DVT with a temporary contraindication to anticoagulation ($n = 14$; 48%), prophylactic filtration against PE recurrence in high-risk surgical cases ($n = 10$; 35%), and complications of anticoagulation therapy ($n = 5$; 17%). The patient characteristics and filter indications are provided in **Tables 1 and 2**. No recent history of postthrombotic syndrome, DVT, or PE was observed in the time since filter implantation in any of the patients. The mean interval between the time of implantation and the time of retrieval was 25.6 months ± 6 (range, 14.8–40.8). For eight patients, filter extraction was performed after a mean delay of 32.6 months. The longest dwell time was 1,224 days (40 mo).

Preextraction cavograms revealed less than 15° tilt in 11 patients (38%) and a tilt more than 15° in two patients

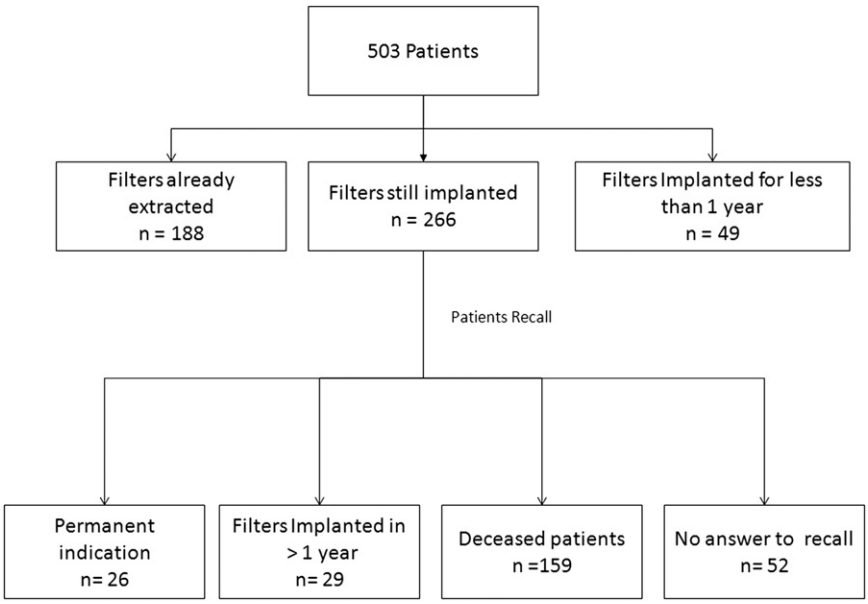

Figure 1. Patient disposition flowchart.

Table 1. Characteristics of Patients with Retrievable IVC Filters Inserted More than 1 Year Previously (N = 29)

Characteristic	Value
Age (y)	
Mean ± SD	55 ± 21.6
Range	26–86
Sex	
Male	11 (38)
Female	18 (62)
PE risk factor	
History of DVT	13 (45)
Immobilization	29 (100)
Postoperative status	20 (39)
Malignancy	7 (24)
Cardiac diseases	2 (7)
Polytrauma	6 (21)
Pregnancy	0
Respiratory insufficiency	3 (10)

Values in parentheses are percentages. DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism.

(6.8%). IVC wall penetration less than 3 mm outside of the contrast agent column was observed in seven patients (24%), and greater penetration (ie, > 3 mm) was observed in one patient (3.4%). No cases of migration, fracture, or IVC thrombosis were observed.

Filters were retrieved successfully in all cases. In two cases, significant tilting (> 15°) was observed, and the typical retrieval technique failed. In these instances, a combined approach was employed. Briefly, the extraction was performed with the jugular access kit, and a 5-F pigtail catheter was simultaneously inserted into the upper cone filter or laterally into the filter via a femoral approach. This procedure reduced the filter tilt and facilitated extraction.

Table 2. Indications for IVC Filter Placement

Indication	Incidence
Prophylaxis in addition to anticoagulation	10 (35)
Contraindication to anticoagulant	14 (48)
Intracranial hemorrhage	4 (14)
Neurosurgery	2 (7)
Polytrauma	6 (21)
Other major surgery	2 (7)
Complication of anticoagulation:	5 (17)
Extension of DVT or next DVT/PE despite ad hoc anticoagulation	0

Values in parentheses are percentages. DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism.

The case with severe IVC wall penetration (> 3 mm) occurred in a fully asymptomatic patient who had received a filter 750 days previously (**Fig 2**). Extraction was achieved successfully without any complications, and final cavograms revealed no evidence of IVC stenosis, intimal tears, or dissections. Patients were followed 1 month after filter extraction, and no PE/DVT recurrences, instances of postthrombotic syndrome, or other complications related to IVC filtration were observed. In addition, none of the patients exhibited pre- or postprocedure complications. The mean fluoroscopy time was 14 minutes ± 3 (range, 6–38 min), the mean dose–area product was 6572 cGy/cm^2, and the mean contrast medium volume was 60 mL ± 10 (range, 40–90 mL).

DISCUSSION

The main result of the present study was the high success rate of IVC filter retrieval after long-term implantation

Figure 2. Pre- **(a)** and post-extraction **(b)** cavograms. A major IVC wall penetration (outside the contrast column) occurred in a fully asymptomatic patient who had been implanted 750 days earlier (black arrow). Removal procedure was performed with a dedicated angulated extraction device; no additional maneuver was needed to extraction. In this patient, the filter was extracted successfully without any complications. The final cavogram **(c)** revealed no IVC stenosis, intimal tears or dissections

(ie, > 1 y). Despite cases of filter tilting and IVC penetration, we did not observe failures or complications of these extractions. The success rate of short-term extractions of ALN filters (< 1 y) has been previously reported to range between 80% and 100%, without high complication rates (12). Long-term extractions of various optional filters have been reported in case reports or small case series. Reported delays have ranged from 317 to 3,006 days (6–9,15–17). Increased filter dwell time has been described to be a negative predictive factor for retrieval success in some previous reports. Smouse et al (17) described a direct relationship between extraction success rates and the duration of filter implantation in a study of Günther Tulip filters. However, in the present study, increased implantation duration was not associated with an increased risk of extraction failure. Major tilting has also been previously reported to negatively affect for the success of filter extractions (17). In addition, tilting often requires additional maneuvers during the extraction procedure, including the use of different devices, such as snares, guide wire loops, and inflation balloons (18). These procedure can increase patient morbidity. Regarding safety, despite the risk of IVC filters adhering to the vena cava wall, as suggested by Kuo et al (19), no complications occurred during the pre- and postextraction periods. Filter penetration, which is defined as IVC wall penetration less than 3 mm outside of the contrast agent column, is usually reported as a filter side effect, and extraction is controversial. Oh et al (20) examined the feasibility and safety of various filters in 62 patients and found that pain was the most common side effect reported during and after filter extraction.

The simplicity of late retrieval procedures is also suggested by examinations of dosimetric parameters. The fluoroscopic times and dose–area products are similar to those reported after filter extractions following a short delay in studies of ALN filters and other devices (12,21–23).

Limitations of the present study include the relatively small number of patients who had their filters extracted after 1 year and the high number of patients lost during follow-up. A stricter follow-up protocol, as recommended by Minocha et al (24), should increase patient referral for extraction.

In conclusion, the ALN optional filter can be retrieved safely after more than 1 year following implantation. Future studies may address the best retrieval time according to each indication, but systematic follow-up care of these patients should be encouraged.

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