Mid-term Experience with the ALN Retrievable Inferior Vena Cava Filter

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Objective. To report the mid-term results of 63 patients who received a new commercially-available retrievable vena cava filter, ALN.

Methods. Between January 2001 and October 2005, 63 patients (mean age 65 ± 15 years) underwent placement of ALN filters. Filter removal was performed when anti-thrombotic prophylaxis was considered unnecessary or when the patient could safely resume full anticoagulant therapy.

Results. Thirty-five patients (55%) had ilio-femoral venous thrombosis and 28 patients (45%) had ilio-caval thrombosis. Overall, 49% had pulmonary embolism. Technical success for filter insertion was 100%, without any complications. None of the procedures aborted or was converted due to technical difficulties. After a median follow-up of 21-months (range 1e48, median 18), there were no cases of pulmonary embolism or vena cava thrombosis. Two patients died of a cause unrelated to deep venous thrombosis during the follow-up period, without clinical evidence of pulmonary embolism or filter-associated complications. No device migration was observed. There were 20 (31.7%) retrieval attempts: in 16 cases filters were retrieved successfully, but 4 cases were aborted. The mean implantation period of the retrieved filter was 179 days (range 53e370).

Conclusion. Our results confirm the clinical efficacy of the ALN filter for preventing potentially fatal pulmonary embolism whilst implanted and in absence of post-insertion complications, even when left in place indefinitely.

Keywords: Inferior vena cava filter; Deep venous thrombosis; Pulmonary embolism.

Introduction

Venous thromboembolism is a common, lethal disease that recurs frequently and causes serious long-term complications. Full dose anticoagulation is the gold standard therapy in patients suffering from venous thromboembolic disease (VTD). However, for patients with recurrent disease, with contraindications to anticoagulation therapy, or with common femoral vein thrombosis, pulmonary embolism (PE) may be prevented by using prophylactic caval filters, either permanent or temporary.

With the availability of devices that readily can be placed percutaneously, vena cava filter has become the most common treatment alternative for PE prevention and the number inserted annually has markedly increased. Nevertheless, placement of permanent IVC filters can be associated with a number of long-term complications. Retrievable filters are a new generation of IVC filters and represent a very attractive treatment option; in fact; these filters may be left in place permanently or they may be safely retrieved after when they become unnecessary.

We studied a group of 63 patients who were selected for retrievable filter implantation and reviewed the techniques, indications, as well as the complication rates.

Materials and Methods

The ALN filter (ALN Implants Chirurgicaux®, Ghisonaccia-FR) is a stainless steel hydrodynamic retrievable IVC filter. It has six short legs that ensure its adherence to the vena cava walls, and three long legs that guarantee the correct central positioning along the main axis of the vena cava. This filter is

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characterized by low thrombogenicity and rarely is associated with occlusion, because of the small portion of vena cava it occupies and the low amount of metal used for its manufacture. Moreover, the exclusion of welding points gives this device an excellent corrosion resistance. The ALN filter can be placed from the femoral, brachial or jugular vein approach, but it can be retrieved only via the jugular vein.

Informed consent was obtained from all the patients. The interventional team comprised an interventional radiologist and a vascular surgeon. Under local anaesthesia, all patients underwent preliminary imaging of the vena cava. The number and the position of the renal veins were noted to identify the most appropriate site for placing the filter. Filters were placed via left/right brachial vein (n = 28, 44%), contralateral femoral vein (n = 24, 38%), right internal jugular vein (n = 11, 18%); in all cases a 7-French catheter was used. In all but 4 cases (neoplastic “free-floating” thrombosis of the renal vein protruding into the IVC), filters were placed in the infrarenal IVC and a cavo-gram was performed at the end of the procedure, in order to check for filter position and tilting.

Filter removal was performed when anti-thrombotic prophylaxis was considered unnecessary or when the patient could safely resume full anticoagulant therapy. A preliminary cavo-gram, performed via the femoral approach, assessed filter position and tilt with respect to the caval axis and thrombi entrapped within the filter. Filter extraction always was performed via the right internal transjugular approach, using the 9-French Extraction/Repositioning device made up of a coaxial, longitudinally movable crampon system mounted distally on a steel preformed wire. Once the crampon cone was positioned at the apex of the filter, the sheath was advanced over the filter retracting the hooks from the cava wall and then the filter was withdrawn.

Follow-up protocol included clinical evaluation with duplex-ultrasonography 1, 3, 6 and 12-months, and yearly thereafter, with thoraco-abdominal computed tomography-angiography and abdominal X-rays 6-months after filter implantation.

Categorical variables were presented as mean ± standard deviation; χ²-test or Fischer’s exact test were adopted when needed. Survival was estimated using the Kaplan-Meier method.

### Results

Between January 2001 and October 2005, 63 consecutive patients underwent placement of ALN filters. The study included 32 males and 31 females, mean age 65 ± 15 years (range 22–89, median 67). Most of the patients (91%) were hospitalised; they were referred from the departments of internal medicine (n = 30), general surgery (n = 11), cardiology (n = 6), orthopaedic surgery (n = 4), urology (n = 4), obstetrics and gynaecology (n = 3), neurosurgery (n = 2), intensive care (n = 2) and medical oncology (n = 1). Associated risk factors for VTD were: cancer (n = 23), previous VTD (n = 22), recent major surgery (n = 10), recent major trauma (n = 6) and puerperium (n = 2).

The diagnosis of deep venous thrombosis (DVT) was confirmed by means of colour-coded duplex ultrasonography and/or computed tomography-angiography (CT-A) in all patients, while the presence of PE was confirmed by CT-A and/or lung scan: thirty-five patients (55%) had ilio-femoral thrombosis, whereas 28 patients (45%) had ilio-caval thrombosis documented by duplex and/or CT-A. Overall, 49% (31/63) had PE diagnosed by CT-A and/or lung scan [18/35 (51%) of the ilio-femoral group and 13/28 (46.4%) of the ilio-caval group]. Indications for filter placement were PE prophylaxis (33, 52%), temporary contraindication to anticoagulant therapy with or without proven PE (29, 47.5%), and anticoagulant therapy failure (1, 1.7%). Concomitant anticoagulant therapy for some period of time while the filter was in place was administered in 33 patients (52.4%); 20 patients received therapeutic doses of low molecular weight heparin (LMWH), 9 patients oral anticoagulant therapy, and 4 patients prophylactic doses of LMWH.

Technical success for filter insertion was 100%, without any complications; in particular no patient developed puncture-site haematoma or insertion-site thrombosis. None of the procedures aborted or was converted due to technical difficulties.

After a median follow-up of 21-months (range 1–48, median 18), there were no cases of PE or vena cava thrombosis. Two patients (3.1%) died of DVT-unrelated causes [1 mesothelioma, 1 cirrhosis] during the follow-up period without clinical evidence of PE or filter-associated complications; autopsy information was not available for any of these patients. No device migration was observed.

In the remaining 61 patients, 28 retrievals of ALN filters were not attempted for various clinical reasons: 12 cases of patient refusal, in 8 patients the referring physicians decided against removal because of ongoing contraindications to anticoagulation, 8 because the patients were in unstable condition. The remaining 11 filters are scheduled to be retrieved in the next few months.

Twenty (31.7%) retrieval attempts were performed in 20 patients. The ALN retrieval was attempted
through right internal transjugular approach in all patients. In 16 cases (80%) filters were retrieved successfully, and all showed small amounts of organized thrombus strands on the legs of the filters. Retrievals required a mean of 12 minutes of fluoroscopy (range 8–21). The mean implantation period of the retrieved filters was 179 days (range 53–370). Four cases were aborted: the reason for failure of removal was tilting with respect to the caval axis of 15° in 3 patients and tight adherence to the cava walls in 1 patient (Fig. 1). The mean implantation period of the retrieved filters was 152 days (range 64–184).

Among the patients with retrieved filters, none presented with recurrent DVT or PE.

Of the 41 patients (65%) with filters remaining in place, 3 (7.3%) were lost to follow-up. Overall, among patients available for follow-up, none reported recurrent DVT, PE, or filter-related IVC thrombosis. No filter migration was observed. During follow-up, none of the patients required reinsertion of a permanent filter after ALN retrieval.

At 1 month and 12-months follow-up, Kaplan-Meier life-time analysis estimated a survival rate of 98% and 96%, respectively.

Discussion

Vena cava filters have been available widely to prevent life-threatening PE since the early seventies.3,4,10,11 The purpose of the modern retrievable filter is to avoid long-term device-related complications described with first-generation permanent filter, especially in patients who might benefit from PE prevention over a short period of time.8–16 The ALN filter is a stainless steel hydrodynamic retrievable IVC filter; few trials have recently investigated the efficacy and safety retrieval of the ALN device.5,6 Our study confirmed the excellent adherence to the vena cava walls, and the low thrombogenicity with minimal occlusion of this device. Although IVC thrombosis has been reported up to 9.3% with first-generation permanent devices, we did not encounter any incidence of this complication.5,14 Although the reported incidence of filter movement toward the heart, including spontaneous intra-cardiac migration, has been shown to vary between 1% and 13%, we observed no short or long-term migration, even in the 6 cases where large thrombi were trapped within the basket of the filter. We also observed a low rate of filter tilting (3.4%), and there were two episodes of asymptomatic filter legs trans-caval migration during retrieval attempts.

Previous published data showed an acceptable rate of successful retrieval after medium to long-term implantation periods.5,6 Our experience compares favourably, we retrieved quite a large number of devices. In particular, the results of our study add useful information on the use of ALN filters owing to a longer follow-up than previously reported and a longer average period to retrieval (179 days). Interestingly, in our experience, time from the placement procedure did not appear to influence the retrieval procedure and modification of the filter position (e.g. tilting, trans-caval migration of the filter legs) was the only event that prevented filter retrieval.5

Our experience supports the efficacy of retrievable ALN filters in patients at high risk of PE, particularly those in whom the use of anti-thrombotic therapy is contraindicated. In our series we did not observe recurrent or fatal PE during the time the filter was in place. Moreover, the thrombus capture rate was higher than reported in previous data (12–18%): all
retrieved filters showed small strands of organized thrombus on the legs of the filters and no symptomatic PE appeared during and immediately after the removal procedure despite the trapped emboli within the filter, which were detected in up to 30% patients.

**Conclusion**

Our results confirm the clinical efficacy of the ALN filter either in preventing potentially fatal PE during implantation times.

**References**