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A New Percutaneous Vena Cava Filter

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A new, percutaneous vena cava filter was developed and tested in 11 dogs. Nitinol wire (0.045 cm diam) spirals were straightened and passed through an 8 French Teflon catheter into the inferior vena cava. The filter resumed its original spiral shape on warming to body temperature and was left in place up to 6 weeks. Long-term patency and capture of injected radiopaque clots were demonstrated. This new filter design may be a simple alternative to currently used implants.

Pulmonary thromboembolism has been treated surgically by both ligation [1] and plication [2, 3] of the inferior vena cava. During the last 10 years, transvenously placed caval filters [4, 5] and occluding balloons [6] have been developed. While most of these techniques are effective in trapping emboli, a surgical cutdown of a peripheral vein is required and long-term patency is inconsistent [7]. These drawbacks have prompted recent investigators to search for a more easily placed and effective vena cava filter [8, 9].

Recently, Simon and associates [8, 10] developed a filter using nitinol wire. Nitinol, a unique alloy with a heat-dependent memory, can be passed as a straight wire through relatively small angiographic catheters. When extruded and warmed to body temperature, the wire resumes its original complex shape.

We recently developed a new technique for the nonsurgical placement of arterial endoprostheses using nitinol helices [11]. We believed that this same basic shape could be modified to act as an effective percutaneous caval filter. The design is simpler than those previously reported and may be less thrombogenic since less wire is introduced into the vena cava. Its method of introduction, ability to capture emboli, and long-term patency are the subject of this report.

Materials and Methods

Filter Design

The characteristics of nitinol wire have been described in detail [8, 11]. Briefly, nitinol is a nickle-titanium alloy with a heat-sensitive memory. If the wire is given a certain shape and annealed at greater than 500°C, it will memorize that shape. On cooling in ice water, the wire becomes soft and can be straightened without destroying its memory. When the wire is heated to its transition temperature (about 30°C for the alloy used in this study), it rapidly resumes its original shape, becoming more rigid than stainless steel.

Vena cava filters were made by wrapping nitinol wire (0.045 cm diam) on a specially designed steel mandrel (fig. 1A). The cone-shaped mandrel was threaded so that the distance between the threads was 2.75 mm. In this fashion, a helical spiral was produced with constant openings of 2.75 mm between each turn of the wire (fig. 1B). At the apex of the spiral, the wire was drawn out to form a large stabilizing loop that kept the cone of the filter centered in the middle of the caval lumen. The first filter in the study embolized to the lung within 2 weeks of placement. In all other filters, therefore, a small, 2 mm hook was made at the end of the stabilizing ring, which penetrated the caval wall and securely

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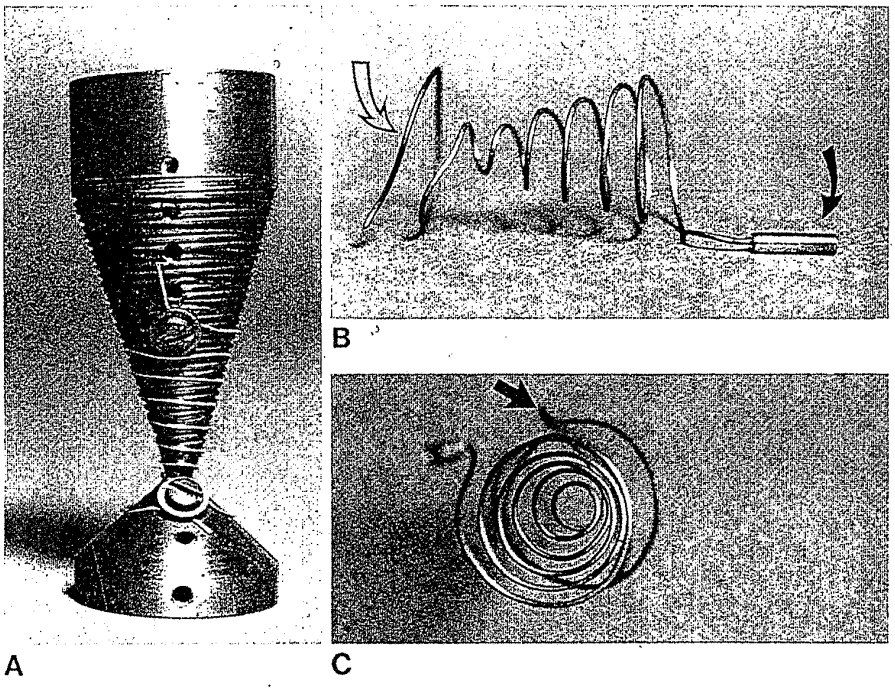

Fig. 1.—A, Stainless steel filter mandrel. Nitinol wire is wrapped on mandrel and annealed in Bunsen burner flame. Open area of filter can be varied by changing tightness of spiral. B, Nitinol spiral filter. Delivery wire is screwed to adapting plug (*closed arrow*) and filter is drawn into catheter. When extruded in body, filter resumes its shape. Stabilizing ring (*open arrow*) centers filter cone in lumen of vena cava. C, Filter viewed from below. Spiral design provides effective sieve without restricting blood flow. Anchoring hook (*arrow*) extends 2 mm from stabilizing ring.

anchored the filter (fig. 1C).

Most investigators have stated that nitinol wire should be annealed at 525°C for 20–30 min [8]. We found that equally good results are obtained by heating the mandrel and wire in the flame of a Bunsen burner until the wire changes from its unannealed straw color to a deep blue. This process is simpler and can be accomplished in less than 5 min.

After annealing, the mandrel is allowed to cool and the wire is removed in ice water. Usually, an "oversized" filter is constructed by winding extra turns of the wire on the mandrel. In this way the filter could be fitted exactly to a given vena cava size by trimming one or more of the spiral turns, thus decreasing the overall diameter of the filter.

Animal Studies

Eleven adult mongrel dogs (15–30 kg) were anesthetized with intravenous sodium pentobarbital (30 mg/kg) and maintained on spontaneous respiration. An 8 French introducing sheath was placed percutaneously in a femoral vein and connected to a heparinized (2 U/ml) saline solution. An inferior vena cavogram was obtained by injecting 15 ml of 60% diatrizoate contrast medium at 10 ml/sec through the sheath.

The diameter of the infrarenal part of the vena cava was measured and the filter trimmed accordingly. An adapting plug [11] was attached to the trailing wire of the filter, and a delivery wire was screwed to the filter. The filter was then immersed in sterile iced saline and drawn into a 60-cm, 8-French Teflon catheter. When fully straightened, the filter was about 20 cm long.

The catheter with the loaded nitinol wire was inserted through the introducer and passed under fluoroscopic control to the desired level in the inferior vena cava. The filter was deposited in the vena cava by withdrawing the catheter over the adapting wire. As the straightened nitinol wire came into contact with the blood it rapidly resumed its original filter shape. Once extruded, the filter was pulled down to the desired level and then quickly advanced by pushing on the delivery wire. This caused the hook on the filter to engage the wall of the cava thus anchoring the filter. A venogram was obtained immediately after extrusion of the filter to document its position and anchoring. If the position of the filter was not optimal, it could be withdrawn into the catheter and positioned again. To release the filter, the delivery wire was unscrewed and withdrawn together with the catheter from the vena cava.

The ability of the filter to capture emboli was tested in five animals acutely and in one chronic animal at the time of sacrifice. Emboli were prepared by drawing fresh blood into a thin-walled polyethylene catheter (3 mm diam, 10 cm long). A small amount of tantalum powder was added to the blood for opacification. After 10 min, the clot was injected into a femoral vein. This was monitored fluoroscopically and plain films of the abdomen and chest were made to document the effectiveness of the filter.

Long-term patency studies were performed in six animals. Venograms were repeated at 2 weeks and again at 6 weeks before sacrifice (fig. 2). The animals were killed by an overdose of pentobarbital, and the abdomens were opened and examined for evidence of retroperitoneal bleeding. The venae cavae were isolated and the filters examined for evidence of thrombosis.

None of the animals received long-term anticoagulation.

Results

Filters were placed successfully in all animals. In two animals, the original placement of the filters was not optimal. These filters were withdrawn into the catheter and successfully repositioned.

Venograms performed immediately after placement

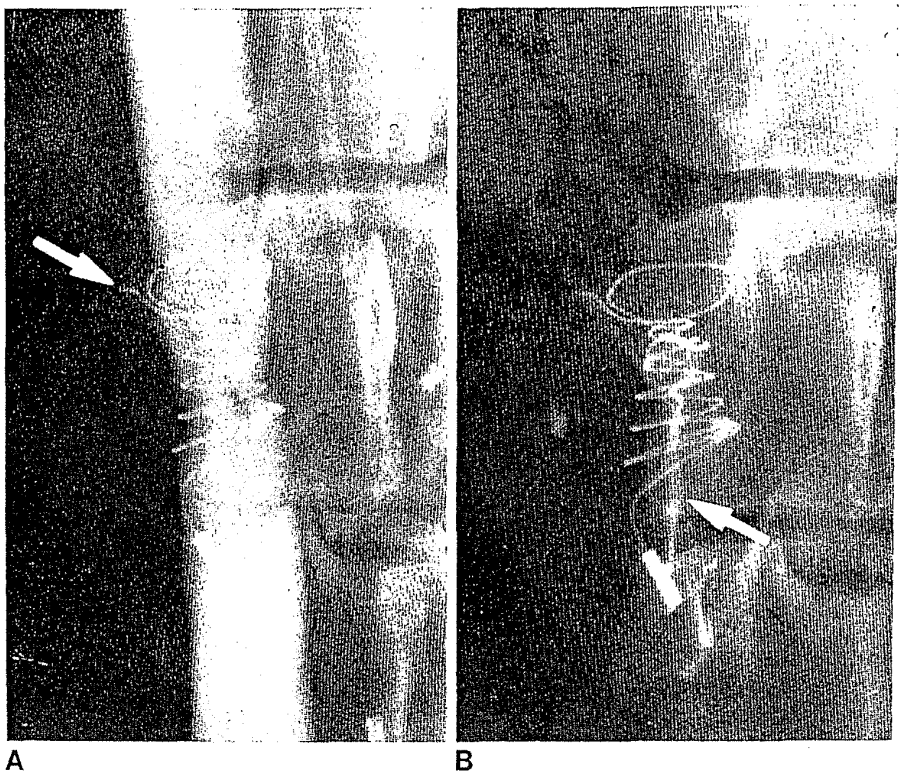

Fig. 2.—A, Vena cavogram 6 weeks after percutaneous placement of nitinol spiral filter. Vena cava is widely patent and anchoring hook has penetrated wall (*arrow*). At autopsy, hook was completely covered by mound of fibrous tissue. B, Same filter after injection of radiopaque autologous clot. Clot (3 mm × 10 cm) (*arrow*) was completely captured by filter.

showed patent filters in all cases without evidence of thrombosis. Of the six chronic animals, four had widely patent filters at 2 and 6 weeks (fig. 2A). In one animal, the lumen was 60% stenosed at 2 weeks and occluded at 6 weeks. This filter was the only one placed with the cone pointing down instead of up. The unanchored filter that embolized to the lung was found lodged in the left pulmonary artery at 6 weeks. The pulmonary artery was still widely patent and the filter was free of thrombus.

The capture of 3 mm × 10 cm autologous clots was complete in all six filters studied (fig 2B). In several instances, the clot fragmented into several smaller pieces on extrusion from the catheter; however, even small 1–2 cm emboli appeared to be captured by the filter. Opacified clot could not be found on postembolization chest radiographs. It is possible that very small fragments passed through the filter and were not detected on the chest film.

On postmortem examination, the anchoring hook protruded through the wall of the vena cava 1–3 mm and was covered by a small mound of fibrous tissue. No pericaval bleeding was noted. The largest rings of the filter were incorporated into the wall of the vena cava by 6 weeks. In most cases, small fibrous bands extended between the spirals of the filter.

Discussion

Surgical interruption of the vena cava in patients prone to pulmonary thromboembolism largely has been superseded by transvenous mechanical vena cava filters. The main disadvantage of these filters is the need for a surgical cutdown in a usually very sick patient. A percutaneous introduction technique of standard filters has been described, but because of the large size of the delivery capsule, this technique has not gained popularity [12, 13]. The development of an effective percutaneous filter therefore would be a great improvement over present techniques.

The nitinol spiral filter developed in our laboratory possesses several advantages over other vena cava filters: (1) It can be introduced percutaneously using an 8 French catheter; (2) the filter is easily trimmed to be adapted to different vena cava sizes; (3) it can be withdrawn and repositioned easily; (4) proper orientation of the filter cone is maintained by a stabilizing loop; and (5) the open area of the filter can be adjusted by winding a tighter or looser spiral on the mandrel.

The disadvantage of the present design is the mode of fixation. While one anchoring hook was adequate for normal animals, we believe that a more secure system of fixation needs to be developed before human trials can be considered.

While only a small number of long-term filters was tested, the thrombogenicity and biocompatibility of the filter seem comparable to those in present use [14]. In vivo thrombogenicity studies have not been performed on the nitinol filter developed by Palestrant et al. [10]; therefore, we cannot compare the relative thrombogenicity of the two filter de-

signs. Undoubtedly, however, the most important factor in determining thrombogenicity of a venous prosthesis is the degree to which it obstructs blood flow. Thus an inverse relation exists between thrombogenicity and the open area of the filter. The more wire, the better the filter action but the greater the tendency to thrombose. In humans, long-term anticoagulation may favorably influence this balance. We believe that the spiral filter shape used in this study may provide the most effective sieve with the least amount of wire, thereby decreasing thrombogenicity.

It is interesting to note that the thrombosed filter was the only one oriented with the apex of the cone down. It is possible that the orientation of a filter affects its thrombogenicity. Greenfield et al. [15] claim that the optimal orientation of a cone-shaped filter is with its apex directed upward. It is claimed that with this orientation a large embolus occludes less of the lumen and has a self-anchoring effect by distending the filter against the caval wall. For this reason, we chose to orient our filter with the apex directed upward.

In summary, an effective vena cava filter has been developed, which overcomes many of the disadvantages of currently used filters. The filter is introduced percutaneously through a small catheter and effectively stops propagated emboli. With the development of a more effective anchoring system, the design may be tested in humans.

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