Interruption of the inferior vena cava using the Vascor filter: preliminary series of 51 cases

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Between February 1991 and October 1991, vena cava filters made of Vascor (Toulon, France) were inserted into 51 patients. The male:female ratio was 29:22 and mean age 74 (range 45-94) years. Diagnosis of thrombophlebitis was established by venography in 48 patients (94%) and ultrasonography in three (6%). Thrombosis was unilateral in 49 patients and bilateral in two, involved the pelvic veins in 38 (75%) and the leg veins in 13 (25%). Of the 51 patients, 17 (33%) presented pulmonary emboli and 12 (24%) had waving supracrural dots. The Vascor umbrella filter is a two-stage stainless-steel device with attachment tabs for anchoring and centring. It can be placed either percutaneously using a 7-gauge French introducer via the jugular, subclavian or brachial vein or surgically. In the present series, placement was achieved percutaneously via the jugular vein, in 49 cases (96%) and surgically in two (4%). Postoperative and follow-up examinations included coagulation tests, Doppler ultrasonography and abdominal radiography. In the immediate postoperative period, one patient developed a pneumothorax which was treated by pleural drainage and five died from cancer within the first month after placement. There were no postoperative accidents and no patient had recurrent embolism. In three patients, the filter tilted 30° and in one caval thrombosis was identified. Follow-up examinations were performed in 46 patients, with a mean duration of 12 months. Ten patients have died. Caval thrombosis occurred in two patients (4%) but proximal migration of the filter and recurrence of pulmonary embolism have not been observed.

Keywords: pulmonary embolism prevention, vena cava filter

Venous thrombosis with subsequent pulmonary embolism can develop spontaneously in certain medical and surgical settings. The main precipitating factors are malignant tumours, a previous thrombosis, cardiac insufficiency, obesity and prolonged bedrest. In 1985, Berquist and Lindblad's¹ published findings showing pulmonary emboli reported post-mortem in 23.6% of 1274 surgical patients. Embolism was the cause of death in 53% of cases.

Several surgical methods to prevent propagation of pulmonary embolization from the thrombosis in the lower limbs have been proposed. In 1934 Homans noted the relationship between peripheral venous thrombosis and embolism and recommended ligation of the inferior vena cava. Partial interruption of the inferior vena cava was proposed in the 195 Os and 1960s to avoid the adverse effects of ligature. Moretz et al.² proposed a metal filter, Spencer³ described a caval plication technique and Miles et al.⁴ used a screen filter.

In 1969 Mobbin-Uddin et al.⁵ proposed the first intracaval device which could be placed under local anaesthesia. However, this umbrella with silicone ribs generated thrombosis in 95% of patients and led to the same complications as ligature. Since the introduction of the Greenfield filter in 1973, percutaneous interruption of the inferior vena cava has become a safe and reliable therapeutic method⁶. During the 1980s percutaneous placement systems were developed. These filters can be placed through the internal jugular vein or the femoral vein by vascular surgeons in operating rooms, or by interventional cardiologists or radiologists in catheterization laboratories.

With the introduction of this simple technique, the use of percutaneous interruption of the inferior vena cava...
cava has greatly expanded. In France, the number of filters placed has risen from 3000 in 1985 to 10 000 in 1988. Ten models are available on the French market. In addition to the Greenfield filter there are the Antheor, Cardial, Dil, Filcard, Gianturco, LGM, Pietri, Promed, with a diameter of 0.35 mm. The triangular tapered Simon Nitinol, and Vascor to name but a few. This huge choice of apparatus required clinical studies to allow a comparison of effectiveness and complication rates.

Patients and methods

Patients

In the 7-month period between March and October 1991, Vascor (Toulon, France) umbrella filters were inserted in 51 patients. The male:female ratio was 29:22 and the mean age was 74 (range 45-94) years. A diagnosis of deep vein thrombosis was established by venography in 48 patients (94%) and duplex ultrasonography in three (6%), in whom venography was prevented by either severe pulmonary embolism (two) or the patient’s critical condition (one).

The precipitating causes of deep vein thrombosis were: surgical insult (17 patients (33%): orthopaedic surgery in five, vascular surgery in four, digestive; surgery if three and urological surgery if one); carcinomas (15 patients (29%)); prolonged bedrest (nine patients (18%), associated with cardiac disease in four); coagulation abnormalities (four patients (8%): two allergies to heparin, one reaction to antivitamin K and one thrombocytosis).

Venous thrombosis was unilateral if 49 patients and bilateral if two, and involved pelvic veins if 38 (75%) and leg veins if 13 (25%). Among the 38 patients where the thrombosis extended into the pelvic veins 12 (24%) had loose thrombosis.

Pulmonary embolism was observed if 17 patients (33%). The site of thrombosis was if a leg vein if 13 patients and if a pelvic vein if four. In two patients, massive thromboembolism was confirmed by blood gas measurements, showing hypoxia and hypercapnia, and ultrasonographic visualization of right heart distension associated with pulmonary hypertension. The diagnosis of pulmonary embolism was confirmed by angiography if fine patients, and ventilation—perfusion scintiscanning in six.

Assessment of coagulatory status at the time of filter placement revealed that: 14 patients (27%) had an absolute contraindication to anticoagulants; 10 (20%) had received no anticoagulation therapy; 27 (53%) had been inadequately treated for thromboembolitic disease (ticlopidine (one), antivitamin K (seven, including one complication) and heparin (19)).

The Vascor filter

The Vascor filter is a two-stage umbrella device with three tabs on the lower stage and six on the upper.

During placement, the lower tabs are pushed out of the introducer first to centre the device distally; the upper tabs are then deployed to anchor the device proximally. All tabs are made of non-magnetic stainless-steel wire attachment hooks are arranged at different levels, lowering attachment at different points in the vena cava.

This configuration allows introduction with a 7-gauge French introducer (Figure 1).

*In vitro* tests were carried out in a cava simulator at flow rates of 500 ml/min, 1000 ml/min and 1500 ml/min using artificial turbulences. Thrombi were simulated using polyethylene beads of various diameters, i.e. 8, 5, and 4 mm. The filter caught 100% of the 8-mm beads regardless of the number placed in circulation (from one to ten beads) and 80% of the 8-mm beads. Conversely, 100% of the 4-mm beads escaped the filter. These results are comparable with the authors’ test data for other commercially available filters.

The effect of tilting the filter off the centre line of the vena cava was evaluated. The maximum inclination for a Vascor filter is 22°. The percentage of beads stopped at a flow rate of 1000 ml/min was the same regardless of the position of the filter.

The Vascor filter was designed for use with a long catheter through the upper vena cava, or the jugular, subclavian or brachial veins. It is unsuitable for the femoral route. Placement of the filter is done with the aid of a radio-opaque 7-gauge French introducer. The filter is
Placement of the Vascorfilter: Ph. Rudondy et al.

Figure 2 Cartridge used to introduce the filter into the 7-gauge French catheter

Packaged in a syringe-like cartridge which facilitates introduction into the catheter (Figure 2). This is important because manual handling can damage the device.

Operative technique

The filter was introduced through the jugular vein in all patients. It was placed in the vena cava below the kidney. The approach was percutaneous in 49 patients (96%) and surgical in two (4%). A brightness amplifier was used to monitor the progression of the guide wire which features a flexible and J-shaped tip which can be used as an alternative in case of difficulty in passing the Pirogoff venous trunk that enters the ostium of the inferior vena cava or locates the renal veins. In one kyphotic patient, entry into the inferior vena cava was not feasible and a hydrophilic guide wire had to be used. Location of the function between the vena cava and the renal vein was achieved in relation to the spine (L2) by cavography in 31 patients (60%) or by catheterization of the right renal vein in 20 (40%). The filter was positioned so that flow in the renal vein crossed its proximal end. The filter was ejected slowly from the catheter to ensure its placement in the midline of the vein.

Results

Intraoperative complications

Placement was successful in all but two patients, in whom the percutaneous technique had to be abandoned and a surgical approach to the vein used instead. In one of these two patients a pneumothorax occurred because of a puncture of the lung and pleural drainage was required. No air emboli occurred. A downward puncture and use of a 7-gauge French catheter with an antireflux valve (BALT, Montmorency, France) offer the best guarantee of preventing this complication. Neither pulmonary emboli nor caval thrombosis occurred. There were no major position problems caused by misplacement in the renal vein or puncture of the vena cava, but minor defects in relation to the function between the vena cava and the renal vein were observed in six patients. These errors did not impair the efficiency of the filter or hinder the flow in the renal vein. A 20% tilt at the distal end of the filter was noted in three cases, including one patient with a severe dorsolumbar scoliosis. Tilting probably resulted from jerking movements of the umbrella during ejection.

Immediate postoperative period

Clinical examination and laboratory (coagulation) tests were performed until the patients were discharged from the hospital. Heparin was administered at therapeutic doses in 37 patients (14 had a contraindication to anticoagulation). Patients were advised to get out of bed the day after the procedure. Ultrasonography of the peripheral veins and the vena cava, as well as conventional abdominal radiography, were done within the first week (Figure 3). Four patients underwent computed tomography. Five patients died from cancer during the first month after placement. Pulmonary embolism did not recur in any of the patients in the present series. Caval thrombosis was diagnosed in one patient who was allergic to heparin. Ultrasonography demonstrated aggravation of peripheral thrombosis in five patients not treated with heparin. No migration was observed except for the three filters that tilted during placement.

Late follow-up

At the time of writing, mean follow-up of the 46 surviving patients is 12 (range 9—17) months. Follow-up examinations have included ultrasonography of the vena cava and/or abdominal radiography every 6 months. Eight patients were lost to follow-up after
Discussion

Prevention of embolism

Several factors can lead to recurrence of emboli after percutaneous interruption of the inferior vena cava. Small dots can pass through the filter especially if it is tilted or incompletely deployed. Thrombus on the top of the filter can generate more thrombi. In the case of caval thrombosis, emboli can propagate through the collateral circulation. In the present study, the Vascor filter was 100% effective and embolisms never recurred. However, as only 28 patients have been followed up for a mean of one year, no definite conclusion about long-term results can be drawn.

The in vitro tests supported the high efficiency of the Vascor filter irrespective of whether the device was centred or tilted. Similar data are available for other systems. Donaldson et al.\textsuperscript{10} reported filtering efficiency to be 95-99% in patients with pericaval devices. The efficiency of the Mobbin-Uddin umbrella, by far the most widely used endovenous filter, is 98\%\textsuperscript{.}\ The Greenfield filter, which is considered to be the gold standard for endocaval processes, has an efficiency of 96-99\%\textsuperscript{12}. The efficiency of the LGM filter is 98\%\textsuperscript{13, 14}.

Patency

Caval thrombosis after filter placement is characterized by recurrence or the extension of deep venous thrombosis to the other leg. The risk of this complication is increased if heparin is not used or is contraindicated as in three patients of the present series. Caval thrombosis can be identified using conventional radiography, showing a decrease in filter diameter or tilting, and by plethysmographic evidence of delayed emptying\textsuperscript{13}. The patency rate of the Vascor filter in this series was 94%. This figure is similar to those reported by various authors using the Greenfield filter, i.e. 83-97\%\textsuperscript{12, 15-17} and the LGM filter, i.e. 92\%\textsuperscript{13}. Lower patency rates are observed in patients with pericaval clips, i.e. 66-86\%\textsuperscript{18, 19}.

Postoperative sequelae of peripheral or caval venous thrombosis are dependent on the pre-existing state of the venous bed\textsuperscript{2}. Some patients with previous deep venous thrombosis-related damage stabilize and others deteriorate. In some patients, caval or peripheral obstruction is exacerbated after the procedure. Venous abnormalities were observed in 30-50\% of patients after percutaneous interruption of the inferior vena cava; in 6-14\%, these were severe. These figures are comparable with those observed after drug treatment of thrombosis\textsuperscript{20}.

Placement

The main problems associated with placement of endovenous filters are: (1) mechanical trauma during placement; (2) inaccurate ejection; (3) poor centring in the inferior vena cava; (4) distal or proximal migration; and (5) perforation of the inferior vena cava.

Mechanical trauma during placement

The risk of mechanical trauma during placement depends on the introducer system. Although the ability of the Vascor filter to be inserted through a 7-gauge French introducer greatly reduces this risk, one pneumothorax was observed because the venepuncture was too low. This complication, which can be life-threatening for a patient with pulmonary embolism, was treated by pleural drainage.

The superior vena caval route is much safer than the femoral route, which is reportedly associated with a high complication rate of 8\%\textsuperscript{12}. The superior vena cava can be approached through the internal jugular, subclavian or brachial veins with the Vascor filter. In the authors’ opinion, the femoral route is hazardous for two reasons. First, it is possible to enter through the initial site of thrombosis, which is dangerous. Second, catheterization is hindered by the anatomy of the iliac vein and by arterial compression on the left side.
Placement of the Vascor filter: Ph. Rudondy et al.

Inaccurate ejection

The filter must be ejected so that it is neither too high nor too low with respect to the renal and lumbar veins. The accuracy of ejection depends mainly on the operator's experience and skill. The most serious consequences of inaccurate ejection occur with respect to the renal vein and can result in bilateral thrombosis of the renal veins. Migration can also arise into the iliac vein on the side opposite the site of the thrombosis. In some patients, it may be necessary to insert a second filter either in the correct position or the vena cava or above the renal vein. The incidence of inaccurate ejection reported in various series varies from 6 to 12%.21

Poor centring in the inferior vena cava

Optimal filtering requires that the filter should be parallel with the centre line of the vena cava. The maximal deviation should be ±50. The best guarantee against tilting the filter is to avoid any jerking movements during ejection. This ensures that the tip of the catheter remains in the centre of the vena cava. The Vascor ejection system is very smooth and the attachment tables have been designed to maintain centring. In the present series, tilting of the filter occurred in four patients (8%). This incidence is comparable with figures reported elsewhere which vary from 7 to 12%. In vitro experiments with the Vascor filter demonstrated that filtering efficiency was the same regardless of centring. According to Gomez et al.21, the maximum allowable inclination is 250 for a filter with a diameter of 25 mm. In determining the inclination of the filter, the degree of scoliosis that can after the centre line of the inferior vena cava must be taken into account and this can be reliably evaluated only by cavography.

Distal or proximal migration

Filters can migrate distally or proximally. The incidence of distal migration varies widely depending on the radiological follow-up technique used. With the Greenfield filter, the proximal migration rate ranged from 012 to 50%. With the LGM filter, Ricco et al.14 reported a proximal migration rate of 13.1%. Although uncommon, distal migration of endovenous filters has been reported in the literature 6, 23-26. It occurs most frequently using the Mobbin-Uddin filter with a diameter of 23 mm. Because of the major risks of migration to the right ventricle, cavography should be performed either before placement to determine the diameter of the vena cava or during placement. Most models on the market, including the Vascor filter, are designed for vena cava with diameters <28-30 mm. The cadaverous dissections of Le Fioch-Prigent27 showed that the mean diameter of the vena cava at the subrenal level was 27.7 mm. A special umbrella or an Adams de Weese clip may be necessary in cases with vena cava >30 mm. The subrenal level was 27.7 mm. A special umbrella or an Adams de Weese clip may be necessary in cases with vena cava >30 mm.

Perforation of the inferior vena cava

Perforation of the vena cava is a potentially serious complication which can occur during or after the operation as a result of placement in an ectopic position (renal vein). Cavai puncture is more common in a vena cava of small diameter, the wall of which is distended (e.g. tricuspid insufficiency) or compressed (e.g. tumour mass). This complication did not occur in the present series with the Vascor system, but an incidence of between 1 and 33% was reported with the original Greenfield filter.2, 15, 16, 28 Before the attachment system was redesigned to avoid this complication (Greenfield-Titane). Patients with caval perforation are often symptom-free but a retroperitoneal haematoma may develop in anticoagulated patients. Perforation of adjacent organs (e.g. the ureter or the digestive tract) can necessitate a major surgical procedure. Data from in vitro studies have provided solutions to the other potential complications associated with an umbrella. In the Vascor filter, overlapping disruption or bending of the branches of the filter have been avoided by the correct design of the ejection system.

Indications

Some 62% of patients in the Department of Cardiovascular Surgery at the authors' hospital are referred from cardiology or internal medicine in which the work-up is carried out. Thus, the possibility of drug therapy using anticoagulants or anti-thrombotic agents with or without temporary caval interruption has already been excluded. The authors do not use caval umbrella filters in those with a caval thrombosis who are eligible for surgery or in young patients with recent high post-traumatic or postoperative deep venous thrombosis. Indications are currently classified as absolute and relative, but a current study at the University Hospital of St Etienne should provide additional clarification29.

Absolute

At the present time only patients with venous thrombosis and pulmonary embolism who cannot be adequately managed with anticoagulant therapy are considered to fulfill this absolute indication for a filter. In the current series, 14 patients (27%) fulfilled this criteria of these patients, 12 presenting with thrombosis and pulmonary embolism had contraindications to anticoagulant or fibrinolytic treatment. The remaining two had diffuse thrombotic, venous, pulmonary and arterial manifestations, and were allergic to heparin.

Relative

Relative indications in the present series include: loose clots in the pelvic veins in recently operated patients (12%); iliofemoral thrombosis in cancer patients (10%); femoropopliteal thrombosis and pulmonary embolism (5%); massive thrombosis managed by...
heparin (5%); recurrent thrombosis in patients with a previous history of embolism (3%); and iliofemoral thrombosis managed with anticoagulants (2%). No indications for caval interruption associated with venous surgery, aortic aneurysm surgery or general surgery were observed. There were no patients with a high risk of thrombosis.

**Conclusion**

The ideal caval filter system would combine a filter that effectively stopped propagation of thrombi without reducing blood flow and an introducer that allowed quick and safe placement. In the authors’ experience the Vascor filter came very close to meeting these conditions. Thrombus control was excellent and the patency rate was about 95%. The complication rate was low. Distal migration, perforation of the vena cava and mechanical trauma were not observed. The small size of the percutaneous introducer allows placement through small veins with minimal trauma. Long-term tolerance appears to be excellent. A multicentre prospective study is required to define the absolute indications for filter placement.

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CARDIOVASCULARSURGERY JUNE 1994V0L2N03 349