Editors' Choice

Long-term computed tomography follow-up results of strut penetration of inferior vena cava filters

Shin Seok Yang, MD, *and* Woo-Sung Yun, MD, *Daegu, Korea*

CME Activity

Purpose or Statement of Need The purpose of this journal-based CME activity is to enhance the vascular specialist's ability to diagnose and care for patients with the entire spectrum of circulatory disease through a comprehensive review of contemporary vascular surgical and endovascular literature.

Learning Objectives
- Understand the importance of removing venacaval filters when they are no longer needed
- Understand the classification system used for venacaval penetration after filter placement
- Know when to remove venacaval filters

Target Audience This activity is designed for vascular surgeons and individuals in related specialties.

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ABSTRACT

Objective: This study aimed to investigate the incidence of inferior vena cava (IVC) filter strut penetration and risk factors of organ involvement.

Methods: From June 2003 to August 2015, there were 138 patients with deep venous thrombosis who received an IVC filter. Among 104 patients who did not have the IVC filter retrieved, 66 had follow-up computed tomography and were included in this study. The IVC filters used were 21 Günther Tulip (Cook Medical, Bloomington, Ind), 26 Celect (Cook Medical), and 19 OptEase (Cordis Corp, Bridgewater, NJ) filters. Filter strut penetration was categorized by a previously published scale of grade 0 to grade 3, and organ involvement was specifically assessed. Multivariate analysis was used to identify risk factors for organ-involving strut penetration (grade 3).

Results: The median age of the patients was 66 years (27-84 years), and 46% were male. Median computed tomography follow-up duration was 14 months (1-137 months). IVC strut penetration was detected in all patients. Grade 1, grade 2, and grade 3 were 29%, 36%, and 35%, respectively. The risk factor of grade 3 penetration was indwelling time ≥30 months on binary logistic regression analysis (odds ratio, 4.395; 95% confidence interval, 1.179-16.385; $P = .027$).

Conclusions: Regardless of type of IVC filter, the incidence of strut penetration was high. The risk of adjacent organ involvement increases over time. Retrievable IVC filters need close follow-up and retrieval as soon as they are no longer needed. (J Vasc Surg: Venous and Lym Dis 2019;7:646-52.)

Keywords: Venous thromboembolism; Vena cava filters

From the Division of Transplantation and Vascular Surgery, Department of Surgery, Yeungnam University Medical Center, Yeungnam University College of Medicine.

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Correspondence: Woo-Sung Yun, MD, Associate Professor, Division of Transplantation and Vascular Surgery, Department of Surgery, Yeungnam University Medical Center, Yeungnam University College of Medicine, 170 Hyunchoong-ro, Nam-gu, Daegu, Korea (e-mail: wsyun@me.com; wsyun@ynu.ac.kr).

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In a survey of the national trends for inferior vena cava (IVC) filter placement and retrieval in the United States for the past two decades, the annual placement number decreased after a peak in 2008, and retrieval rates have increased over time.[1] This was the result of acknowledgment of the long-term safety issues of retrievable IVC filters.[2] A 2010 Food and Drug Administration safety communication regarding removal of retrievable IVC filters played a major role in changing that trend.[3]

Although IVC filters are used to prevent fatal pulmonary embolism, there can be filter-related complications, such as filter fracture, migration, limb embolization, IVC penetration, and IVC thrombosis.[4] One of the most common complications is IVC penetration. Transmural incorporation by filter hooks is needed to stabilize the filter to the IVC wall.[5] When the filter strut penetration progresses, it can cause critical injury to adjacent organs.[6-10]

Many authors have reported on the incidence of strut penetration.[11] However, reported incidences vary, partly because of different follow-up duration. In this study, we attempted to investigate the incidence and risk factors of strut penetration, focusing on involvement of intra-abdominal organs.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Key Findings:** Inferior vena cava filter strut penetration was found in all 66 patients who did not have the filter retrieved during a median 14 months of follow-up. The incidence of strut penetration into an organ was 35%. The risk factor of organ-involving strut penetration was indwelling time ≥30 months.
- **Take Home Message:** Organ-involving strut penetration is common in long-term follow-up, and the longer after filter placement, the higher is the risk. Retrievable inferior vena cava filters need close follow-up and retrieval as soon as they are no longer needed.

METHODS

We retrospectively reviewed our database of 138 patients who had IVC filter placement between June 2003 and August 2015. Before this study was conducted, Institutional Review Board approval was received. The Institutional Review Board waived the requirement for obtaining informed consent of the patients. The filter removal rate was 25% (34/138). Of 104 patients who did not have the IVC filter retrieved, 66 with a subsequent abdominal computed tomography (CT) scan after filter placement were enrolled in this study. We did not routinely perform CT follow-up for patients with IVC filters. A CT scan was conducted when IVC filter removal was being considered or recurrent deep venous thrombosis was suspected. CT scans done for other purposes were also used. No CT scan was required for symptoms related to filter strut penetration.

The median age of patients was 66 years (27-84 years), and 46% were male. Other characteristics of the patients are summarized in Table I. The most common reason of IVC filter insertion was the presence of IVC thrombus (44%). Most filters were placed in the infrarenal IVC (89%) and 11% were deployed suprarenally (Table II). Regarding type of filter, Günther Tulip (Cook Medical, Bloomington, Ind), Celect (Cook Medical), and OptEase (Cordis Corp, Bridgewater, NJ) were used in 32%, 39%, and 29% of cases, respectively. Post-filter placement venacavography revealed filter tilting ≥5 degrees in 55%. Filter tilt angle was measured on final venacavography at the time of placement using the method previously described.[12]

Table I. Patients' demographic data (N = 66)

Characteristics	
Age, years, median	66 (27-84)
Sex, male	30 (46)
Body mass index, kg/m^2, mean	24.2 (16.7-34.7)
Indication of filter	
Contraindication to anticoagulation	13 (20)
IVC floating thrombus	19 (29)
Thrombolytic therapy with IVC thrombus	10 (15)
Thrombolytic therapy without IVC thrombus	18 (27)
Progression of PE or extensive PE	3 (5)
Unknown	3 (5)
Use of anticoagulation	54 (82)

IVC, Inferior vena cava; *PE,* pulmonary embolism.
Categorical variables are presented as number (%). Continuous variables are presented as median or mean (range).

Table II. Radiologic findings (N = 66)

Radiologic findings	
IVC diameter, mm, mean	21.6 (14.5-28.1)
Level of filter	
Suprarenal	7 (11)
Infrarenal	59 (89)
Type of filter	
Günther Tulip	21 (32)
Celect	26 (39)
OptEase	19 (29)
Tilting of filter, degrees, median	5.8 (0-20.4)
<5	30 (46)
≥5 and <10	20 (30)
≥10 and <15	10 (15)
≥15 and <20	5 (8)
≥20	1 (2)

IVC, Inferior vena cava.
Categorical variables are presented as number (%). Continuous variables are presented as median or mean (range).

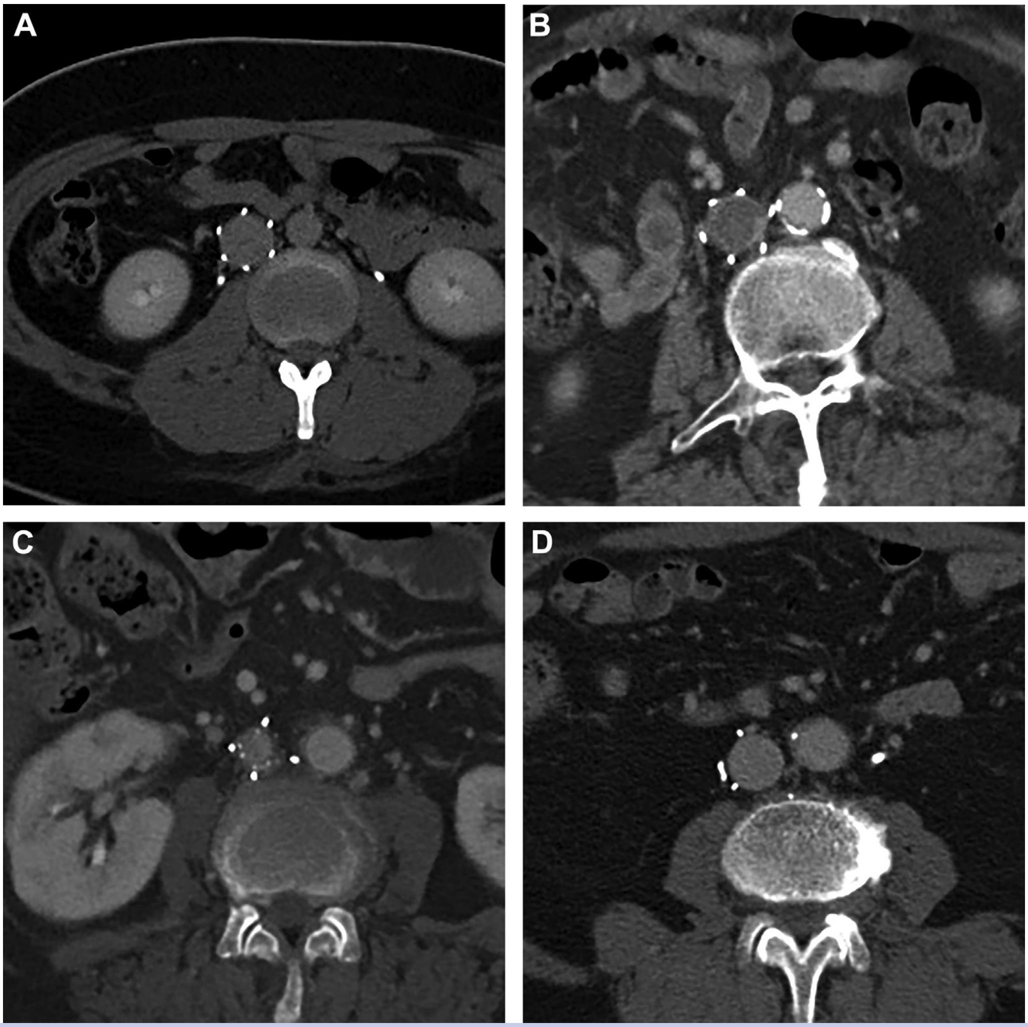

Fig 1. Grading system of strut penetration. **A,** Grade 0 penetration. **B,** Grade 1 penetration. **C,** Grade 2 penetration. **D,** Grade 3 penetration.

By review of CT images, strut penetration was categorized as grade 0 to grade 3 according to the grading system that was reported by Oh et al[13] (Fig 1). Grade 0 means that all struts remained confined entirely within the IVC lumen. Grade 1 is defined as a strut that is immediately adjacent to an external aspect of the IVC wall, likely reflecting tenting of the IVC wall. The definition of grade 2 is that the strut is entirely outside the IVC lumen within the retroperitoneum as evidenced by a "halo" of retroperitoneal fat around an axially viewed strut. Grade 3 involves strut interactions with adjacent organs, such as, liver, bowel, and aorta, outside the IVC.

The primary end point of this study was the incidence of IVC penetration. The secondary end point was the identification of risk factors for grade 3 penetration. Univariate and multivariate analyses were performed with patients' clinical data (age, sex, body mass index, use of anticoagulation therapy, and filter indwelling time) and radiologic findings (diameter of IVC, site of filter [infrarenal vs suprarenal], filter types, and filter tilting). For univariate analysis, independent *t*-test was applied to compare the means of continuous variables that normally distributed, and χ^2 test and Fisher exact test were used to compare categorical variables between the

Table III. Incidence of strut penetration

Grade	Günther Tulip (n = 21)	Celect (n = 26)	OptEase (n = 19)	Total (n = 66)
Grade 1	3 (14)	3 (12)	13 (68)	19 (29)
Grade 2	10 (48)	11 (42)	3 (16)	24 (36)
Grade 3	8 (38)	12 (46)	3 (16)	23 (35)

Values are reported as number (%).

Table IV. Specific sites of strut penetration

Involved organs	No. of patients with grade 3 penetration (n = 23)
Vertebral body	9 (39)
Aorta or common iliac artery	8 (35)
Liver	4 (17)
Small bowel	3 (13)
Diaphragm	1 (4)
Lymph node	1 (4)

Values are reported as number (%).

grade 3 group and the other groups. For multivariate analysis, a binary logistic regression model was used. Statistical analysis was done with SPSS version 22.0 software (IBM Corp, Armonk, NY).

RESULTS

The median time interval between filter insertion and the most recent follow-up CT was 14 months (1-137 months). There was no case of grade 0 penetration. Grade 1 strut penetration was 29%, grade 2 was 36%, and grade 3 was 35%. Grade 2 or grade 3 penetrations tended to be common in conical design filters (Günther Tulip and Celect) compared with the OptEase filter (87% vs 32%; $P < .001$; Table III).

Table IV and Fig 2 demonstrate the specific organs that were involved in the grade 3 penetrations. Of the 23 grade 3 cases, the vertebral body was most commonly involved in 39% and the aorta or common iliac artery was involved in 35%, followed by liver, small bowel, diaphragm, and lymph nodes.

On univariate analysis, larger IVC diameter, infrarenal IVC, conical design filter, and filter tilting ≥5 degrees were related to grade 3 strut penetration (Table V). Grade 3 strut penetration rates increased with indwelling time ≥30 months, but it was not statistically significant ($P = .051$). However, on multivariate analysis, only indwelling time ≥30 months was identified as an independent risk factor of grade 3 strut penetration (Table VI).

DISCUSSION

The exact incidence of IVC filter penetration is still unknown, probably because most studies are retrospective reviews or case reports. However, it is obvious that strut penetration is one of the most common issues in IVC filter complications.[4]

On meta-analysis of 88 clinical studies and 112 case reports enrolling a total of 9002 patients, the overall

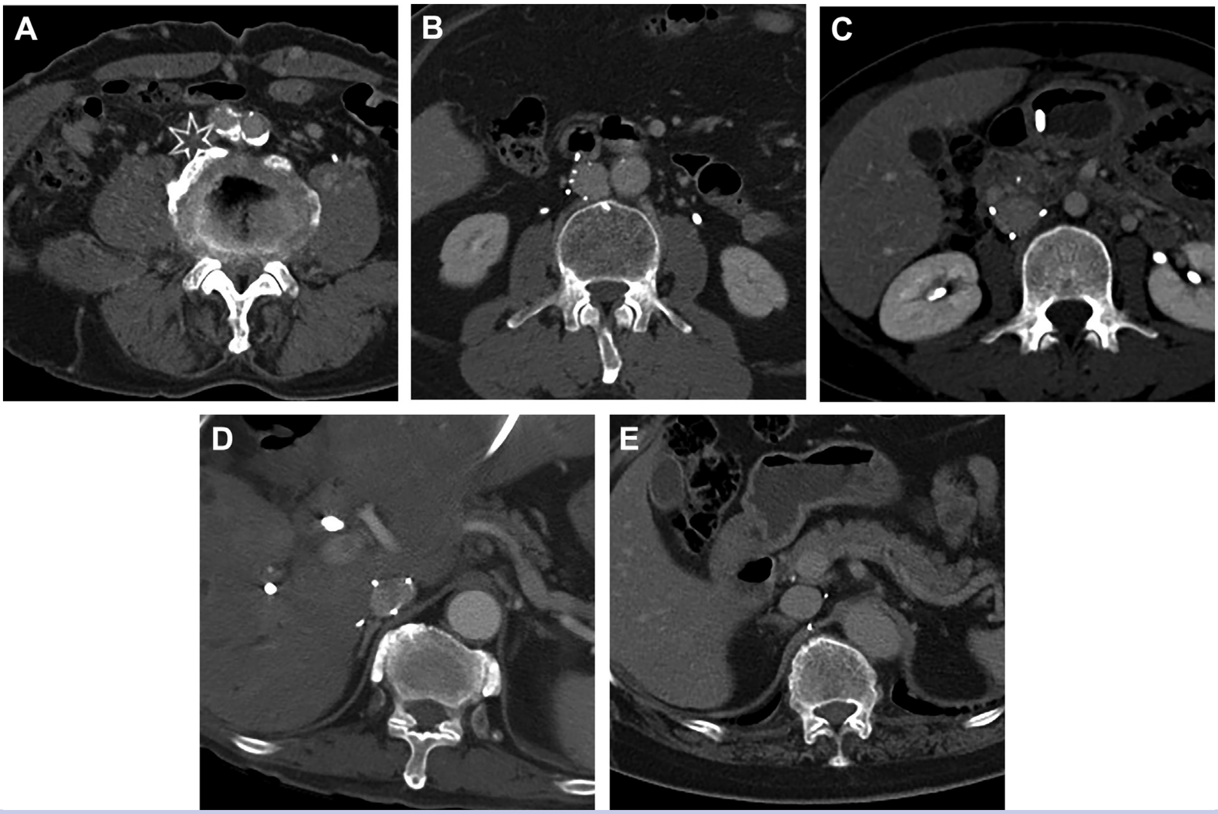

Fig 2. Grade 3 strut penetrations. **A,** OptEase filter struts interacting with the right common iliac artery wall and vertebral body. **B,** A penetrated Celect filter strut inside the vertebral body. **C,** A Tulip filter tip inside the small bowel. **D,** Tulip filter strut penetration into the liver. **E,** A posterior strut of Celect filter involving the right crus of the diaphragm.

Table V. Univariate analysis

Variables	Grade 1 or 2 (n = 43)	Grade 3 (n = 23)	*P* value
Age			.465
<70 years	30 (70)	14 (61)	
≥70 years	13 (30)	9 (39)	
Sex			.777
Male	19 (44)	11 (48)	
Female	24 (56)	12 (52)	
Body mass index			.270
<22 kg/m^2	14 (35)	5 (22)	
≥22 kg/m^2	26 (65)	18 (78)	
Anticoagulation therapy			1.000
Yes	35 (81)	19 (83)	
No	8 (19)	4 (17)	
IVC diameter, mm	21.0 ± 2.8	22.7 ± 3.3	.024
Level of filter			.045
Infrarenal	41 (95)	18 (78)	
Suprarenal	2 (5)	5 (22)	
Design of filter			.039
Conical (Tulip and Celect)	27 (63)	20 (87)	
Nonconical (OptEase)	16 (37)	3 (13)	
Tilting of filter			.021
<5 degrees	24 (56)	6 (26)	
≥5 degrees	19 (44)	17 (74)	
Filter indwelling time			.051
<30 months	31 (72)	11 (48)	
≥30 months	12 (28)	12 (52)	

IVC, Inferior vena cava.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

penetration rate was 19% (1699/9002).[11] It was more common in conical filters than in nonconical filters (21% vs 4%; $P < .01$). Organ involvement by penetrated strut was detected in 4% (322/9002). Duodenum was the most common site, followed by lumbar vertebrae and aorta. Eighty-seven percent of organ involvement by penetrated strut was caused by conical filters. Of the 1699 patients with penetration, symptomatic patients were 8% and asymptomatic patients were 45%. Clinical symptoms were not investigated in 47%. Five percent (83/1699) had major complications requiring surgical or endovascular intervention.

Table VI. Multivariate analysis

Variables	OR	95% CI	*P* value
Body mass index ≥22 kg/m^2	1.286	0.305-5.414	.732
IVC diameter, mm	1.154	0.924-1.441	.207
Level of filter, suprarenal	2.953	0.439-19.877	.266
Filter design, conical	4.138	0.768-22.301	.098
Tilting of filter ≥5 degrees	2.646	0.705-9.933	.149
Filter indwelling time ≥30 months	4.395	1.179-16.385	.027

CI, Confidence interval; *IVC,* inferior vena cava; *OR,* odds ratio.

Although we could not review all our patients with an IVC filter, filter strut penetration was detected in all of the patients who had a follow-up CT study. Grade 3 penetration rate was high at 35%. This is much higher than what was previously reported.

There are several probable reasons for this discrepancy in penetration rate between the meta-analysis and our study. First, filter perforation is time dependent. Several previous studies have shown that IVC filter penetration tends to progress over time.[14-16] A retrospective study showed 73.6% (204/277) incidence of perforation on follow-up CT >90 days after placement, whereas the incidence dropped to 18.2% (65/358) on follow-up CT ≤90 days.[15] Go et al[17] reported an 84% rate of IVC filter penetration after a mean 407 days of CT follow-up. The median follow-up duration of our study was 14 months with a maximum of 137 months, a relatively long period. The authors of the previously mentioned meta-analysis did not report follow-up duration. Another reason of filter penetration underdiagnosis is the diagnostic modality used. CT was used in only 54.8% of 1699 cases with IVC penetration, and 42.3% was diagnosed by venacavography. Moreover, considering that the meta-analysis included studies that were published from 1970 to 2014, the image quality in the first half of the period was probably not as good as that in the second half for detecting strut penetration. Interestingly, both permanent and retrievable filters were included in the meta-analysis. The authors did not attempt to differentiate them and to analyze them separately. It is known that the penetration rate of retrievable filters is much higher than that of permanent filters.[2,14] The lower penetration rate in that meta-analysis could be attributed to permanent IVC filters. Last, the quality of evidence was heterogeneous (9 high, 44 moderate, 34 low, and 113 very low). The authors also pointed out that not all researchers might have carefully assessed for IVC penetration. When they conducted subgroup analysis for the 18 clinical studies that had diagnostic criteria according to the guideline, the incidence of penetration increased to 34% (634/1870). It is evident that to accurately estimate the incidence of IVC filter penetration, more detailed assessment (eg, time variable, diagnostic modalities and criteria) should be considered.

We found that indwelling time ≥30 months is a risk factors of grade 3 IVC filter penetration (odds ratio, 4.395; confidence interval, 1.179-16.3685; $P = .027$). Besides long indwelling time, other factors were also found to increase risk of strut penetration. These include conical filter design, use of retrievable filter, female sex, malignant disease, smaller IVC diameter, and tilting of filter.[2,15,17,18]

McLoney et al[15] retrospectively reviewed CT scans of 465 patients with an IVC filter. Mean follow-up duration was 277 days for Celect filters, 437 days for Günther Tulip filters, and 286 days for Greenfield filters. Multivariate analysis showed that female sex (45.5% vs 30.8; $P = .002$) and the patient's history of malignant disease (43.7% vs 29.9%; $P < .001$) were risk factors. They also reported that the rate of strut penetration was significantly lower for Greenfield filters than for Celect filters or Tulip filters (Greenfield, 2%; Celect, 49.4%; Tulip, 43.1%; $P = .002$). They assumed that the high incidence in female patients could be due to a smaller diameter of IVC. However, the IVC diameter of female patients was significantly larger than that of male patients (2.0 $\pm$ 0.5 cm vs 1.9 cm $\pm$ 0.4 cm), and patients with strut penetration had a larger IVC diameter than patients without filter penetration (2.0 $\pm$ 0.5 cm vs 1.9 $\pm$ 0.4 cm). The correlation between sex and IVC diameter was very low, which suggested that the high strut penetration rate in the group of female patients is not likely to be due to the difference in IVC diameter between male and female patients.

Our study also showed that larger caval diameter was related to strut penetration beyond our expectation, but this was not confirmed with multivariate analysis. In general, radial force of the filter strut to the IVC wall is greater in smaller IVCs; but the larger the caval diameter, the more the filter is unfolding, and a strut of a cone-shaped filter would be more perpendicular to the wall and more likely to perforate. This is a potential explanation for large diameter of the IVC being a risk factor for filter penetration. However, another study showed that IVC diameter is negatively correlated with strut penetration.[19] IVC diameter $\leq$24.2 mm was identified as a risk factor of IVC penetration on retrospective analysis of 45 retrievable IVC filters (odds ratio, 6.4; 95% confidence interval, 1.3-31.5; $P = .021$). However, IVC diameter is not constant. It is influenced by respiration, body fluid status, patency of the lower extremity venous system, and heart failure. Therefore, it is difficult to accurately evaluate the relation between strut penetration risk and IVC diameter with a static imaging study.

On a retrospective review of 262 patients with IVC filter,[17] high-grade penetration (grade 2 or grade 3) was more frequently detected for retrievable filters than for permanent filters (49.0% vs 5.3%; $P = .0001$). It was also more common for filters $\geq$30 days old than for filters <30 days old (57.3% vs 18.2%; $P < .0001$). The authors also suggested that high-grade penetration tended to be associated with conical design filters, but it did not meet statistical significance ($P = .0645$). In our study, the incidence of high-grade penetration was higher for Celect and Günther Tulip filters than for the OptEase filter in univariate analysis. However, a conical design was not an independent risk factor of organ involvement (grade 3 penetration) on multivariate analysis.

If a profound filter penetration is encountered during planning of filter removal, physicians may be hesitant to remove it as it is possible that filter removal may damage the IVC wall or involved organs. Holly et al[20] reported successful IVC filter retrieval with aortoiliac arterial strut penetration. The number of cases was 17, and mean indwelling time was >63 months. The technical success rate was 100%, and there was not any immediate or delayed major adverse event. However, they needed special techniques or devices including loop wire technique for eight cases, rigid endobronchial forceps for five cases, and excimer laser sheath-assisted photothermal ablation for one case. In only three cases (18%) was filter removal possible with standard snare retrieval technique. As the number of cases was small, it is difficult to conclude that all penetrated IVC filters can be safely removed. In some cases, filter removal failed, and the reported failure rate ranged from 3% to 12%.[21-23] Not all IVC filters can be endovascularly retrieved. Although the symptomatic IVC penetration by filter strut is relatively rare and the clinical significance of asymptomatic strut penetration is still unclear, strut penetration of nonretrieved filters may keep progressing, with risks that are difficult to predict. Considering this, retrievable filters should be removed as soon as possible if they are no longer needed. Besides the physician's neglect, the stricter criteria for IVC filter placement can prevent this avoidable complication. In our study, absolute indications for IVC filter placement were present in only 24%.

CONCLUSIONS

The incidence of IVC filter strut penetration was high, and the incidence of grade 3 penetration was 35% during a median time of 14 months. Long indwelling time >30 months was the risk factor of grade 3 penetration. Our study has some limitations. This study has a retrospective design, and not all patients with an IVC filter were analyzed, indicating a selection bias. We could not demonstrate the incidence of strut penetration relative to time because we did not have serial imaging available. Also, because of the retrospective nature of the study, we could not investigate IVC filter penetration-related symptoms. Nevertheless, our study reports one of the longest follow-up outcomes of indwelling IVC filters.

AUTHOR CONTRIBUTIONS

Conception and design: WY
Analysis and interpretation: WY
Data collection: SY, WY
Writing the article: SY, WY
Critical revision of the article: WY
Final approval of the article: SY, WY
Statistical analysis: WY
Obtained funding: WY
Overall responsibility: WY

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