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ORIGINAL ARTICLE

ALN RETRIEVABLE VENA CAVA FILTER - EFFICACY, SAFETY AND RETRIEVABILITY -

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Abstract **Background**: Retrievable inferior vena cava (IVC) filter devices have been developed to overcome the long-term complications of permanent filters. It is of interest to evaluate the retrievability of retrievable IVC filters and how safely the IVC filters indwelled for a long period of time can be retrieved. We reviewed a group of 44 patients, who were selected for ALN retrievable filter implantation and reviewed the indications, efficacy as well as complications.

Material and Methods: 300 venous thromboembolism (VTE) patients were treated in our institution between 2003 and 2014. IVC filters were inserted in 84 cases (28%) and 44 of 84 patients received ALN retrievable filter implantation. We retrospectively reviewed the indications, efficacy and complications of 44 patients with ALN filters.

Results: All 44 patients had deep vein thrombosis (DVT) and 39 patients (88.6%) also had pulmonary embolism (PE). The most frequent associated risk factor for DVT was cancer (n=19). The filter was implanted for a median duration of 708.8 days (range 68-1717). While the filter was in place, at least one venous thromboembolic event occurred in 4.5% (2 of 44 patients). Filter retrieval was attempted in 8 patients (18.2%) after a median period of 271.9 days (range 79 - 559). Filter retrievals were successful in all cases.

Conclusion: This study showed the efficacy of ALN filter. It also demonstrated the safety of retrieval after a long-term placement.

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Key words: IVC filter; ALN filter; VTE.

Introduction

Pulmonary thromboembolism (PTE) is a serious cause of morbidity and mortality[1, 2]. The PTE mortality rate is known to vary between countries. In Japan, nearly 3500 cases of PTE are diagnosed annually and the mortality rate is reported to be 14%[3]. Anticoagulant therapy remains the standard of care for venous thromboembolism (VTE). If the patient has a contraindication to anticoagulants, an inferior vena cava (IVC) filter is considered to prevent the passage of life-threatening emboli to the lungs[2, 4]. It has been reported that IVC filters significantly reduced the development of pulmonary emboli and were effective in preventing PTE[5]. However, IVC filters have potential adverse effects, including recurrent deep vein thrombosis (DVT), IVC thrombosis, migration, fracture, and infection[6]. Retrievable IVC filter devices have been developed to overcome the long-term complications of permanent filters while maintaining the benefits of filtration. These filters may be left in place permanently or they may be safely retrieved after they become unnecessary[7]. In the United States, Food and Drug Administration (FDA) recommends that physicians and clinicians responsible for implanting and for providing ongoing care of patients with retrievable IVC

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filters consider removing the filter as soon as protection from PTE is no longer needed[8]. In clinical practice, filter retrieval times are often delayed because of a prolonged need for IVC filtration or because loss of contact with patients during the follow-up period[9]. It is of interest to investigate the retrievability of retrievable IVC filters and how safely the delayed IVC filters can be retrieved. We retrospectively reviewed a group of 44 patients, who were selected for ALN retrievable filter (ALN Implants Chirurgicaux Ghisconaccia, France) implantation and reviewed the indications and efficacy as well as complications. ALN filter has been available in Japan since 2009.

Materials and Methods

The diagnosis of DVT was confirmed by ultrasonography and computed tomography (CT). The presence of PE was confirmed by CT. The filter was placed to prevent pulmonary embolism or PE recurrence. The ALN filter is a hydrodynamic retrievable IVC filter made of stainless steel. ALN filter consists of six short legs that adhere to the vena cava wall, and three long legs that keep the filter in the central position along the main axis of the vena cava. Placement of ALN filter can be performed through the femoral, brachial, or jugular vein. It can only be retrieved from the jugular vein[6].

Under local anesthesia, filters were placed via contralateral femoral vein (n= 38, 86.4 %), where there was no thrombus, and right internal jugular vein (n= 6, 13.6%). A 7-French catheter was used in all cases. In all but 1 case (pregnant patient), filter was placed in the suprarenal location. After the filter placement, all the patients underwent cavo-gram to check the filter position and tilting.

Filter was retrieved when the patient no longer required anti-thrombotic prophylaxis or when a patient could resume full anticoagulant therapy safely. ALN filter was extracted from the right internal jugular vein with 9-French extraction device.

Follow-up protocol included clinical evaluation with abdominal X-rays 3, 6, and 12-months after filter implantation, and with yearly computed tomography.

Categorical variables were presented as mean ± standard deviation.

Informed consent was obtained from all individual participants included in this study.

This study was approved by Hirosaki University ethical committee.

Results

From 2003 to 2014, 300 VTE patients were treated in our institution and 84 retrievable IVC filters were placed. Since 2012, ALN filter has been used and we implanted 44 ALN filters in 44 patients between 2012 and 2014. There were 80 VTE patients treated in this time period. The study included 22 males and 22 females, mean age 63.0 ± 16.2 (range 22-86). The patient characteristics are provided in Table 1.

More than half of the patients (n=28, 63.6%) were hospitalized when the diagnosis of DVT or pulmonary embolism (PE) was made; they were referred from the departments of orthopedic surgery (n=7, 25%), internal medicine (n=6, 21.4%), gastrointestinal surgery (n=5, 17.9%), neurology (n=3, 10.7%), cardiovascular surgery (n=3, 10.7%), neurosurgery (n=2, 7.1%), and obstetrics and gynecology (n=2, 7.1%).

All patients had DVT and 39 patients (88.6%) also had PE. DVT was caval in 5 (11.4%), proximal in 31 (70.1%), and distal in 8 (18.2%) patients.

Associated risk factors for DVT were: cancer (n=19), prolonged bed rest including operation (n=14), orthopedic casts after trauma (n=3), steroid intake (n=3), previous DVT (n=2), coagulation factor disorder (n=2), presence of

Table 1. Patient characteristics (n=44)

Characteristics	Data
Age (y)	
Mean ± SD	63.0 ±16.2
Range	22-86
Sex	
Male	22 (50)
Female	22 (50)
PE risk factor	
Malignancy	19 (43.2)
Immobilization	14 (31.8)
Orthopedic casts after trauma	3 (6.9)
Steroid intake	3 (6.9)
Previous DVT	2 (4.5)
Coagulation factor disorder	2 (4.5)
Presence of central venous line	1 (2.3)
Pregnancy	1 (2.3)
Inflammation	1 (2.3)
Uterine leiomyoma	1 (2.3)
Indication for filter placement	
Prophylaxis for high risk of DVT or PE	34 (77.3)
DVT or PE contraindication to anticoagulant therapy	8 (18.2)
DVT or PE while on anticoagulation	2 (13.6)

Value in parentheses are percentages.
DVT = deep vein thrombosis
PE = pulmonary embolism

central venous line (n=1), pregnancy (n=1), inflammation (n=1), and uterine leiomyoma (n=1). Some patients had more than one of the above stated risk factors.

Indications for filter placement included prophylaxis for high risk of DVT or PE (n=34, 77.3%), DVT or PE contraindication to anticoagulant therapy (n=8, 18.2%) and DVT or PE while on anticoagulation (n=2, 13.6%).

Filter insertion was successful in all patients. No patients developed puncture-site hematoma or insertion-site thrombosis. The filter was implanted for a median duration of 708.8 days (range 68-1717 days). While the filter was in place, venous thromboembolic event occurred in 2 patients (4.5%). In detail, the patient was a 65 year-old man who had two-staged operation for descending aortic aneurysm. After graft replacement of ascending aorta and cephalic artery debranching, postoperative CT revealed PE and DVT. ALN filter was implanted immediately. After 12 days of filter implantation, CT revealed IVC thrombosis in the proximal side of the filter. Second filter was inserted through the right jugular vein and catheter directed thrombolysis with urokinase was performed. Thoracic endovascular aortic repair with left carotid-subclavian artery bypass was performed after IVC thrombus dissolution and 2 filters were retrieved successfully 79 days after the first filter insertion. The other case is a 58 year-old man presenting with submassive PE and DVT. The filter was implanted and thrombolytic therapy was applied. Fifteen days after filter implantation, the patient suddenly became dyspneic while walking in the hospital. Percutaneous cardiopulmonary support (PCPS) was applied immediately. Abdominal X-ray revealed tilted filter with one of the legs pointed away. We suspected that the thrombus went through the filter and caused PE. The patient survived without neurological complications.

Table 2. Clinical events during filter implantation (n=44)

Events	Data
Number of days of filter implantation, median (range)	708.8 (68-1717)
Immediate complication	
puncture-site hematoma	0
insertion-site thrombosis	0
Venous thromboembolic event	
PE	1 (2.3)
DVT	1 (2.3)
Number of days between filter placement and VTE event	19.5 (24, 15)
Filter thrombosis (asymptomatic)	2 (4.5)
Death (casuse of death: cancer)	1 (2.3)
Number of days between filter placement and death	57

VTE = venous thromboembolism

Table 3. Filter retrieval (n=8)

Variables	Data
Filter retrieval	8/44 (18.2)
Number of days between filter insertion and retrieval	271.9 (79-559)
Extraction failure	0
Number of days between filter retrieval and last day of follow-up	826 (560 - 1273)
Clinical event after filter retrieval	
venous thromboembolism	0
death	0

Data are presented as number (%) unless otherwise indicated.

Filter was not retrieved in this case because removing the broken filter requires operation and we could not obtain patient's consent. Both patients were receiving therapeutic doses of anticoagulant drugs when the event occurred. Asymptomatic thrombus-trapping by a filter was seen in 2 patients (4.5%). Table 2 indicates clinical events during filter implantation.

Among 44 filters implanted, 25 (56.8%) were addressed for retrieval and filter retrieval was attempted in 8 patients (18.2%) after a median period of 271.9 days (range, 79 to 559 days) [table 3]. In 17 patients the retrieval of ALN filter was not attempted for different clinical reason: in 1 patient removal was not performed as a result of ongoing contraindication to anticoagulation, in 6 cases for unstable medical condition, in 5 cases due to the refusal of the patient, in 2 patients due to old age, and the remaining 3 filters are scheduled to be retrieved in the next few months.

Filter retrievals were successful in all 8 cases. In one case, significant tilting (>15°) and filter embedded in the IVC wall were observed. In this case, typical retrieval technique failed. Extraction was possible using a double approach through the jugular and femoral veins. The femoral route was used to introduce a snare, pulling the filter gently. This maneuver was able to reduce the tilt and a simultaneous jugular approach was used to catch the filter with the extraction kit.

The median follow-up after filter removal was 826 days (range, 560 to 1273 days). Among the patients with retrieved filters, none presented with recurrent DVT or PE. Of the 36 patients (81.8%) with filters remaining in place, one patient died 57 days after the filter replacement because of lung cancer. There is no reported recurrent DVT, PE or filter-related IVC thrombosis and no filter migration was

Table 4. Commonly sited indications for IVC filter replacement

Proximal DVT with absolute contraindication for anticoagulation
New or 'extending' DVT/PE despite therapeutic anticoagulation
Complication of anticoagulation
Free floating' thrombus in the IVC, iliac, or femoral veins
Spinal cord injury
Poor compliance with anticoagulation
Multiple long bone/pelvic fractures
Prophyraxis in high-risk patient populations (e.g. bariatric)
Closed head injury
Severe cardiopulmonary disease (including COPD) with concomitant DVT
Prophylaxis in joing replacement surgery
Cor Pulmonale with DVT/PE
Risk of fall with anticoagulation
DVT/PE in pregnancy (controversial)
Pre-/post-pulmonary embolectomy

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

observed.

Discussion

The overall incidence of VTE is increasing in Japan and VTE events are important cause of morbidity and mortality. The number of IVC filters placed has been steadily increasing for a variety of indication due to increasing data demonstrating clinical efficacy, ease of insertion through the percutaneous route with potential retrievability and a low rate of complications[10, 11, 12, 13].

The main result of our study was the high success rate of IVC filter retrieval after long-term implantation. For the PE prophylaxis, indications of IVC filter remain controversial and interpretation varies among different authors in the literature[14, 15]. Table 4 lists the more commonly cited indications for placement of filter[16]. It is a popular practice to place IVC filters for reasons outside of the established guidelines in the clinical settings[17]. Although IVC filters have been proven to prevent recurrent DVT, they are associated with increased incidence of recurrent DVT. PREPIC study concludes permanent filters decrease the risk of symptomatic pulmonary embolism while increasing the risk of DVT at 8 years, but there is no long-term survival benefit from long-term filter implantation[18].

Retrievable filters offer a theoretical advantage in that they can be removed when no longer indicated, thus limiting long-term thrombolic complications[16]. Several trials[4, 19, 20, 21, 22, 23, 24, 25, 26, 27] investigated the efficacy and safety retrieval of the ALN filters (Table 5). Our study confirmed the high technical success of retrieval rate.

Insertion of retrievable filters for venous thromboembolic disease has been performed more widely in the recent years[28]. However, the rate of filter retrieval varies significantly among institutions. In our study, only 25 (56.8%) of 44 filters implanted were addressed for retrieval and 8 filters (18.2%) were finally retrieved.

Previous published data showed an acceptable rate of successful retrieval after medium to long-tem implantation period[4]. Our result compares favorably, the average period of retrieval was 271.9 days. Imberti et al. states filter retrieval was highly successful when planned within the first 3 months after implantation; after 3 months, the likelihood of retrieval failure was as high as

Table 5. Retrieval rate, mean dwelling time, successful extraction rate and reported complications of ALN filters (Literature review)

Study	Number of filters removed and placed	Mean dwelling time of filters; range (days)	Extraction success (successful retrieval/ retrieval attemts)	Reasons for failed retrieval	Reference
Pieri et al	7/18	63; 49-192	100(7/7)		19
Barral et al	13/54	22; 11-90	100(13/13)		20
Pancione and Mecozzi	28/96	72; 30-120	100(28/28)		21
Imberti et al	14/30	123; 30-345	78(14/18)	1 severe tilting 3 adherence to IVC wall	4
Mismetti et al	55/217	51; 6-352	92.7(13/55)	4 severe filter thrombosis	22
Pancione et al	71/276	74; 30-130	93(66/71)	1 inexperience 4 adherence to IVC wall	23
Pellerin et al	122/123	93; 6-722	99(122/123)	1 severe tilting	24
Laguna et al	26/201	-	96.2(26/27)	1 severe tilting	25
Pellerin et al	29/29	768; 444-1244	100(29/29)		26
Caronno et al	16/63	179; 53-370	80(16/20)	3 severe tilting 1 adherence to IVC wall	27

50%[4].

Time following the placement procedure did not appear to influence the retrieval procedure in our study. However, one should keep in mind that any endovascular device left in situ may cause unexpected problem. Effort should be made in order to improve overall retrieval rates. The goal is to increase retrievals in patients who no longer have an indication for the filter. Prompt retrieval decreases the filter related trouble, including DVT, filter fracture and migration. An effective system that improve the retrieval rate of an IVC filter include education of the patient and the family, accurate tracking system to minimize patient loss to follow-up, and dedicated personnel responsible for overseeing the entire process[29].

In most of the previous studies, severe tilting and adhesion to the IVC wall were the main reasons for retrieval failure. Although one case of filter tilting was found in our study, we did not observe a failure of this extraction. Previous studies in patients with permanent vena cava filters reported mean rates of recurrent pulmonary embolism that ranged from 2.6 to 3.8%[30]. In study conducted by Mismetti et al., 17% (37 of 217 patients) had at least one VTE event and fatal PE occurred in 5 patients (2.3%); two events happened within 24 hours after filter placement, and the three other events occurred from 8 to 11 days after its placement [30]. We had one case (2.3%) of proximal DVT 24 days after the filter placement and one case (2.3%) of symptomatic PE 15 days after the filter placement.

The reported incidence of filter fracture is as high as 2% to 10%, and three anatomic factors which thought to predispose a device to failure are: (1) deployment in a tortuous vena cava; (2) deployment over the renal ostia; (3) deployment adjacent to a vertebral osteophyte[4].

Limitation of this study includes the relatively small sample size, the small number of patients who had their filters extracted and short follow-up time.

Conclusion

In conclusion, our study suggests that ALN filters can be easily implanted and safely retrieved after long time. The retrieval failure rate was low and we did not observe fatal complications. ALN filter offer a broad range of clinical applications, because they can be used

as permanent filters or they can be removed when they become unnecessary. A randomized study is needed to assess its safety and efficacy in preventing PE.

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