Safety of a non time limited Retrievable Vena Cava Filter: A Pathologic Study


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Purpose

Since 1973 (the 1rst Greenfield vena cava filter)(1), numerous types of IVC filters have been proposed as a primary or secondary prophylactic tool to prevent pulmonary embolism (PE).

The PREPIC Study (2,3), first randomized controlled study able to evaluate the ratio benefit /risks of permanent caval filtration, showed a significative reduction of PE occurrence (50% at 2 years and 43% at 8 years follow-up) but with a significative increase of deep venous thrombosis (DVT) events (50% at 8 years follow-up).

The most attractive alternative to permanent vena cava filter seems to be (3,5,6) the retrievable (optional) filters which may be either left in place permanently or retrieved if patient no longer requires vena cava Interruption.
Purpose (2)

The one we have chosen is the ALN filter (ALN Implants Chirurgicaux, France) because of its conical shape, its stability and its easiness of insertion and retrieval, without any retrieval time.

The aim of this study is to evaluate with a pathologic study the safety of early and late retrieval of this device.
**Methods and Materials**

### 1. Study design

- ALN filters have been inserted in 315 patients
  - in the same department from December 1999 up to now
  - for definitive or temporary contra-indications to anticoagulant mainly due to
    * acute bleeding (52%)
    * major planned surgery (33%)
    * recurrent DVT/PE despite correct anticoagulant therapy (13%)
    * PE prophylaxis in very high risk patients (2%).

- 87 patients underwent a filter retrieval
  - sex ratio 46F/ 41M , mean age 64
  - filters no longer required in 64 cases
  - anticoagulants being again indicated in 23 cases

- 72 removed filters have been sent for pathologic examination
Methods and Materials (2)

2. Device

- The ALN filter is made of 316 L amagnetic stainless steel struts. The filter is cone-shaped.

- Its two levels of anchorage and centering are distinguished by the length of the struts.

- The upper level provides an active anchorage. It consists of 6 shorter struts whose distal extremities are curved in hooks.

- The lower level consists of 3 legs providing the centering. These legs have a concave curvilinear shape reducing the traumatic risk.

- These legs are all from unequal length, avoiding the intertwining inside the catheter (introduction sheath).
Methods and Materials (3)

3. Device design

1st level of Anchorage

6 shorter struts

2nd level of Centering

3 longer struts

Weight
Less than 1 gramm

55 mm high

Suitable up to 32 mm
Methods and Materials (4)

4. Device

The ALN extraction kit consists of a pincer with 9 branches designed to catch the filter.
5. Pathologic study

- 72 pathologic examination reports of the ALN filter are available

- Tissue stick to the filter was removed and fixed in formalin to perform paraffin embedded sections. An HES (Hematoxylin Eosin Saffron) coloration was performed.
Results

1. Retrieval procedure

Among the 315 patients who had received an ALN filter during the study period, 87 patients (27.6%) met the criteria of filter retrieval.

The final retrieval success rate was 100% as follows:

- Including 84% at first attempt and without further procedure with a mean retrieval procedure time of 14.2 min +/- 10.7 (range 4-120)

- Including 13% requiring additional procedures

- Including 1% with a venal tear on the IVC wall but without clinical manifestation

- Including 1% with surgical approach, the filter being sticked in the jugular vein
2. Additional procedures

- for 5 patients (5.7% of total retrieval) a thromboaspiration was required because of clots in the filters and a second attempt was performed successfully

- For 6 patients (6.9%) a major tilting of the filter (more than 15° /axis of the IVC) it has been necessary to use a femoral approach in order to allow the centering of the filter
Pathologic study

- 72 pathologic examination reports have been split into 3 categories as follows:
  - A = Organizing Thrombus
  - B = Acute Thrombus
  - C = Vessel Fragments
Results (1)

Types of Pathologic Examination

- Acute Thrombus: 37.5%
- Organizing Thrombus: 26.39%
- Vessel Fragments: 8.33%
- OT + V.Frag: 23.61%
- AT + V.Frag: 4.17%
Vessel Fragments

A,B: Vessel Fragments with area of scaring

C: Hemosiderin Deposit in Vessel Wall
Acute Thrombus

Acute Fibrin Platelet Thrombi with Intact Hematies

Acute Thrombus is a common finding and is secondary to the procedure
Organizing Thrombus

Organizing Thrombi with Fibrin Platelet, altered Hematies (A) and scant Fibrosis (B)
A- Dystrophic cells of unknown origin in a patient with carcinoma disease.
Immunohistochemical Search for Tumor Emboli

B- AE1/AE3 Keratins negative cells.
C- CD31 IHC Positive cells: endothelial dystrophic cells.

In our experience we never identified carcinoma cells in patients with neoplastic disease.
Results (2)

- No link could be established between the necessity of additional procedure and the duration of implantation as follows:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Implantation Period (month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilting</td>
<td>0.43</td>
</tr>
<tr>
<td>Tilting</td>
<td>0.67</td>
</tr>
<tr>
<td>Thromboaspiration</td>
<td>0.93</td>
</tr>
<tr>
<td>Tilting</td>
<td>1.43</td>
</tr>
<tr>
<td>Tilting</td>
<td>1.53</td>
</tr>
<tr>
<td>Tilting</td>
<td>1.83</td>
</tr>
<tr>
<td>Tilting</td>
<td>3.07</td>
</tr>
<tr>
<td>Tilting</td>
<td>3.13</td>
</tr>
<tr>
<td>Tilting</td>
<td>3.13</td>
</tr>
<tr>
<td>Tilting</td>
<td>3.9</td>
</tr>
<tr>
<td>Thromboaspiration</td>
<td>4.43</td>
</tr>
</tbody>
</table>
Results (3)

No link could be established between the duration of implantation and the type of pathologic examination reports as follows:

<table>
<thead>
<tr>
<th>Type of Pathologic Examination report</th>
<th>Duration of Implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A = Organizing Thrombus</td>
<td>13.6, 4.3, 0.23</td>
</tr>
<tr>
<td>B = Acute Thrombus</td>
<td>13.63, 0.43, 4.2</td>
</tr>
<tr>
<td>C = Vessel Fragment</td>
<td>13.1, 4.95, 0.7</td>
</tr>
<tr>
<td>A+C</td>
<td>13.1, 8.99, 4.5</td>
</tr>
<tr>
<td>B+C</td>
<td>11.23, 13.6, 13.1</td>
</tr>
</tbody>
</table>

- **Mean Implantation Period (month)**
- **Min Impl. Period**
- **Max Impl. Period**
Results (4)

- The former thrombi are more often found in filters at short implantation time, meaning that the filter has achieved its first role, blocking thrombi coming from the lower limbs. This constatation confirms the result of the Icoper Study (7,8) showing that 80% of recurrent fatal PE occur within the first month of venous thromboembolism disease.

- We never had any pathologic examination report which could be attributed to endothelization around a leg of the filter.
Discussion

As recently shown by Imberti and al (9), the ALN filter was successfully retrieved in 100% of the cases by several teams in different countries, without any clinical complications nor alterations on the post-procedure cavogram (this rate being slightly lower for the other optional filters)(10-12).

We showed through this pathologic study that there is no link between the time of implantation and the pathologic examination report.

We can suppose that the easiness and the safety of the retrieval is mainly due to the configuration of the ALN filter.
Discussion (2)

- Nine free limbs construction (distal position of the limbs are unattached to other parts of the filter) ensuring the easiness to gather the legs in the sheath during the retrieval

- With three long and incurved legs ensuring the self centering of the filter with a good adaptation to the size of the vena cava without its deformation

- Six anchoring legs of unequal length ensuring the stability of the filter during the insertion and the stay in the patient (no migration of the filter)
- During the retrieval procedure, you have to push down the outer catheter while maintaining the top of the filter with the retrieval pincer. And thanks to the 90° angle of the anchoring hooks and to the conical shape of the filter, the hooks remove from the vena cava wall in a perpendicular way, avoiding IVC laceration as it has been shown in the pathologic study.

- Due to the conical shape of the filter and its stability system, the contact between the filter and the vena cava wall is very thin (unlike some other optional filters). This could explain that no endothelization is noticed and therefore the retrieval remains easy even after a long stay in (up to 25 months).

The previous points could explain why the filter does not have any time limit for removal unlike the other available optional filters (13-20).
Removal Procedure
Conclusion

This pathologic study confirms that the ALN filter can be easily and safely retrieved after a short, middle and long period of implantation.

We did not find any correlation between the delay of retrieval and the few difficulties of the procedure and the pathologic examination reports.

We think this could be related to the configuration of the device.
References

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20 Oliva VL, Retrievability of the new recovery G2 inferior Vena cava Filter. Presented at the 31st annual scientific meeting of the Society of Interventional Radiology; March 2006; Toronto