

Retrievable Inferior Vena Cava Filters: Indications, Indwelling Time, Removal, Success and Complication Rates

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ABSTRACT: **Background:** Various vena cava filters (VCF) are designed with the ability to be retrieved percutaneously. Yet, despite this option most of them remain in the inferior vena cava (IVC).

Objectives: To report our experience in the placement and retrieval of three different types of VCFs, and to compare the indications for their insertion and retrieval as reported in the literature.

Methods: During a 5 year period three types of retrievable VCF (ALN, OptEase, and Celect) were inserted in 306 patients at the Rabin Medical Center (Beilinson and Hasharon hospitals). Indications, retrieval rates, median time to retrieval, success and complication rates were viewed and assessed in the three groups of filter types and were compared with the data of similar studies in the literature.

Results: Of the 306 VCFs inserted, 31 (10.1%) were retrieved with equal distribution in the three groups. In most patients the reason for filter insertion was venous thromboembolic events (VTE) and contraindications to anticoagulant therapy. Mean age was 68.38 ± 17.5 years (range 18–99) and was noted to be significantly higher compared to similar studies (53–56 years) ($P < 0.0001$). Multi-trauma patients were significantly older (71.11 ± 14.99 years) than post-pulmonary embolism patients (48.03 ± 20.98 years, $P < 0.0001$) and patients with preventive indication (26.00 ± 11.31 , $P < 0.0001$). The mean indwelling time was 100.6 ± 103.399 days. Our results are comparable with the results of other studies, and there was no difference in percentage of retrieval or complications between patients in each of the three groups.

Conclusions: In 1 of 10 patients filters should be removed after an average of 3.5 months. All three IVC filter types used are safe to insert and retrieve.

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cava (IVC) filters reduce the risk of new or recurrent PE in those with VTE [5,6]. Anticoagulation remains the treatment of choice for VTE, although its use is limited in cases of recent trauma, unsuccessful previous anticoagulant treatment or patient's non-compliance [7].

It is commonly accepted among clinicians that insertion of IVC filters is a safe, effective and time-approved procedure, and their use is constantly increasing [8]. However, there are insufficient clinical data on the efficacy of prophylactic vena cava filter (VCF) insertion and retrieval, including in trauma patients [2,9,10].

The aim of the present study was to describe the current use of different types of retrievable IVCs in a large tertiary center in Israel; to compare their efficacy, safety, time to retrieval and complication rate, as well as to compare the clinical outcomes with reported data from equivalent hospitals.

PATIENTS AND METHODS

We conducted a retrospective study, approved by our medical center institutional review board, in which we reviewed medical records and radiologic images of patients who underwent VCF insertion and retrieval in two hospitals (Beilinson and Hasharon) of the Rabin Medical Center, a tertiary facility. From January 2009 to December 2013, 334 such patients were identified. Twenty-five were excluded because of incomplete data. An additional two patients underwent filter placement in the superior vena cava, and in one patient VCF insertion was performed in a different hospital and only the retrieval attempt was done in our hospital.

A total of 306 IVC temporary filters were inserted in the study patients, and of them, 31 were retrieved. Most of the procedures and all multi-trauma VCF placements were performed in Beilinson Hospital and the remainder in Hasharon Hospital: 276 (90.2%) and 30 patients (9.8%) respectively. Follow-up of the patients and the treatment results were based on the medical files and the imaging data in both hospitals.

PATIENT SELECTION AND DATA COLLECTION

Patients referred for VCF placement were divided into three groups according to indications for the procedure: (i) patients

Venous thromboembolism (VTE) is a common medical pathology with a reported incidence in the United States of 69–422 per 100,000 [1–3]. Untreated patients may develop pulmonary embolism (PE) in up to 40% of all patients with proximal deep vein thrombosis (DVT) [1,2,4]. Inferior vena

with VTE and contraindications for medical treatment, failure of anticoagulant therapy or complications from such treatment, (ii) multi-trauma patients, and (iii) patients with prophylactic indications (such as pregnant females with known history of DVT and high risk of thromboembolic events, and females with tibia fracture and clinical suspicion of PE).

The clinical data included gender, age, clinical diagnosis, indications for IVC filter insertion, filter types, median time to retrieval, and complications. Radiologic data included angiographic evaluation prior to filter insertion, ultrasound examination according to the recommendation of the treating physician, and computed tomography for patients requiring clinical and radiologic follow-up for any reason.

FILTER TYPES AND PLACEMENT TECHNIQUE

Three types of VCF filters from different vendors were used: CelecTM (Cook, USA), ALNTM (ALN Implants, France) and OptEaseTM (Cordis, The Netherlands). All filters were inserted under fluoroscopic guidance in the angiography suites via the right common femoral or the right internal jugular vein according to vein patency, access availability and individual operator selection. Prior to the insertion procedure, all available cross-sectional images were reviewed for evaluation of IVC patency and size, location of the renal veins, and assessment of access site anatomy and patency. The preferred target landing zone was the juxta-infrarenal IVC to reduce the risk of thrombi accumulation below the renal veins and above the filter, and to avoid caval filter occlusion and possible thrombus dislodgement facilitated by the patent renal vein flow.

If patients had no further need of the VCF and the IVC was patent, these patients were referred for retrieval. All filter retrievals were performed under local anesthesia via the right jugular vein for the Celec and ALN filters since their retrieval hooks are located in the cranial end. The OptEase filters were accessed via the femoral vein route as their hook is located in the caudal part.

STATISTICAL ANALYSIS

Data analysis was carried out using SPSS 21.0 statistical analysis software (IBM Inc, Chicago, IL). Normality of continuous variables distribution was assessed using the Kolmogorov-Smirnov test (cutoff at $P = 0.01$). Continuous data are described as mean \pm standard deviation while nominal data are described using frequency counts and are presented as n (%). Associations between filter retrieval and, separately, indication, and each of the other variables were assessed using the chi-square test, exact as appropriate. Age was compared by indication using one-way analysis of variance (ANOVA) followed post hoc by Bonferoni's test. Age was compared by retrieval using the *t*-test for independent samples. Retrieval was modeled using logistic regression analysis, and odds ratios (OR) with 95% confidence intervals (CI) were estimated. All tests were two-sided and considered significant at $P < 0.05$.

RESULTS

The patients' mean age was 68.38 ± 17.5 (range 18–99), which was significantly higher than reported by other study groups (53–56 years) [8,10-14]. One-way analysis demonstrated that age differed significantly by indication ($P < 0.0001$ across the three indications for the procedure). In post hoc pair-wise comparisons, patients with polytrauma were significantly older (71.11 ± 14.99 years) than patients with post-PE (48.03 ± 20.98 years, $P < 0.0001$) and patients with a preventive indication for filter insertion (26.00 ± 11.31 , $P < 0.0001$). Post-PE patients and those who had undergone a preventive procedure did not significantly differ from one another in age ($P = 0.166$, NS).

The three types of retrievable IVCs were CelecTM (Cook), ALNTM (ALN Implants) and OptEaseTM (Cordis). Their use was random, according to the operator's experience. ALN filters were used in 51.3%, Celec Cook in 27.8%, and OptEase in 20.9% [Table 1].

Most of the VCF insertions were performed in patients presenting with VTE and contraindications to anticoagulant therapy, failure of the therapy, or complications resulting from such treatment (88.2%). Of all the patients 10.8% were multi-trauma patients with high risk for PE events. Prophylactic VCF insertion was performed in only 0.7% of all insertions [Table 2].

One technical failure occurred during the insertion procedure: namely, filter migration into the renal vein that was noticed during insertion (Celec). The filter was retrieved and replaced by an ALN filter during the same angiography session. In another patient the filter tilted in the renal vein (ALN). The filter was left in place without further intervention; it was not removed later based on our knowledge that despite the tilt,

Table 1. Filter types and retrieval rates

| | ALN TM | | Cook Celec TM | | OptEase TM | | All types | |
|---------------|-------------------|------|--------------------------|------|-----------------------|------|-----------|------|
| | Absolute | % | Absolute | % | Absolute | % | Absolute | % |
| Non-retrieved | 139 | 88.5 | 78 | 91.8 | 58 | 90.6 | 275 | 89.9 |
| Retrieved | 18 | 11.5 | 7 | 8.2 | 6 | 9.4 | 31 | 10.1 |
| All inserted | 157 | 51.3 | 85 | 27.8 | 64 | 20.9 | 306 | 100 |

Table 2. Indications for filter insertion

| Indications | Frequency | % |
|--------------|-----------|-------|
| Post-PE* | 271 | 88.6 |
| Multi-trauma | 33 | 10.8 |
| Preventive** | 2 | 0.7 |
| Total | 306 | 100.0 |

*Venous thromboembolic events, including patients with recurrent deep vein thrombosis or post-pulmonary embolism (PE), and oncologic patients with contraindication to anticoagulation therapy

**Including two patients: one pregnant woman with high risk of thromboembolic event and family history of antiphospholipid antibody syndrome, and one female patient before elective orthopedic surgery with suspected previous fat embolism that was not proven radiologically

Table 3. IVCF indwelling time (days)

| Filter type | Mean | SD | Median | Minimum | Maximum |
|--------------|--------|---------|--------|---------|---------|
| ALN™ | 126.8 | 125.105 | 102 | 21 | 487 |
| OptEase™ | 58.33 | 40.683 | 53 | 14 | 113 |
| Cook Celect™ | 77.33 | 72.478 | 47.5 | 6 | 169 |
| Total | 100.63 | 103.399 | 77 | 6 | 487 |

considered by some to compromise proper functioning of the filter, it is still able to trap large clots [15].

Retrieval of the VCF was performed in some patients, for two reasons. The first was death of the patient. Almost one-fifth of the patients (19.3%) died within the first 30 days after VCF insertion due to reasons unrelated to the VCF insertion or presence. The second was the need for VCF in the long term; namely, in patients with previous and recurrent VTE events, patients who were chronically immobilized, those with advanced cancer, and those who were non-compliant with anticoagulation therapy. Thus only 10.1% of the VCFs were removed, a low rate comparable to that in other studies [7,10,16,17], as was the mean indwelling time (100.6 ± 103.4 days) [7,10,11,17,18] [Table 3]. Among the patients who underwent filter retrieval the rate was similar for all filter types: ALN 11.5%, OptEase 9.4%, Celect 8.2% [Table 1].

Prior to retrieval, cavography was performed to exclude thrombi on the filter limbs even if the patient had a recent imaging study of the IVC. If the filter was free from visible thrombi, retrieval according to the manufacturer's instructions involved the use of snare loops, graspers, diagnostic catheters and sheaths.

No intra- or periprocedural complications during filter retrieval were recorded, and there was no difference in percentage of retrieval or complications between patients in the three groups.

DISCUSSION

Over the last decade retrievable VCF use has become widespread because of its safety and ease of placement, if the instructions for use of each filter are followed strictly [1,2,12,15], even in duplicated IVCs [19]. There is consensus regarding use of these filters in patients at high risk of VTE-related events and contraindications to, failure of, or complications of anticoagulant therapy. Inferior vena cava (IVC) filters reduce the risk of new or recurrent PE in patients with VTE; the PREPIC study group reported statistically significant decreases in PE rates in patients with VTE who received a filter as compared to those who did not at both 12 days and 8 years (1.1% vs. 4.8%, and 5.2% vs. 15.1%, respectively) [5]. Another study demonstrated that the 3 year recurrent or subsequent PE rate was 1.7% after filter placement but 5.3% in those without

a filter [6]. However, there are insufficient clinical data on the efficacy of prophylactic VCF insertion and retrieval, including in trauma patients [2,9,10].

Several complications have been reported. These include filter migration, especially in large IVC; limb penetration of the filter through the IVC into the surrounding tissue resulting in adjacent organ injury; severe tilt causing failure of filter retrieval; filter fracture; and caval occlusion due to thrombi accumulation within the filter's struts [3,10,15]. Still, the rates of these complications are very low when weighed against their efficacy, justifying the VCF insertions [7].

No major or minor complications during insertion and retrieval were noted, validating its safety for both insertion and extraction. Furthermore, our age group was older by one decade than reported in the literature [8,10-13], and still we found no increase in complication rates.

Although the mean indwelling time was slightly longer than noted in the manufacturer's recommendations, we found that the extra indwelling time did not increase the number of retrieval failures or cause delayed thrombus formation.

Our results do not point to any one of the three types of VCF as being superior. The low retrieval rate of 10.1% is similar to other medical reports [3], although some clinics reported higher rates of up to 59% [20]. The low numbers of prophylactic insertions are not different from other reports and a large prospective study is needed to evaluate its efficacy.

This research has several limitations: the study was retrospective and therefore limited by patient selection bias; the selection of filters was random and the rate of retrievals was low. However, the strengths of the present study include the use of several filter types, the demonstration of long-term safety and efficacy of the modern use of retrievable IVCs, and the availability of clinically relevant data regarding outcomes and complications for most patients over a significant follow-up period.

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