CLINICAL STUDY

Retrospective Review of 516 Implantations of Option Inferior Vena Cava Filters at a Single Health Care System

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ABSTRACT

Purpose: To retrospectively evaluate the safety, efficacy, and retrievability of Option inferior vena cava (IVC) filters.

Materials and Methods: All patients (N = 516; 247 women; mean age, 67.1 y ± 15.1; range, 19.5–101.6 y) who received an Option filter between August 2009 and March 2015 at a single health care system were analyzed.

Results: The study duration was 68 months, with median clinical follow-up of 7.1 months (range, 1 d to 61.8 mo). During follow-up, 73 of 83 patients (88.0%) underwent successful filter retrieval, 153 died (including three after successful retrieval), and 293 remained alive with filters in situ. Seventeen cases of breakthrough pulmonary embolism (PE) occurred (3.4%). Among 323 patients with direct filter imaging, there were two cases of tilt $> 15^{\circ}$, one case of filter deformity, 16 cases of intracaval migration > 2 cm, and no cases of filter fracture. There were six cases of caval occlusion, nine cases of thrombus trapped inside the filter, and 57 cases of limb penetration on computed tomography scans or radiographs of the IVC. Retrieval failures were attributed to filter tilt or tip embedment in the caval wall (n = 4), complete IVC thrombosis (n = 3), thrombus inside the filter (n = 2), or inability to disengage filter legs (n = 1). Recurrent deep vein thrombosis occurred in 34 patients, including 32 with filters in situ and two whose filters had been removed.

Conclusions: Most Option filters were left in situ for permanent indications. Rates of successful retrieval, device-related complications, and breakthrough PE were similar to those associated with other retrievable filters.

ABBREVIATIONS

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

The Option filter was designed by Rex Medical Systems (Conshohocken, Pennsylvania) and marketed by Argon Medical Devices (Plano, Texas). The filter is conically shaped and made of nickel–titanium (nitinol) alloy, with six expandable and collapsible struts that extend symmetrically from a central apex containing a retrieval hook. Retention anchors at the end of each strut secure the device to the vessel wall. The filter is deployed through a 6.5-F sheath and over a wire for self-centering purposes.

The US Food and Drug Administration approved the Option filter for permanent and retrievable uses in 2009 (1). However, few studies have been published regarding this device (2–4). The purpose of the present study was to evaluate the utility, safety, efficacy, and retrievability of the Option filter with clinical and imaging follow-up.

MATERIALS AND METHODS

Study Design

This retrospective study was approved by our institutional review board. All patients who received an Option filter between August 2009 and March 2015 were identified through our health care system database (including the main hospital complex and four affiliated

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hospitals, with 4,450 beds across the system). Demographic information and clinical data were gathered from electronic medical records (EPIC, Madison, Wisconsin). During the study period, 516 consecutive patients (247 women; mean age, 67.1 y ± 15.1; range, 19.5–101.6 y) underwent Option filter placement, with 316 filters placed at the main hospital and 200 at affiliated hospitals.

All relevant images were retrieved from our radiology picture archiving and communication system (Agfa, Mortsel, Belgium) to analyze filter-related complications and functional status. Images included IVC radiographs (ie, cavograms) obtained at filter retrieval; plain radiographs of the chest, abdomen, pelvis, and lumbar spine; and computed tomography (CT) scans of the chest, abdomen, and pelvis. Lower-extremity venous ultrasound images were used to evaluate deep vein thrombosis (DVT).

Filter Placement and Retrieval Techniques

Filter placement was performed according to Society of Interventional Radiology (SIR) guidelines (5), with the filter deployed through the femoral or internal jugular vein. Information about complications and filter placement failures was retrieved from medical records.

Patients who returned for filter retrieval were identified by the original referring service or the interventional radiology filter clinic at the main hospital campus. At the four affiliated hospitals, the decision regarding filter removal was made primarily by the services that placed the filter (cardiology, vascular surgery, and interventional radiology). The retrieval procedure was performed according to the previously reported standard technique with a GooseNeck snare (ev3, Plymouth, Minnesota) (6). If the standard retrieval technique failed, advanced retrieval techniques were used (6–9). Records of procedure and fluoroscopy times for all retrievals were assessed. Procedure time was defined as the time from skin puncture to hemostasis. Fluoroscopy time was defined as the duration of real-time x-ray imaging. Technical success for filter retrieval was defined as complete removal of an intact filter from the patient without complications (2). To analyze the relationship between indwelling time and retrieval success, we used a 6-month cutoff, as most indications for temporary protection should be resolved by 6 months.

Image Analysis

Two fellowship-trained interventional radiologists reviewed all images; discordances (n = 7) were resolved by a third interventional radiologist. All imaging used for analysis was obtained for other clinical indications. An image was classified as a direct image if it contained the filter or as an indirect image if it did not contain the filter but could be used to locate potential migrated fracture fragments. The latest image was analyzed if the patient had more than one similar study. Fractures were identified through a review of all direct images, including plain radiographs or CT scans of the abdomen, lumbar spine x-ray, and retrieval cavograms. If there were no direct images available, indirect images were used to locate potential migrated fracture fragments, including plain radiographs or CT scans of the chest and pelvis. Cases of caval wall penetration, defined by SIR guidelines as a filter leg extending > 3 mm outside the caval wall (10), were identified by using filter retrieval cavograms and abdominal CT scans performed with or without intravenous contrast medium. Limb penetration involving organs was assessed with CT scans with or without intravenous contrast medium. Filter tilt > 15° and intracaval filter migration > 2 cm were identified by using previously described methods (11). If a retrieval cavogram was not available, the latest postplacement plain abdominal radiograph or CT scan containing the filter was used to compare filter positions based on bony landmarks. The paired images of filter placement and retrieval IVC radiography, the latest plain radiographs of the abdomen and lumbar spine, or coronal reformatted maximum-intensity projection abdominal CT images were resized to match by using Photoshop CS2 (Adobe Systems, San Jose, California) and overlaid with appropriate transparency so that filter tilt and local migration could be identified (11). Clot trapping, caval stenosis, and caval occlusion were evaluated on the retrieval cavogram and contrast-enhanced abdominal CT with the filter remaining in situ. The time interval from filter placement to the last image was calculated to determine the imaging follow-up period.

Clinical Data Collection

Clinical follow-up time was defined as the time from filter placement to the last clinic visit or telephone contact. All available CT pulmonary angiograms or standard contrast-enhanced CT scans of the chest were reviewed for any new filling defect in the pulmonary arteries to determine breakthrough pulmonary embolism (PE) or new PE after filter insertion. The status of anticoagulation therapy after filter placement was identified through the electronic medical records. Postplacement imaging studies and clinical follow-up notes were used to identify cases of recurrent DVT. Mortality data were obtained via the Social Security Death Index and our electronic medical record system.

Statistical Analysis

SPSS software (version 13.0 for Windows; IBM, Armonk, New York) was used for data management and analysis. Two-sample t tests were applied to compare retrieval procedure and fluoroscopy times between the standard retrieval technique and advanced retrieval technique groups and retrieval procedure times between patients with indwelling time < 6 months and those with indwelling time ≥ 6 months. A Mann–Whitney test was performed to compare the fluoroscopy times for patients with indwelling times < 6 months and ≥ 6 months. χ^2