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Non-permanent Inferior Vena Cava Filters for Prophylaxis and Treatment of Lower Limb Venous Thromboembolisme

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Abstract

Objectives: The purpose of this study was to evaluate and compare our recent clinical experience with temporary inferior vena cava (IVC) filters (TF) and retrievable IVC filters (RF). Materials and methods: Patients who received TF or RF implantation between October 2002 and May 2009 were studied. The early clinical outcomes between the 2 groups were compared. **Results**: Nonpermanent IVC filters were placed in 119 patients (34 in TF and 85 in RF). Retrieval of RF and removal of TF were successful in 98.7% and 100%, respectively. The incidence of filter-related complications for TF was significantly higher than for RF (26.5% vs 3.5%; $P = .0004$). However, no symptomatic pulmonary embolism (PE) was observed during filter placement. **Conclusion**: TF and RF provided similar protection from PE. We prefer RF because they can be left in permanently if it is impossible to remove or retrieve the filter for some reason.

Keywords

pulmonary embolism, thrombus, IVC filter

Introduction

Pulmonary thromboembolism (PTE) is a serious disease that often leads to disability and death. Anticoagulation therapy has been the standard treatment for patients with deep vein thrombosis (DVT) and PTE.[1] Percutaneous placement of an inferior vena cava filter (IVCF) is also an effective method to prevent fatal PTE caused by lower extremity DVT.[2] In general, an indication for IVCF implantation includes contraindications to anticoagulation therapy, recurrent PTE despite anticoagulation, and prophylactic IVCF placement in patients at high risk of PTE.[3-5] When patients are hospitalized, the risk of DVT increases. This is particularly true for patients who undergo major surgery or gynecologic surgery, or have serious trauma, certain medical conditions, or prolonged immobility from any illness.[6,7] Venous thromboembolism (VTE) related to a transient risk factor (eg, surgery, trauma) is associated with a definitely lower risk of recurrence.[8] When we use a filter to prevent PTE, we first select a nonpermanent IVCF, such as a temporary (TF) or retrievable filter (RF), because it may offer temporary risk reduction during hospitalization without the long-term complications associated with a permanent IVCF. In this study, we reviewed our clinical experience with nonpermanent IVCF insertion. In particular, we evaluated and compared our recent clinical experience with temporary IVCF and retrieval IVCF.

Patients and Methods

Patients

Institutional review board approval was obtained from our hospital for this study. We retrospectively reviewed 119 patients (26 men and 93 women, mean age, 56.2 $\pm$ 14.8 years) who underwent prophylactic IVCF placement in our Department of Cardiovascular Surgery between October 2002 and May 2009. Three different nonpermanent filtering devices were used during this period. Temporary filter designs have been used since April 2002. An Antheor (Boston Scientific, Natrick, Massachusetts) was only used until it was taken off the Japanese market in July 2004. Neuhaus Protect (Toray Medical, Tokyo, Japan) temporary IVC filters and Günther Tulips retrievable IVC filters (Cook, Bjaeverskov, Denmark) have been used since August 2004. There were 2 cohorts of patients, those who received RFs (RF group)

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Table 1. Patient Demographics and VTE status Before Filter Placement

	Temporary Filters, N = 34 (n/%)	Retrievable Filters, N = 85 (n/%)	*P* Value
Mean (±SD) age	60.2 ± 15.4 years	54.7 ± 14.4 years	.0699
Female gender	27/79.4	66/77.6	.8326
Patients with cancer	12/35.3	38/44.7	.893
PE with DVT	4/11.8	16/18.8	.3522
PE without DVT	3/8.8	2/2.4	.1345
DVT only	22/64.7	40/47.1	.0798
No VTE	5/14.7	27/31.8	.0951

Abbreviations: DVT, deep vein thrombosis; VTE, venous thromboembolism.

and those who received TFs (TF group). In the RF group, there were 85 filter placements. Mean age was 54.7 years, with a range of 27 to 87 years. In the TF group, there were 34 filter placements. Mean age was 60.2 years and the range was 24 to 81 years.

Indications for Filter Placement

Insertion indications included the following: thrombosis of the IVC within 2 weeks from onset (TF vs RF, 9/26.5% vs 32/37.6%), DVT in the early postoperative period (3/8.8% vs 3/3.5%), history of pulmonary embolism (PE) and DVT presentation (6/17.6% vs 11/ 12.9%), and surgery that eliminated compression of the vein by excision of a tumor or aneurysm compressing the vein (16/47.1% vs 39/45.9%).

Filter Placement

Informed consent was obtained from each patient after a discussion of the potential risks associated with thromboembolic complications and the benefits of placement and removal of IVC filters. Inferior vena cava filter placement was performed by experienced intervention cardiologists at the Department of Surgery of Kurume University Hospital, in an angiographic room, using fluoroscopic guidance to place the filter at the optimal position. In general, a temporary IVC filter was inserted via a subclavian vein access and a retrievable IVC filter via an internal jugular vein access. A filter was deployed infrarenally as much as possible. Inferior vena cavography was always performed before and after filter insertion. Inferior vena cavography was then conducted to rule out thrombosis and venous anomalies and to mark the level of the iliac venous confluence and the renal venous ostia.

Filter Removal and Retrieval

Prior to filter removal, computed tomography (CT) imaging was performed within 10 days of the operation to determine the presence of any thrombi in the filter and free-floating thrombi in the IVC or iliac and femoral veins. If there was no evidence of a trapped clot within the filter by CT imaging, the filter was removed when inferior vena cavography was performed to inspect for complications, including filter migration, wall penetration, or filter-associated thrombosis. If the IVC filter could not be removed within 14 days because DVT that could develop into PE was detected distally, the IVC filter was displaced toward a position above the initial position. Computed tomography imaging was also performed 10 days after the filter was displaced. The filter was removed if no thrombi were detected within the filter and DVT. If there was evidence of a trapped clot within the filter by CT imaging, a decision concerning whether to remove the filter was made according to the expected life span of the patient in the case of an elderly patient with a malignant condition when a RF was used. However, when the prognosis of a patient was favorable or a TF was used, direct thrombolytic therapy was performed. If the filter became clot-free, or if the clot size became less than 1 cm, we proceeded to remove the filter. The methods of RF removal have been previously reported.[8]

Data Analysis

All data are expressed as the mean ± standard deviation. The groups were compared by Student *t* test or the chi-square test using Stat-View software (SAS Institute, Cary, North Carolina). A *P* value of less than .05 was considered statistically significant.

Results

Patient Demographics

A total of 34 TFs (33 Antheor filters and 1 Neuhaus protect filter) and 85 Günther Tulips RFs were inserted. Mean patient age at the time of IVC filter placement was 60.2 ± 15.4 in the TF group and 54.7 ± 14.4 in the RF group. The RF group was slightly younger than the TF group. The other patient characteristics were similar between the TF and RF groups. The distribution of VTE before filter placement in the TF group included 4 patients (11.8%) who had a PE with DVT before filter placement, 3 (8.8%) who had a PE without DVT, 22 (64.7%) who had only DVT, and 5 (14.7%) who had no VTE before filter placement. In the RF group, 16 (18.8%) had a PE with DVT, 2 (2.4%) had a PE without DVT, 40 (47.1%) had only DVT, and 27 (31.8%) had no VTE before filter placement. There were no significant differences in VTE status before filter placement between the 2 groups (Table 1).

Table 2 lists the primary underlying conditions at the time of filter placement for VTE or prophylaxis. The largest group was gynecology for both the TF and RF groups. The indications for filter placement are listed in Table 3 for both groups. The clinical indications were similar for both the TF and RF groups. In addition, most filters were inserted during surgery that eliminated compression of the vein by excision of the tumor

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Table 2. Underlying Primary Diseases at the Time of Filter Placement

	Temporary Filters N = 34 (n/%)	Retrievable Filters N = 85 (n/%)
Gynecology	12/35.3	41/48.2
GI	10/29.4	10/11.8
Musculoskeletal and connective tissue	0/0	6/7.1
Unknown	1/2.9	6/7.1
Respiratory	0/0	5/5.9
Renal/GU	1/2.9	5/5.9
Hematologic	0/0	4/4.7
Circulatory	3/8.8	2/2.4
Complications of pregnancy	3/8.8	1/1.2
Neurologic and sense organs	2/5.9	3/3.5
Injury/trauma	0/0	2/2.4

Abbreviations: GI, gastrointestinal; GU, genitourinary

Table 3. Indication for Filter Placement

	Temporary Filters N = 34 (n/%)	Retrievable Filters N 85 (n/%)	*P* Value
Current IVC thrombus	9/26.5	32/37.6	.2465
DVT in the postoperation	3/8.8	3/3.5	.2331
Current PE with DVT	6/17.6	11/12.9	.5075
Compression of the vein	16/47.1	39/45.9	.9074

Abbreviations: DVT, deep vein thrombosis: IVC, inferior vena cava; PE, pulmonary embolism.

or aneurysm compressing the vein Table 4 showed the summary of the early outcome of this study.

Filter Placement

In all, 5 filters (14.7%) and 12 filters (14.1%) were placed in a suprarenal position in the TF group and RF group, respectively. In addition, 2 of 5 filters in the TF group were placed at the level of the hepatic vein because of a giant tumor. Percutaneous insertion was performed via the jugular vein in 6 of the 34 patients in the TF group and in all patients in the RF group. Subclavian vein access was chosen for the remainder of the patients in the TF group. No patients in both the groups experienced any complications associated with the IVC filter insertion, including hemorrhage at the insertion site or pneumothorax.

Morbidity

In the TF group and RF groups, there were 9 and 3 complications during the filter placement (26.5% and 3.5%, respectively). The frequency of complications in the TF group was significantly higher than that in the RF group ($P = .0004$). However, these

Table 4. Early Outcome**[NOT CITED]**

	Temporary Filters N = 34 (n/%)	Retrievable Filters N = 85 (n/%)	*P* Value
Duration of filter placement	13.0 ± 10.7 days	10.6 ± 4.3 days	.1351
Complication of filter placement	9/26.5	3/3.5	.0004
New symptomatic PE or DVT	0/0	0/0	.9999
Capture of thrombus	2/5.9	9/10.6	.4044
Failure to retrieve	0/0	1/1.2	.9999
Displaced filter	5/14.7	4/4.7	.0775
Conversion to permanent filter	4/11.8	11/12.9	.8605
Mortality	0/0	0/0	.9999

Abbreviations: DVT, deep venous thrombosis; PE, pulmonary embolism.

complications included no patients with new DVT and PE. Intra-abdominal hematoma due to anticoagulation occurred in 2 TF patients. Since a temporary IVC filter cannot be left as a permanent filter, anticoagulation therapy was performed to prevent in situ thrombosis within the filter. These patients received a blood transfusion while the anticoagulant therapy was discontinued. There were no bleeding complications that necessitated the use of low-molecular-weight heparin in the RF group, although a giant thrombus was captured or in situ thrombosis developed. High fever due to a catheter-related infection was observed in 6 TF patients and in 2 RF patients. However, there were no signs of infection after the removal of any filter. One patient receiving a TF complained of pain at the insertion site of the catheter. The pain was alleviated by loosening the fixation at the insertion point of the catheter. In the RF group, the 3 legs of a Günther Tulips filter inserted for PE prophylaxis in a 42-year-old woman before oophorectomy projected outside the IVC wall during an operative manipulation around the IVC for lymph node resection. The IVC filter was removed by a transection cavotomy.

Trapping of Thrombi

A thrombus was captured in the filter in 2 (5.9%) and 9 patients (10.6%) in the TF group and RF group, respectively. In the TF group, the thrombi were successfully dissolved in both patients and the filters could be successfully removed. In the RF group, 4 filters were left as permanent filters because floating thrombi remained in a proximal vein and the prognoses of these patients had not improved. Two filters were retrieved into the sheath together with the thrombi because the thrombus diameter was about 1 cm. One filter was surgically removed because of IVC penetration during the operation. Since major thrombi were captured in 2 filters, the second RF filter was placed in a position above the first filter before removal of the first RF filter. After retrieval of the first filter, cavography revealed a thrombus within the second filter. The size of the thrombus in the second filter was smaller than that in the first filter. The

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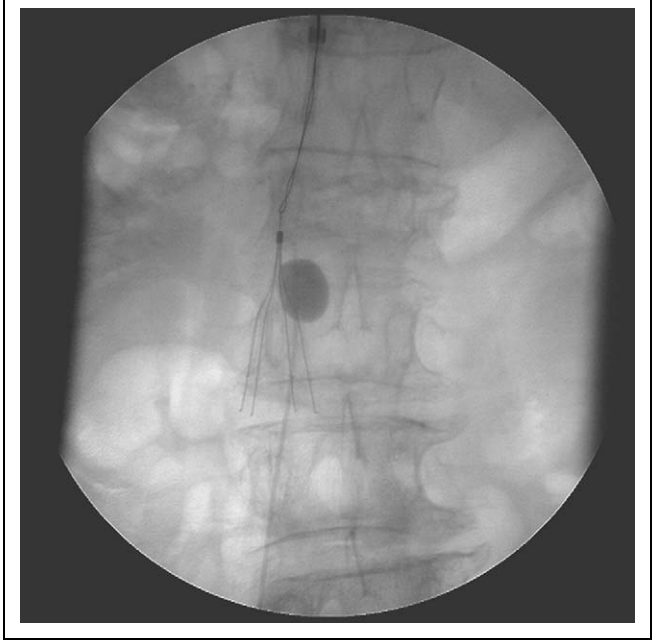


Figure 1. We attempted to capture the filter at its hooklet with an additional balloon transfemoral catheter to correct the tilt of the filter.

anticoagulant therapy was subsequently continued. The disappearance of the thrombus within the second filter was confirmed by CT and the filters were retrieved on day 22 and day 12, respectively, after initial insertion of the filter,

Filter Removal

Thirty-seven attempts at temporary IVC filter (Antheor 36 attempts, Neuhaus protect 1 attempt) removal were made in 30 patients after a mean period of 13 days. An Antheor filter was displaced in 1 patient whereas an Antheor filter was replaced in 4 patients because of a floating thrombus remaining in an iliac vein. Filter removal was successful in all 37 attempts (100%).

Seventy-eight attempts at retrieving a retrievable IVC filter (Günther Tulips) were made in 74 patients after a mean period of 10.6 days. Filter retrieval was successful in 77 (98.7%) of 78 attempts. Four filters could not be retrieved in the standard fashion since they had tilted by more than 20° because the retrieval hooklet was abutting the IVC wall. We attempted to capture the filter at its hooklet with an additional balloon transfemoral catheter to correct the tilt of the filter (Figure 1). Of the 4, 3 filters could eventually be retrieved using this manipulation. The remaining filter could not be successfully retrieved because one of the filter legs was tilted 75% toward the left renal vein.

Permanent Filtration

Of the 34 patients with temporary IVC filters, 4 (11.8%) underwent replacement of a permanent IVC filter (Greenfield). One patient was noncompliant for anticoagulant therapy and 2 patients had a limited life expectancy because of recurrent colon cancer. The remaining patient was a neurosurgery patient and thus had an ongoing contraindication to anticoagulation.

A Günther Tulips filter was left as a permanent filter in 11 (12.9%) of 85 patients. Seven patients had a limited life expectancy due to advanced malignant disease (2 colon cancer, 1 lung cancer, 1 leukemia, and 3 ovarian cancer). One patient was noncompliant for anticoagulant therapy, 1 patient had recurrent VTE despite adequate anticoagulation therapy, and retrieval was a failure in another because of filter tilt. The remaining filter was not retrieved because of a major blood clot in the filter and current PE even though sufficient anticoagulation was performed.

Prevention of PE

No fatal PE occurred in either group. In 1 patient with a Günther Tulips filter, a new PE was diagnosed 10 days after filter insertion by CT angiography. In this patient, the indication for filter placement was the presence of PE and an IVC floating thrombus because of polycythemia. A new PE developed because 1 of the legs of the filter was tilted toward the left renal vein and the thrombus could not be captured. However, the patient was asymptomatic. The filter was left as a permanent filter because it was not retrieved. The thrombus in the IVC and PE were eliminated by wafarin treatment over a 3-month period, and the patient thus far has not had any complications related to the permanent IVC filter placement.

Discussion

The most common indications for permanent IVC filter insertion are reported to be an absolute contraindication to anticoagulation, recurrent thromboembolism while receiving adequate anticoagulation, and noncompliance with anticoagulation.[2] However, Ferris et al[3] have reported long-term complications with 7 types of permanent filters. The complications were PE death (2.4%), recurrent PE (3.3%), IVC thrombus (19%), IVC penetration (9%), migration (6%), fracture (2%), and new DVT (22%). Several of these complications could potentially be avoided using TFs or RFs. Crochet et al[7] have also indicated that the rate of IVC occlusion increases with time, and therefore early removal of the filter could reduce this complication. In addition, even though patients with acute VTE who had active gastrointestinal bleeding, intracranial bleeding, hematuria, hemoptysis, trauma, or epistaxis were contraindicated to undergo anticoagulation initially, anticoagulant therapy did become possible in several months by treating the underlying diseases and an IVC filter became unnecessary. Yavuz et al[9] reported that VTE after retrieval of IVC filters was rare if the anticoagulant therapy was adequate. In the randomized prospective study of Decousus et al[10] in patients with acute VTE treated with anticoagulation alone or anticoagulation plus a permanent filter, the incidences of recurrent DVT and PE at 2 years were 6.3% and 11.6%, respectively, in patients without filters, and 20.8% and 3.4%, respectively, in patients with

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filters. This report demonstrated that permanent IVC filter placement might be associated with an increased risk of DVT. Other complications associated with permanent filters are delayed migration into the lungs and duodenum, filter rupture resulting in material fatigue-related phenomenon, and penetration of the IVC during anchorage procedures, and these complications related to permanent filters could potentially be avoided using TFs or RFs.[11]

The nonpermanent IVC filter is attractive as a means with which to temporarily reduce risk in patients without the long-term complications that can be associated with permanent IVC filters. Nonpermanent filters can be classified as TFs or RFs. Temporary filters, such as Antheor and Newhaus protect, are attached to a guide wire or catheter that projects from the insertion site, allowing them to be removed after temporary use.[12] The advantages of these TFs include the possibility of thrombolytic treatment through the catheter if a thrombus is trapped in the filter.[8] In addition, if the position of the catheter is moved, long-term placement is possible. Disadvantages include the risk of infection of the external catheter and pain at the site of the fixed catheter.[11] Other TFs, such as Tempofilter II, feature a cone-shaped filter with 8 smooth legs and no hooks. The cone is held in place in the IVC by a non-thrombogenic tethering catheter. When using the Tempofilter II, an anchoring device was placed under the platysma muscle and the catheter did not project from the insertion site.[13] The Tempofilter I and Antheor were withdrawn from the market because of problems related to structural stability. The temporary IVC filters that are still currently available are Neuhaus protect and Tempofilter II.

Retrievable filters have no complications related to catheters that are seen with TFs. In addition, these filters are designed to be permanent if retrieval is not planned.[14] Sugimoto reported IVC thrombosis at the filter level and persistent iliofemoral venous thrombosis during TF placement, therefore, surgical removal of the IVC filter was indicated.[15] If a RF had been used in this case, surgical filter removal would have been unnecessary. Nonpermanent filters have been shown to be an effective method of PE prophylaxis that allows retrieval of the device after it is no longer needed, which reduces the risk of long-term complications. However, TFs require tethering outside the body, which introduces the risk of infection. In addition, even though there were no technical difficulties with respect to removal because the temporary IVC filter was connected to the catheter, these filters cannot be left as a permanent filter if its removal is impossible when a giant thrombus is captured in the filter.

We generally recommend the use of a RF because in many cases it may be left in place permanently, such as in prolonged PE prophylaxis, when there is a large volume of thrombus within the filter, or if there is technical failure associated with the retrievable procedure. However, Van Ha et al[16] reported that a RF required cardiotomy for removal from the right-hand side of the heart because of migration. If the position of the filter must be placed at the level of the hepatic vein because of a giant tumor, a TF, which was tethered outside the body, is useful because it could be easily removed if the filter migrates into the right atrium. In addition, we recommend the use of a TF because the legs of a Günther Tulips filter may project outside the IVC wall when surgical manipulation around the IVC for lymph node resection is performed.

We normally recommend RF placement. However, we recommend TF placement when the filter must be placed at the level of the hepatic vein or lymph node resection around the IVC must be performed. In the future, we hope to be able to further clarify the distinctions between the use of TFs and RFs.

Conclusion

With regard to the selection of filter devices, although TFs can still be used depending on the specific characteristics of each individual case, RFs will most likely continue to maintain their dominant position.

Declaration of Conflicting Interests

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