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THE ALN PERMANENT/ REMOVABLE VENA CAVA FILTER

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Vena cava filters have a rather troubled 30-year history, all ups and downs, made mostly of incomprehension either for what is expected from these devices or for their demonization that still continues in some milieus.

In order to avoid any misunderstandings, it must be clear that the only function a filter can carry out is to keep an embolus, and only when that embolus is a thrombus, from reaching the pulmonary arteries. That embolus must be above a certain size, below which the filter cannot capture it. The function occurs according to simple, universal mechanics laws that do not depend on individual reactions and therefore occur in every case.

It must be understood that Vena Cava Filters vary greatly one another in terms of function, efficiency and safety, and the pretension of grouping them in a single category, as is often the case, and expressing opinions on "vena cava filters" is at best naïve from a scientific standpoint. Unfortunately the operator implanting the filter does not always have the necessary technical training to wholly evaluate the efficiency and safety of the device and ease of use is often the only consideration regarding the choice of filter. This has the effect of diverting the manufacturers R+D efforts from what should be the real goals of their research. Evidence of this is the existence of filters flawed by obvious design errors, for example: Distal inverted cone designs that cause stagnation volumes, or cone designs manifestly too short that do not effectively trap clinically significant emboli.

Further evidence of this is of filters that enjoyed a great popularity due to their ease of use, but that were then rapidly withdrawn due to problems they "unexpectedly" brought on. Those filters, that were so easy to spot and to condemn by a good technician, yet were generally accepted by clinicians, are responsible for much of the bad press by the lumping together what is technically good, not so good and not good at all with regard to vena cava filters. And yet what is not good at all may still enjoy commercial success.

The hydrodynamic ALN vena cava filter is the result of an 11-year study at ALN Laboratories. Highly efficient in terms of capturing emboli down to a diameter of 2-3 mm, and of occlusivity, i.e. the percentage of caval section it occupies, and of the low amount of metal used. The latter two being basic factors to assess the thrombogenicity of the device. Additionally the architecture has no points that cause reduced blood flow, hence its virtual absence of thrombogenicity.

In a number of cases this design feature has made it possible to perform super-renal implantation without compromising renal flow.

The ALN filter is manufactured from AISI 316 L stainless steel, an alloy widely used for many years in the prosthetic field that has long proved its usefulness in for this particular application.

The exclusion of welding points gives this device an excellent corrosion resistance, the major, though not sole, cause of vena cava filter failure. In the eleven-year history there have been no documented fractures in ALN filters.

Device manufacturers have been attempting to produce temporary filters for a long period of time, i.e. catheters with a distal filtering element kept inside the patient's vena cava purely for the length of time necessary to heal a deep vein thrombosis. This idea was also tried briefly by myself, without enthusiasm, and proved an utter failure. The main reasons were the very difficult management such a system requires and, above all, the biologically limited time the catheter can stay in place before having to be removed. In a vast majority of cases, that time was not sufficient to treat a DVT and the temporary filter was habitually replaced by a permanent one.

Another method the manufacturers attempted was to make a permanent filter that could be explanted, a solution whose results were not particularly brilliant as the explant must be carried out within too short a time before the filter becomes irreversibly permanent. In a non-negligible number of cases, a few months after a pharmacological treatment has been started or the patient has suffered a trauma, including surgery, the presence of a caval filter may become unnecessary. Hence it is desirable to remove such a device, which, though scarcely ever dangerous, is still a foreign body, and though correctly designed and manufactured, sooner or later may fracture due to fatigue and corrosion.

Additionally a few patients show a psychologically adverse reaction to something implanted inside their body, even if they are perfectly asymptomatic and can still lead a completely normal life.

In every respect, ALN is a permanent filter and it should be managed as such. It has, nevertheless, the unique characteristic of being removable when and if it is no longer needed without any time limit. Other removable designed filters have an architecture that allow for a maximum of 15 – 20 days before which intimal growth makes it impossible to remove them without surgical explantation.

Implantation of the ALN filter can be via Femoral, Jugular or Basilica Vein approach by means of a 7F system. It can only be removed from a Jugular approach regardless of implantation route with the use of the 9F Extraction / Repositioning device made up of a coaxial, longitudinally movable crampon system mounted distally on a steel preformed wire. Once the crampon cone is positioned at the apex of the filter, the sheath is advanced over the filter retracting the hooks from the cava wall and the filter can be withdrawn without any difficulty. Currently, the procedure is performed only in France, Germany and Italy.

Since November 1999, when the first filter was explanted in Florence, more than 100 ALN devices have been successfully explanted in Italy. Collecting the relevant data though is not easy, as the procedure is uneventful and passes unnoticed.

In a documented series from 26 Italian centres between November 1999 and July 2001, 36 extractions (22M, 14F) were performed on patients whose age ranged from 17 to 81 years with an in vivo time ranging from 8-282 days. During the implant time no patients, pharmacologically treated or not, showed any signs of pulmonary thromboembolism. The time during which the filter was in vivo had no influence on the extraction procedure and the look of the filter seemed not to depend on it. As a matter of curiosity, the filters removed after 282 and 270 days looked particularly "clean". Cavography and TAC investigations, when performed, showed a consistently whole cava in all patients and no patient showed any clinical signs of caval lesions.

When the manufacturer's directions for use were followed, the average extraction time was around 8 minutes. All changes to the approved procedure, such as the use of a Gooseneck Snare, prolonged the operation time and made the procedure more difficult to perform. Twice the removal was not possible due to the mal-position of the filter. In both cases, when the filter was implanted the legs were pushed into two separate vessels, therefore making sheath advancement impossible once the crampons system had surrounded the filter apex.

From the histological point of view the explanted filters showed that the hooks, where they were attached to the cava wall, are covered with a short and thin (1-2 mm) layer of fibrinohematic tissue with granulocytes and inflammatory cells. Occasionally, leukocytes or fibroblasts were present. An inconstant finding, apparently not associated with the time that the device stayed in situ, is a monocellular layer of fibrinohematic tissue with fibroblasts on the outer surface of the ogive. Those tissues do not influence the removal procedures. A series of explanted filters is under investigation at the Laboratory of Biomaterials of the University Of Modena, Italy.

The system briefly described above offers the possibility to reposition an ALN filter in case its placement had not been satisfactory, thus enhancing the overall safety of the device.

In summary the ALN Vena Cava Filter is not a temporary but a permanent Vena Cava Filter and an excellent one at that. The ALN filter has no documented events of thromboses, fractures (a problem that may yet occur in the future) or accidents that led to patient injury or death in its 11-year history. No thromboembolic recurrence has been observed even in patients who have had the filter in situ for many years. As for pharmacological treatment, the ALN filter is neither an indication nor contraindication for any drug therapy as it is biologically inert.

In case the filter is deemed to be no longer necessary, its removal is a straightforward interventional procedure.

Such a filter, which is in no way meant to be an alternative to pharmacological treatments, seems particularly well indicated in patients difficult or impossible to treat with drugs, in the young, in trauma patients, in surgical patients in general and orthopaedic patients in particular, in puerperae and in subjects with behavioural or family problems that hamper the correct intake of drugs.

It should not be forgotten how, for simple chemical reasons, protracted pharmacological therapies with the same drug, beside the wanted action carry unwanted side effects. These occur in all cases and are often accumulation phenomena; they are harmful, very little understood and even less studied. The responsibility for that does not rest with the anima alone, but, and in no negligible way, with the particulate inorganic excipients as well, whose presence is all but indispensable in tablets, pills and so on. So, when dealing with a DVT or a pulmonary embolism patient, the opportunity to help him with a filter like the one described above should always be taken into consideration.

Evaluation on the implant and removal procedures of the permanent/removable ALN vena cava filter. New perspectives on the indications to the positioning of vena cava filters in the prophylaxis and treatment of the thromboembolic disease.

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The permanent/removable ALN caval filter belongs to the hydrodynamic family, is made of AISI 316 L stainless steel, has no welding points and is intended for either permanent or temporary use. The ALN filter is characterized by the absence of stasis volumes, by its very low occlusivity and by its capability to capture thrombi down to 2-millimeters diameter. Where the ALN filter is really innovative is in the possibility it offers to be used either as a permanent or as a temporary filter, as it can be explanted even after a long time. The 7-French introduction kit exists in the jugular, brachial and femoral approach versions. The ablation is carried out by means of a 9-French percutaneous catheter and can be performed only through a right jugular access. The filter is captured with a jaws system passed through the catheter which, when advanced, sheathes the filter.

During the past 15 months a total of about 500 ALN filters have been placed in Italy, around10% of which were removed. Our study reports the evaluation of 25 patients (Males=16, Females=9, median age 41 years, range 17-81) in whom an ALN filter was positioned; in 23 of them both positioning and removal procedures were performed; in the remaining 2 patients the ALN filter was repositioned in a supra-renal location after the original implant. The indications to the positioning of an ALN filter in these patients were: a) Deep Venous Thrombosis and Pulmonary Embolism in association with the specific pharmacological therapy in 15 cases; b) Prophylaxis of thromboembolic disease in 4 pts with cancer who underwent extensive surgical procedures, in 3 orthopaedic patients who underwent total hip replacement and in 3 patients with severe trauma in the lower limbs. No patient showed evidence of thromboembolism after the ALN filter was positioned. In the 23 cases in which the ablation of the filter was performed, the median removal time was 60 days (range 5-275). No evidence of complications showed during the ablation procedures in all patients. The longest ablation procedure took 8 minutes. All explanted filters presented small traces of endothelial growth exclusively located on the distal ring in the longest leg, and along the distal third of the three longer legs. However the endothelium growth did not hinder any of the procedure steps. The two observed complications in ALN filter removals were represented by a filter which failed to reopen during a repositioning procedure and a filter which could not be retrieved as it was incorrectly implanted astride the right and left common iliac veins (the latter case is not included in this report.)

The innovative characteristics of the ALN filter could extend the indications to vena cava interruption in the thromboembolic disease and in surgical procedures associated with a high risk of thromboembolic complications.