

Should We Remove the Retrievable Cook Celect Inferior Vena Cava Filter? Eight Years of Experience at a Single Center

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Background: The inferior vena cava filter (IVCF) is very effective for preventing pulmonary embolism in patients who cannot undergo anticoagulation therapy. However, if a filter is placed in the body permanently, it may lead to other complications. **Methods:** A retrospective study was performed of 159 patients who underwent retrievable Cook Celect IVCF implantation between January 2007 and April 2015 at a single center. Baseline characteristics, indications, and complications caused by the filter were investigated. **Results:** The most common underlying disease of patients receiving the filter was cancer (24.3%). Venous thrombolysis or thrombectomy was the most common indication for IVCF insertion in this study (47.2%). The most common complication was inferior vena cava penetration, the risk of which increased the longer the filter remained in the body ($p=0.032$, $\text{Exp}(B)=1.004$). **Conclusion:** If the patient is able to retry anticoagulation therapy and the filter is no longer needed, the filter should be removed, even if a long time has elapsed since implantation. If the filter cannot be removed, it is recommended that follow-up computed tomography be performed regularly to monitor the progress of venous thromboembolisms as well as any filter-related complications.

Key words: 1. Vena cava filter
2. Pulmonary embolism
3. Venous thrombosis

Introduction

Venous thromboembolism (VTE) is a significant cause of morbidity and mortality that affects approximately 1 in 1,000 people; it is estimated that 600,000 cases of clinically significant pulmonary embolism (PE), resulting in 200,000 deaths, occur annually in the United States [1-3]. Thirty-year autopsy studies showed that 26% of hospitalized patients had a PE and that 9% of these cases were fatal. This

translates to a 1% incidence of PE and a 0.36% incidence of death resulting from PE among all hospitalized patients per year [4]. The incidence of VTE in the Korean population was 13.8 per 100,000 persons in 2008, which is approximately one-tenth to one-fifth of the incidence reported in the Caucasian population [5].

In most cases, VTE is effectively managed with anticoagulation therapy, which is associated with a decrease in the incidence and recurrence of PE, lower

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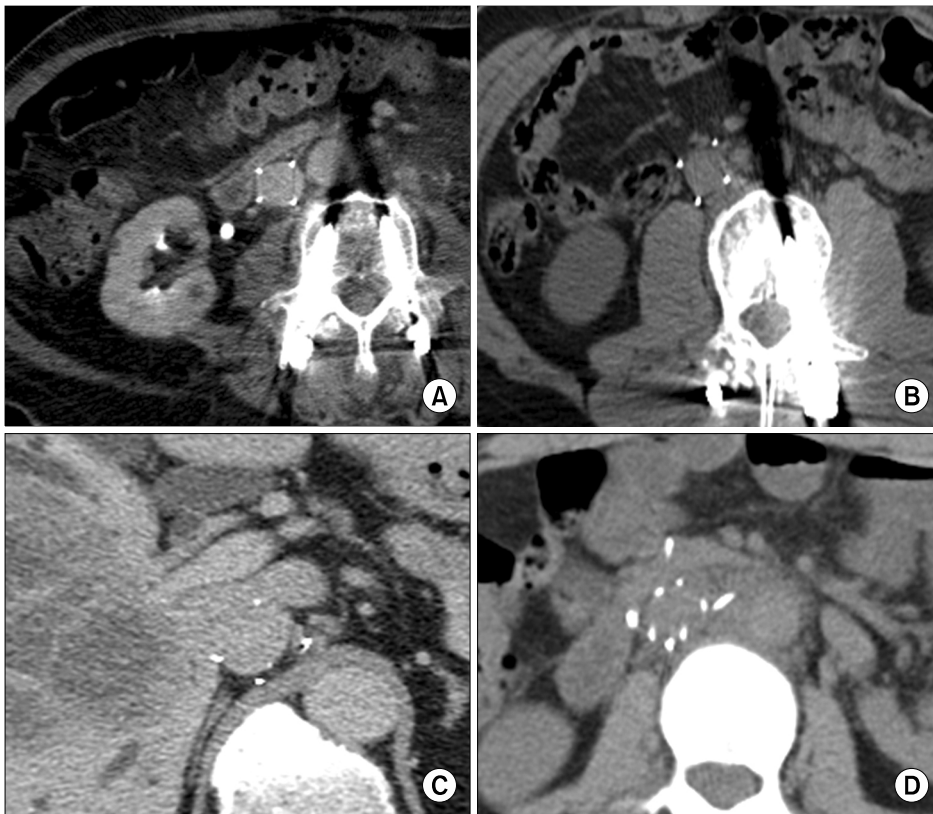


Fig. 1. Inferior vena cava penetration grade. (A) Grade 0, (B) grade 1, (C) grade 2, and (D) grade 3.

mortality, and an acceptably low risk of bleeding complications. However, when anticoagulation therapy is ineffective or contraindicated, or when it results in complications that require it to be discontinued, vena cava interruption with a filter device is recommended [2].

Herein, we review cases from Pusan National University Hospital between 2007 and 2015 in which we performed inferior vena cava filter (IVCF) insertion for various indications.

Methods

We retrospectively reviewed the digital medical records of 159 patients who underwent retrievable IVCF filter implantation between January 2007 and April 2015 at our center. A Cook Select IVCF (Cook Medical, Bjaeverskov, Denmark) was implanted in all patients. We excluded 15 patients who did not undergo follow-up. Of the remaining 144 patients in the study, the IVCF was removed from 91 patients and remained in place in 53 patients.

In this study, we examined the baseline character-

istics of all patients, including the presence of underlying disease, and evaluated the risk factors for deep vein thrombosis (DVT). The indications for IVCF placement were also analyzed.

1) Rate of inferior vena cava filter complications

The rate of complications was surveyed among the 53 patients in our study who did not have their IVCF removed and were also evaluated by follow-up computed tomography (CT) (n=33). The grading system used to assess inferior vena cava (IVC) penetration was based on the system suggested by Oh et al. [6]: grade 0, confined within the IVC; grade 1, immediately adjacent to the external wall of the IVC; grade 2, entirely outside of the IVC (full penetration); grade 3, full IVC penetration and interaction with an adjacent organ. Significant IVC penetration was defined as a penetration of grade 2 or 3 (Fig. 1) [6,7]. Filter migration was considered to have occurred if the IVCF moved from its initial post-implantation position by more than 2 cm relative to an adjacent anatomical landmark [8]. Finally, the relationship between the duration of IVCF implantation and IVC

The Most Common Complication of the Remaining Cook Celect IVCF was IVC Penetration

Table 1. Patient demographics and comorbidities (N=144)

Demographics and comorbidities	Value
Age (yr)	64.2±14.1
Gender (male)	67 (46.5)
Body mass index (kg/m ²)	23.8±3
Smoking	
Current smoker	23 (16)
Ex-smoker	12 (8.3)
No. of packs smoked per year	5.8±17.1
Hypertension	60 (41.7)
Cancer	35 (24.3)
Diabetes mellitus	25 (17.4)
Trauma	16 (11.1)
Immobilization	15 (10.4)
Recent surgery	14 (9.7)
Stroke with paralysis	14 (9.7)
Varicose vein	7 (4.9)
Hip or knee joint surgery	5 (3.5)
Coronary artery obstructive disease	4 (2.8)
Coagulation disorders	3 (2.1)
Pregnancy or postpartum period	2 (1.4)
Hormonal therapy	2 (1.4)
Chronic obstructive pulmonary disease	2 (1.4)
Myeloproliferative disorders	1 (0.7)
Burn	1 (0.7)
Chronic renal failure	1 (0.7)
Central vein catheterization	1 (0.7)

Values are presented as mean±standard deviation or number (%).

penetration was analyzed.

2) Statistical analyses

Continuous data were analyzed with the Student t-test or the Wilcoxon rank-sum test. Summary data are reported as mean±standard deviation or percentages. Results are expressed as means with 95% confidence intervals where appropriate, and p-values <0.05 were considered to indicate statistical significance. The relationship between the duration of IVCF implantation and the probability of IVC penetration was statistically analyzed using logistic regression. Statistical analyses were performed using IBM SPSS ver. 20.0 (IBM Corp., Armonk, NY, USA).

Results

1) Demographics and comorbidities

The demographics and comorbidities of the 144 patients in the study are shown in Table 1. Their

Table 2. Indications for inferior vena cava filter placement (N=144)

Indications	No. of patients (%)
Venous thrombolysis/thromboembolectomy	68 (47.2)
Contraindication to anticoagulation therapy	51 (35.4)
Complication of anticoagulation therapy	11 (7.6)
Free-floating iliocaval thrombus	6 (4.2)
Cancer patient without anticoagulation therapy	5 (3.4)
High risk for anticoagulation therapy complications	3 (2.1)

Table 3. Inferior vena cava filter complications (n=33)

Complication	No. of patients (%)
Vena cava penetration	24 (72.7)
Vena cava obstruction	2 (6.0)
Filter migration	2 (6.0)
Pulmonary thromboembolism after filter insertion	1 (3.0)
No complications	4 (12.1)

mean age was 64.2±14.1 years. Sixty-seven of the participants were men (46.5%). The mean body mass index was 23.8±3 kg/m², and the most common underlying disease was cancer (24.3%). The risk factors for DVT were also studied (Table 1). Recent surgery (9.7%) was defined as major surgery (general, orthopedic, neurologic, or gynecologic) within the previous 3 months [9], and trauma (11.1%) was defined as a major fracture or severe soft-tissue injury requiring hospital admission.

2) Indications for inferior vena cava filter placement

Venous thrombolysis or thromboembolectomy performed to treat DVT was the most common indication for IVCF placement in this study (68 cases, 47.2%). The second most common indication was a contraindication to anticoagulation therapy (35.4%). Trauma (31.4%), recent surgery (5.9%), and burns (2%) were indications among the patients who had a contraindication to anticoagulation therapy. In addition, 5 patients (3.4%) with cancer who were in poor condition and had a short life expectancy received IVCFs instead of anticoagulation therapy (Table 2).

3) Filter complications

Filter complications were surveyed in 33 patients

by follow-up imaging (Table 3). The most common complication was IVC penetration, which was observed in 24 patients (72.7%); 3 of these patients had symptoms. One patient had severe epigastric pain, nausea, and vomiting; CT and endoscopy revealed that an IVCF leg had perforated the duodenum. An emergent laparotomy was performed to remove the filter. Because the filter was placed around the aorta and adjacent structures, the risk of aortic rupture made it too dangerous to completely remove the IVCF; instead, we cut the filter tip that had perforated the duodenum and repaired the duodenum [10]. The other 2 symptomatic patients complained of severe pain, and therefore, their filters were removed. In both cases, the filter had migrated 2 cm but did not result in the obstruction of other vessels or lead to any other symptoms. Among the patients who underwent filter placement, only 1 patient had a PE. This suggests that IVCF is clinically effective for preventing PEs.

In cases with vena cava penetration, CT images were used to grade the level of penetration. Grade 0 was observed in 9 patients, grade 1 in 9 patients, grade 2 in 9 patients, and grade 3 in 6 patients. Among the 33 patients, the mean time to the CT follow-up was 544.3 ± 93.6 days.

The relationship between the duration of IVCF implantation and penetration frequency was analyzed using logistic regression for the 33 patients who did not undergo IVCF removal and also had a CT follow-up. The analysis showed there was a statistically significant ($p=0.032$) increase in the risk of IVC penetration the longer the filter remained in the body; specifically, the risk increased 1.004-fold per day ($\text{Exp}(B)=1.004$).

Discussion

A technique allowing the transvenous delivery of intravascular vena cava devices was developed in 1967 with the introduction of the Mobin-Uddin umbrella filter [6]. In the subsequent decades, several additional filter designs were developed with favorable properties such as ease of deployment, improved clot-trapping effectiveness, the ability to preserve IVC flow, and in later years, optional filter designs allowing filter retrieval [2].

The use of IVCFs varies widely among hospitals.

This variation is the result of many factors, including diverse patient presentations, physician preferences, and hospital-level factors. Recently, the use of IVCFs has been increasing, even for prophylactic use when there is no evidence of PE or DVT [8]; as a result, the indications for IVCF implantation have been expanding [11].

According to the results of the PREPIC (Prevention of Recurrent Pulmonary Embolism by Vena Cava Interruption) trial, vena cava filters reduce the risk of PE but increase the risk of DVT; furthermore, they have no effect on survival. Although their use may be beneficial in patients at high risk of PE, systematic use in the general population with VTE is not recommended [12]. However, since few large-scale studies have been conducted of retrievable filters, we need to consider this option more carefully.

When a retrievable filter is placed, a timeline should be determined for its removal. Retrieval should be performed at a time when the risk for PE is low, when anticoagulation therapy can be restarted if continued VTE treatment or prevention is required, and when retrieval can be undergone safely with a low potential for complications [2]. However, because no definitive guidelines have been developed, the timing of filter removal has been at the discretion of individual physicians based on the patient's condition. The filter retrieval rate was 63% at our center.

In our center, active thrombectomy or thrombolysis was performed in cases of early-stage DVT, for which we routinely performed IVCF insertions. In many cases (68), venous thrombolysis or thrombectomy was performed, along with a routine 1-month follow-up. In patients whose CT images showed no residual thrombus and who were able to start anticoagulation therapy, filter removal was attempted. Of the 68 patients who underwent IVCF insertion during thrombolysis or thrombectomy, 58 were able to have their filters removed; the mean duration of filter implantation was 33.96 ± 49.25 days in these patients. The retrieval rate appears to be higher than has been reported in other studies, although this discrepancy should be considered in light of the ongoing controversy about routine filter placement when thrombectomy or thrombolysis is performed [2].

The most common complication of the patients who did not have their filters removed was IVC penetration. Our analysis showed the risk of IVC pen-

etration increased with the duration of filter implantation ($p=0.032$). The penetration rate was 72.7% based on follow-up CT images, which was a higher rate than expected. Among the patients in whom penetration took place, only 3 were symptomatic. Although most of the patients did not have symptoms, they were thought to have the potential for complications in the future. Thus, regular monitoring is necessary in patients for whom the filter cannot be removed.

In conclusion, IVCFs are very effective for preventing potentially fatal PEs in patients who cannot undergo anticoagulation therapy. If a patient is able to retry anticoagulation therapy and the filter is no longer needed, the filter should be removed—even if a long time has elapsed since implantation—in order to prevent complications that may arise from the filter remaining in the body. If the filter cannot be removed, it is recommended that follow-up CT scans be performed regularly to monitor the filter and to check for any complications, as well as to monitor the progress of the VTE.

Conflict of interest

No potential conflicts of interest relevant to this article are reported.

Acknowledgments

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References

1. White RH. *The epidemiology of venous thromboembolism*. *Circulation* 2003;107(23 Suppl 1):I4-8.
2. Passman MA. *Vena cava interruption and pulmonary embolism*. In: Rutherford RB, Cronenwett JL, Johnston KW, editors. *Rutherford's vascular surgery*. 8th ed. Philadelphia (PA): Elsevier Saunders; 2014. p. 811-32.
3. Heit JA, Silverstein MD, Mohr DN, et al. *The epidemiology of venous thromboembolism in the community*. *Thromb Haemost* 2001;86:452-63.
4. Lindblad B, Sternby NH, Bergqvist D. *Incidence of venous thromboembolism verified by necropsy over 30 years*. *BMJ* 1991;302:709-11.
5. Jang MJ, Bang SM, Oh D. *Incidence of venous thromboembolism in Korea: from the Health Insurance Review and Assessment Service database*. *J Thromb Haemost* 2011;9: 85-91.
6. Oh JC, Trerotola SO, Dagli M, et al. *Removal of retrievable inferior vena cava filters with computed tomography findings indicating tenting or penetration of the inferior vena cava wall*. *J Vasc Interv Radiol* 2011;22:70-4.
7. Lee JK, So YH, Choi YH, et al. *Clinical course and predictive factors for complication of inferior vena cava filters*. *Thromb Res* 2014;133:538-43.
8. Hoffer EK, Mueller RJ, Luciano MR, Lee NN, Michaels AT, Gemery JM. *Safety and efficacy of the Gunther Tulip retrievable vena cava filter: midterm outcomes*. *Cardiovasc Intervent Radiol* 2013;36:998-1005.
9. Heit JA, Silverstein MD, Mohr DN, Petterson TM, O'Fallon WM, Melton LJ 3rd. *Risk factors for deep vein thrombosis and pulmonary embolism: a population-based case-control study*. *Arch Intern Med* 2000;160:809-15.
10. Bae MJ, Chung SW, Lee CW, Kim S, Song S. *Duodenal perforation caused by an inferior vena cava filter*. *Korean J Thorac Cardiovasc Surg* 2012;45:69-71.
11. White RH, Geraghty EM, Brunson A, et al. *High variation between hospitals in vena cava filter use for venous thromboembolism*. *JAMA Intern Med* 2013;173:506-12.
12. PREPIC Study Group. *Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study*. *Circulation* 2005;112:416-22.