IVC Filter Retrieval:

The Argument for Long-Term Retrievability

BY H. BOB SMOUSE, MD

There have been significant therapeutic advances in the treatment of venous thromboembolism and pulmonary embolus since it was first described by Laennec in 1819.[1] Anticoagulation with heparin has been the mainstay of treatment for 30 years. The most recent significant advancement has been the introduction of low-molecular-weight heparins. These agents offer better bioavailability, longer half-life, and less risk of bleeding and thrombocytopenia than unfractionated heparin.[2] Anticoagulation alone is adequate treatment for most patients with venous thromboembolism; however, when anticoagulation cannot be used, or when it fails, vena cava interruption is indicated.

OPTIONAL INFERIOR VENA CAVA FILTERS

Since the introduction of the Mobin-Udin umbrella in 1967, many other filter devices have been developed, including permanent filters, temporary filters (usually attached via retaining wires extending outside the vein) and, most recently, optional (or retrievable) type filters. The optional filter allows either retrieval or maintenance as a permanent filter depending on the future clinical need.

Three FDA-approved optional filters are available in the US, with ongoing development and testing of other prototypes, such as the Celect, a second-generation optional filter (Cook Incorporated, Bloomington, IN). The Günther Tulip retrievable filter (Cook Incorporated) is inserted through the jugular or femoral vein but must be removed using the jugular vein approach. The Recovery Filter (Bard Peripheral Vascular, Tempe, AZ) was the first filter to be given 510(k) clearance for removal (July 2003), and likewise, can be inserted through either the jugular or femoral vein and requires jugular access for removal. The OptEase vena cava filter (Cordis Endovascular, a Johnson & Johnson company, Warren, NJ) received approval in 2004 and has a caudal hook allowing retrieval from the femoral vein and, in some cases, the popliteal vein (after deep vein thrombosis).

NONPERMANENT FILTER INDICATIONS

Most vena cava filters placed in the US are permanent filters that cannot be removed. There are certain cases in which a permanent filter may not be desirable. In a multicenter review, the main indications for nonpermanent filter placement were thrombolytic therapy (51.2%), preoperative implantation excluding Caesarean section (41.5%), pregnancy with deep vein thrombosis (2.7%), and prophylactic implantation in the absence of deep vein thrombosis (4.8%).[3] Other indications for nonpermanent filter placement may also include prophylaxis in trauma patients, short-term contraindication to anticoagulation, and prophylactic placement after pulmonary embolism, although this is controversial. The goal of using retrievable filters is to avoid long-term filter complications, such as thrombosis, migration, inferior vena cava occlusion or perforation, filter fragmentation, and increased risk for deep vein thrombosis.[4] The retrieval data provided by each manufacturer supports the indication that the filter is safe to retrieve. None of the filter manufacturers has recommended a retrieval window. In the case of the Günther Tulip filter, the FDA requested that manufacturers not recommend a specific number of days. Therefore, the FDA has placed the decision on when to retrieve a filter in the hands of physicians.

INSTRUCTIONS FOR USE COMPARISON

Cook Günther Tulip Filter

The safety and efficacy of the Günther Tulip inferior vena cava (IVC) filter was initially evaluated in Germany in 1992; the filter subsequently received approval for use in that country. In a US trial in 2002, data from retrievals in a 41-patient cohort demonstrated that the device could be safely retrieved percutaneously post-implanta-

tion (mean, 11.4 days; range, 2-20 days). The study data were submitted to the FDA, and the device received FDA approval in 2003 (Kaufman J, unpublished data, 2002).

Bard Recovery Filter

The safety of removal was addressed in a series of animal and clinical tests. The results of animal testing (including histology) and the confirmatory experience of 32 patients (mean implantation time, 53 days to removal; range, 1-134 days) show that the Recovery filter may be safely retrieved, and that the benefit of this procedure outweighs the potential associated risks. In other studies, a maximum time of 161 days has been achieved.[5]

Cordis OptEase

The safety and effectiveness of the Cordis OptEase vena cava filter and the OptEase retrieval catheter have been demonstrated via data collected from *in vitro*, animal, and clinical testing and analyses. A retrospective analysis in the 510(k)-approval request described 29 patients with a mean implantation time of 16.4 days (maximum of 48 days).[5]

THE NEED FOR LONG-TERM FILTER IMPLANTATION

There is no discernable optimal window for filter retrieval at present. A review of published data reports successful filter retrievals from as early as 1 day to as long as 161 days after implantation, based on patient need for continued IVC interruption. The length of filter dwell time is determined case by case and is based on specific indications for nonpermanent filter implantation and the medical condition of the patient.

High-Risk Surgery

Several investigators have reported significant risk with certain surgical procedures. The risk of developing postoperative venous thromboembolism is particularly high in orthopedic surgery (knee > hip), and the risk remains elevated for up to 3 weeks after surgery.[6-8] An argument can be made for the need of long-term retrievability if a filter is indicated (ie, bleeding diathesis while on anticoagulation therapy).

Change in Patient Clinical Status

In a report by de Gregorio et al, 88 Günther Tulip filters were implanted in 87 patients with the preimplantation intent of removing the filters within 14 days.[3] However, in 23 of the 87 patients (26%), there was the need to prolong temporary caval filtration beyond the expected 14 days. In one patient, the filter was removed after 62 days, with a mean filter dwell time of 34.8 days for the study.[9]

In our study of 137 Günther Tulip filter implantations in 130 patients, filter retrieval was attempted in 57 patients and successful in 53 patients (93%). The numbers of repositionings (at 2-week intervals) prior to filter retrieval were: one repositioning (n=24), two repositionings (n=14), three repositionings (n=4), four repositionings (n=3), and five repositionings (n=1). Long-term retrievability (without previous manipulation) would decrease the number of subsequent interventions and potential complications.[10]

Trauma Patients

Patients with multiple trauma often have injuries that preclude the use of anticoagulation therapy or sequential compression device prophylaxis. Temporary inferior vena cava filters offer protection against pulmonary embolism during the early immediate injury and perioperative period, when risk is highest, while averting potential long-term sequelae of permanent IVC filters. Rosenthal et al reported on the use of retrievable filters in trauma patients with a mean dwell time of 19±1 days (range, 5-25 days).[4] The wide variability is due to case-by-case need for continued IVC interruption.

THE FUTURE OF RETRIEVABLE FILTERS

Initial recommendations for implantation and retrieval were based upon preliminary data used to obtain FDA approval for retrieval indication. For example, with repeated use and familiarity in retrieval techniques at our institution, we have extended the window for retrieval of Günther Tulip filters from 2 weeks to 4 to 6 weeks. The Bard Recovery filter, the OptEase, and the Günther Tulip filter have all had published retrievals beyond what was initially reported for 510(k) approval. There is a report of successful Bard Recovery retrieval at 161 days.[5] Newer filter designs promise improved retrievability. Animal testing data of the Celect, a second-generation retrievable inferior vena cava filter from Cook Incorporated were reported at the AIM Symposium, ISET, and TCT meetings. There were 23 of 24 successful retrievals (95.8%) at 180+ days after implantation.[11]

The Günther Tulip Retrievability Trial is a Cook Incorporated-sponsored, multicenter (31-site), prospective, nonrandomized trial evaluating the successful retrieval of Günther Tulip filters at various dwell times. Four hundred to 800 patients will be enrolled and, when clinically indicated, the Günther Tulip filters will be removed (without prior manipulation). From these data, the predictability of successful removal at progressive time frames will be calculated.[12]

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CONCLUSION

Retrievable vena cava filters are a significant advancement in the prevention of pulmonary embolism. Permanent IVC filters have been shown to save lives and decrease morbidity; however, they are not without potential adverse side effects. One investigator coined the phrase: "long lives, short indications" when making the argument for removable filters.[13] Many patients are at temporary risk for venous thromboembolism and pulmonary embolism and, therefore, do not need life-long IVC interruption. Relatively speaking, even long-term temporary implantation is a short time period when measured against a patient's life span. Having said that, a word of caution is indicated with the use of retrievable filters. Because the device is considered removable and is easy to deploy, there are reports of broader filter use than what is medically indicated.[13] If a permanent IVC filter is contraindicated, then a removable filter should not be placed, given the small chance of inability to retrieve the filter. Overuse or prolonged implantation times will lead to unnecessary procedures and morbidity. We have seen cases at our institution in which filters were left in place longer than necessary or even permanently because of miscommunication between the primary care physician, the interventionist, and the patient. ■

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