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Filter tilting and retrievability of the Celect and Denali inferior vena cava filters using propensity score-matching analysis

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ABSTRACT

Purpose: To assess the filter tilting and outcomes of the Celect and Denali inferior vena cava (IVC) filters by using a propensity score-matching analysis.

Materials and methods: From January 2009 to November 2017, 181 Celect and 58 Denali filters were inserted in our institution. To assess filter tilt, filter tip abutment or penetration of the IVC wall, and retrieval outcome, independent variables, including age, sex, IVC long diameter, IVC angulation, and proximity of the filter to renal vein insertion, were entered in the propensity model. Comparative analyses were performed before and after propensity score-matching analysis.

Results: Thirty-one patients were enrolled in each group for the final propensity score-matching analysis. The mean filter indwelling time was not significantly different between the groups (26 ± 22 days in Celect and 27 ± 23 days in Denali). After propensity score adjustment, the mean degree of filter tilt was higher in the Celect group (9.5° ± 7.4° vs 5.6° ± 6.7°). Filter tip abutment or penetration of the IVC wall was more common in the Celect group (39% [12/31, abutment: 12, penetration: 0] vs 13% [4/31, abutment: 3, penetration: 1]). The retrieval outcomes were not significantly different before and after propensity score adjustment in both filters.

Conclusion: The Denali IVC filter showed less tilt and low rate of filter tip abutment to the IVC wall after propensity score-matching analysis. The retrieval rate was not significantly different in the short-term filter indwelling setting. More large-scale, long-term follow-up studies are needed to verify these results.

1. Introduction

Retrievable inferior vena cava (IVC) filters have been widely used to prevent life-threatening pulmonary thromboembolisms resulting from acute deep-vein thrombosis in patients contraindicated for anticoagulation therapy [1,2]. Over time, IVC filter designs have been modified, and filters with less tilt and higher retrieval rates are being developed. However, the retrieval failure or difficult retrieval is still a problem, and the main reasons are considered as filter-tip epithelialization or incorporation of the filter struts into the caval wall caused by filter tilt and long indwelling time of the filter [3,4].

Previously, conical-shaped with unique strut designed filters such as the Celect IVC filter (Cook Medical, Bloomington, Ind, USA) were widely used; however, many studies have shown filter tilting and its related problems [3–5]. Recently, the Denali IVC filter (Bard, Peripheral Vascular, Temte, AZ, USA) was introduced, which additionally added shoulder parts in the filter arms to prevent filter tilting, and showed favorable safety and a high retrieval rate [5,6].

Few studies have compared the widely used Celect IVC filter and the recently developed Denali filter [5,7]. However, various confounding factors exist in comparisons of the safety and outcomes of two different filters, such as patient age, sex, IVC diameter and angulation, and proximity to renal vein. To date, no study has accounted for these confounding factors in their comparison between Celect and Denali IVC filters. Therefore, in this study, we used a propensity score-matching statistical technique to eliminate these various biases and compare the filter tilting and outcomes between these two filters.

Abbreviations: IVC, inferior vena cava; PACS, picture archiving and communication system; CT, computed tomography; 3D, three-dimensional

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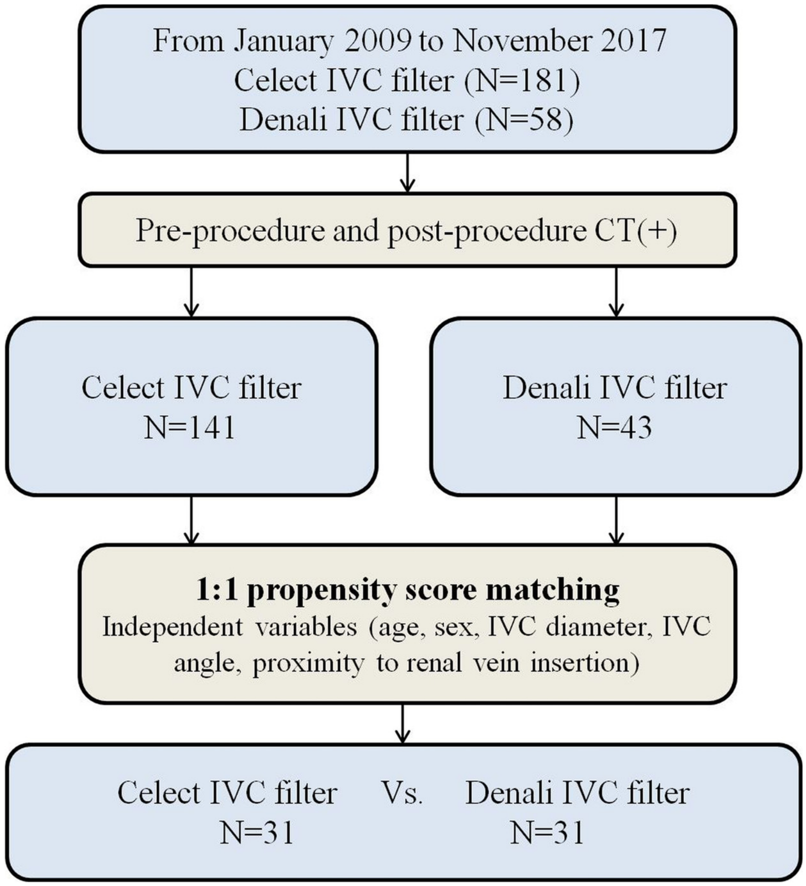

Fig. 1. Flow chart shows patient enrollment of this study.

2. Materials and methods

2.1. Patients

Our institutional review board approved this retrospective case-comparative study. Patient informed consent was waived. To compare filter tilt and retrieval rate between the two different IVC filters, cases were retrospectively collected using the electronic medical chart and picture archiving and communication system (PACS). From January 2009 to November 2017, 181 Celect IVC filters and 58 Denali IVC filters were inserted in our institution. The patient enrollment and exclusion criteria are shown in Fig. 1.

2.2. IVC filter insertion and retrieval

All filters were inserted for patients temporarily or permanently contraindicated to undergo anticoagulation therapy for thromboembolic disease. All procedures of Celect filter insertion and retrieval were performed by one experienced radiologist who had > 5 years of experience in interventional radiology at the study initiation time. All Denali IVC filters are inserted by an interventional radiologist with more than 2 year experience. For IVC filter insertion, the patients were moved to the angiographic suite. After skin anesthesia with 2% Lidocaine, ultrasonography-guided venous puncture was performed. The venous access sites were various for example, right internal jugular, right femoral, or left femoral vein. An inferior venacavogram was acquired to identify the renal vein insertion level and the vena caval anatomy. The catheter/sheath tip was located at lowest position of the IVC and 20 ml of contrast media was manually injected under anterioposterior projection distal subtraction angiography with full inspiration. Then the IVC filter was gently unsheathed and deployed. All filters were deployed in the infrarenal IVC. After deployment, repeated cavography was performed to confirm the position of the filter.

All IVC filter removals were routinely attempted using a right internal jugular venous access with the usual endovascular snare technique. To compare the retrieval rate and safety of the two different IVC filters, we assessed the filter retrieval attempt, success rate, and procedure-related complications, and applied the advanced retrieval technique, which required devices other than the usual snare technique.

2.3. Measurements of imaging data

All the enrolled patients had a pre-filter insertion and pre-filter retrieval venous-phase computed tomography (CT). The pre-filter retrieval CT scans were conducted for evaluation of filter retrievability or follow-up of deep vein thrombosis/pulmonary thromboembolism. All CT scans were performed using the deep-inspiration breath-hold technique. The CT protocol was combining the CT pulmonary arteriography and venography of abdomen and lower extremity. All enrolled patients underwent multidetector contrast enhanced CT using a variety of multidetector CT scanners – Lightspeed 16, Optima 660, Revolution EVO (GE Healthcare, Milwaukee, WI), and SOMATOM Force (Siemens Health Care, Forchheim, Germany). CT pulmonary arteriography followed after intravenous administration of a weight- and scanner-based dose of 80–100 mL Omnipaque 350 (GE Health Care, Seoul, Korea) with an injection rate of 1.5–2 mL/second. After 110 s delay, abdominal and lower extremity venous phase CT were taken. Various image parameters were measured on pre-filter insertion and pre-filter retrieval venous-phase CT. The mean interval between the pre-filter insertion CT and filter insertion was 5 ± 23 days, and that between the filter insertion and pre-filter retrieval CT was 64 ± 151 days. Filter tilt angle, filter tip abutment or penetration of the IVC wall, IVC angle, and vertical position of the filter were measured on a three-dimensional (3D) workstation (AquariusNET, Terarecon, San Mateo, Calif, USA) by using pre-filter retrieval CT data. The filter tilt angle was determined by comparing the long axis of the filter and that of the IVC at the maximal tilted projection on the 3D work station. Filter tip abutment to the IVC wall was determined using visual abutment of the filter tip to the IVC wall, and tip penetration was defined as filter hook penetration out of the IVC wall on 3D reformatted CT image. The IVC angle was measured by comparing between the long axis of the IVC at the level of renal vein insertion and the long axis of the IVC at the level of the IVC filter. The vertical position of the IVC filter was determined by measuring the distance from the renal vein junction to the lower margin of the IVC filter. Filter tip abutment to the IVC wall was defined as visual abutment of the IVC filter hook against the IVC wall in three-dimensional CT data and was determined by consensus between two readers.

The IVC greater transverse and shortest anteriorposterior diameters were measured using the PACS system (Infinitt PACS, Infinitt Healthcare, Seoul, Korea) on the basis of the pre-filter insertion CT scan. On the axial CT image, IVC diameters were measured at a point 4 cm below the lowest renal vein connection to the IVC.

2.4. Statistical analyses

To compare the two different IVC filters, we used various statistical methods. In a univariate analysis, an independent sample *t* test was applied for comparing continuous variables, and the chi-square test and Fisher exact-test were used for categorical variables.

To minimize the effect of potential confounders on selection bias, propensity scores were generated using binary logistic regression. The independent variables entered in the propensity model included age, sex, IVC long diameter, proximity to the renal vein insertion site, and IVC angulation. One-to-one matching between the groups was accomplished by using the nearest-neighbor matching method [8]. We trimmed the sample by excluding 122 patients (Celect group, n = 110; Denali group, n = 12) from among the 184 patients with a non-overlapping propensity distribution with a propensity score difference of > 0.01. Thus, adjusted comparisons by propensity scores were based on data from 31 patients per IVC filter arm. After adjustment for these factors, statistical values were recalculated using paired *t*-test and McNemar's test for the two matched groups. Statistical analyses were performed using SPSS version 16.0 for Windows (SPSS, Chicago, Ill, USA) and MedCalc version 17.5 statistical software (MedCalc Software BVBA, Ostend, Belgium). *P* values of < 0.05 were considered statistically significant in all the analyses.

3. Results

3.1. Baseline characteristics and IVC parameters

Among the 259 patients who had an IVC filter insertion during the study period, 184 who have preprocedural and postprocedural CT scans were finally enrolled in this retrospective study (Celect group, n = 141; Denali group, n = 43). Table 1 shows the patient characteristics for the two groups. The mean patient age and sex were not statistically significantly different in the two groups. Male patients were predominant in both groups (male:female: Celect group, 73:68; Denali group, 27:16; $P = 0.205$). The baseline IVC long and short diameters and IVC angulation were not significantly different between the two groups. However, the distance of the renal vein insertion level to the filter limb distal end was larger in the Celect group (Celect group, 5.9 ± 1.2 cm; Denali group, 5.5 ± 1.7 cm; $P = 0.03$). Vascular access sites were significantly different between the two groups. The transjugular approach was more common in the Celect group, and the transfemoral approach was predominant in the Denali group ($P < 0.05$). The filter indwelling time was not significantly different between the two groups (27 ± 24 days in Celect and 26 ± 21 days in Denali, $P > 0.05$).

3.2. Filter tilt and filter tip abutment or penetration of the IVC wall

The mean degree of IVC filter tilt was higher in the Celect group (8.3° ± 5.4°) than in the Denali group (5.3° ± 5.9°, $P = 0.002$) on 3D reformatted CT image. Filter tip abutments or penetration of the IVC wall was also more common in the Celect group than in the Denali group (37% [52/141, abutment: 45, penetration: 7] vs 12% [5/43, abutment: 4, penetration: 1]; $P = 0.002$).

3.3. IVC filter retrieval and complications

The Denali group had more filter retrieval attempts than the Celect group (71% [100/141] of Celect vs 93% [41/43] of Denali; $P < 0.05$). The success rate of filter retrieval was similar between the two groups (96% in Celect and 98% in Denali, $P > 0.05$). The retrieval failure rate, complications associated with retrieval, and need for advanced retrieval techniques were greater in the Celect group. However, these findings were not significantly different ($P > 0.05$). Retrieval failure and complicated cases are summarized in Table 2 (Fig. 2).

3.4. After propensity score-matching analysis

Thirty-one patients from each group were matched by applying one-to-one propensity score matching. Confounding factors were well-matched between the two groups (Table 1). The degree of IVC filter tilting and number of filter tip abutments or penetrations of the IVC wall were significantly higher in the Celect group in both before and after propensity score-matching analysis. The number of retrieval attempts was also higher in the Denali group both before and after propensity score matching ($P < 0.05$). Although statistical analyses were not performed for retrieval success/failure rate after propensity score matching, the difference in retrieval success/failure rate between the Denali and Celect groups was greater after the propensity score matching (success rate of 96% [96/100] in the Celect group and 98% [40/41] in the Denali group before propensity score matching vs 71% [22/31] in the Celect group and 100% [29/29] in the Denali group after propensity score matching). The overall mean indwelling time was not significantly different before and after propensity score matching ($P > 0.05$).

4. Discussion

While anticoagulant therapy is the treatment of choice for deep vein thrombosis, inferior vena cava (IVC) filters are becoming increasingly popular as the only option to reduce the incidence of pulmonary embolism when anticoagulation is contraindicated [1,2]. IVC filters are typically placed in three clinical scenarios: (1) in patients with venous thromboembolism (VTE) and classic indications; (2) in patients with VTE and extended indications; and (3) in patients without VTE for primary prophylaxis against pulmonary embolism [9]. IVC filter tilting and filter tip abutment to the IVC wall are potential risk factors of difficult retrieval or retrieval failure [10,11]. The potential hazards of maintaining a permanent IVC filter are well known [12,13]. To increase the retrieval success rate, the filter tilt at the insertion and the indwelling time should be minimized [9,10,14]. Recently, a Denali filter with an angled arm was introduced with a low filter tilt rate and high retrieval rate [6]. Few studies have compared the outcomes of the widely used Celect IVC filter and newly designed Denali IVC filter [5,7]. However, these studies had several confounding factors such as differences in age, sex, IVC diameter, IVC angulation, and proximity to the renal vein. To overcome these drawbacks, we introduced a propensity score matching analysis to compare the exact outcome of the two different filters.

Propensity score-matching analysis is an increasingly popular statistical method to reduce selection bias especially in nonrandomized controlled studies of diagnostic radiology [8,15]. This method could

Table 1
Before and after propensity score adjustment.

	Before Propensity Score Adjustment			After Propensity Score Adjustment		
	Celect (n = 141)	Denali (n = 43)	*P* Value	Celect (n = 31)	Denali (n = 31)	*P* Value
Age (years ± mean)	63.1 ± 14.9	60.7 ± 15	0.360[a]	64.7 ± 11.9	63.0 ± 16.0	0.481[c]
Sex (male:female)	73:68	27:16	0.205[b]	20:11	17:14	0.345[d]
IVC long diameter (mm)	22.9 ± 3.6	23.4 ± 3.1	0.425[a]	23.5 ± 4.0	23.3 ± 3.3	0.855[c]
IVC short diameter (mm)	16.0 ± 3.7	16.8 ± 3.1	0.210[a]	16.2 ± 2.6	16.5 ± 3.2	0.745[c]
Filter tilt (degrees)	8.3 ± 5.4	5.3 ± 5.9	**0.002**[a]	9.5 ± 5.9	5.6 ± 6.7	**0.014**[c]
Filter tip abutment or penetration	52/141(37%)	5/43(12%)	**0.002**[b]	12/31(39%)	4/31(13%)	**0.003**[d]
Abutment:penetration	25:7	4:1		12:0	3:1	
Vertical position (cm)	5.9 ± 1.2	5.5 ± 1.7	**0.030**[a]	5.7 ± 1.1	5.7 ± 0.8	0.851[c]
IVC angulation (degrees)	9.8 ± 7.4	7.7 ± 6.8	0.991[a]	8.8 ± **7.7**	8.8 ± 6.6	0.253[c]
0–10°	95	23		21	21	
< 10–20°	32	17		7	7	
< 20°	14	3		3	3	
Access site (IJ/RF/LF)	136/5/0	6/21/16	NA	30/1/0	3/15/13	NA
Retrieval attempt	100/141 (71%)	41/43 (93%)	**0.001**[b]	22/31(71%)	29/31(94%)	**0.002**[d]
Retrieval success	96/100 (96%)	40/41 (98%)	1.000[b]	22/31(71%)	29/29(100%)	**0.002**[d]
Retrieval failure	4/100 (4%)	1/41 (2%)	1.000[b]	0/22 (0%)	0/29 (0%)	< **0.001**[d]
Advanced or complicated retrieval	5/100 (5%)	1/41 (2%)	0.672[b]	0/22 (0%)	1/29 (3%)	< **0.001**[d]
Indwelling time (days, mean ± SD)	27 ± 24	26 ± 21	0.893[a]	26 ± 22	27 ± 23	0.746[c]

IVC, inferior vena cava; NA, not applicable; IJ, right internal jugular venous access; RF, right common femoral venous access; LF, left common femoral venous access; SD, standard deviation.
Significance of bold values = *p* value less than 0.05.
[a] Independent *t*-test.
[b] Chi-square test.
[c] Paired *t*-test.
[d] McNemar's test.

Table 2
Filter retrieval failure and advanced retrieval/complicated retrievals.

	Filter	Age	Sex	IVC diameter (mm)	IVC angle (degrees)	Proximity to the renal vein (cm)	Filter tilt (degrees)	Tip abutment or penetration	Indwelling time (days)	Remarks
Retrieval failure	Celect	46	M	27.7	4.8	6.0	12.1	Penetration	8	Embedded filter tip
Retrieval failure	Celect	33	M	21.5	3.2	1.8	1.3	None	28	Thrombotic occlusion of IVC
Retrieval failure	Celect	82	F	20.1	26.5	5.8	15.2	Penetration	36	Embedded filter tip
Retrieval failure	Celect	71	M	18.5	2.8	7.5	9.3	Abutment	13	Entrapped thrombus
Retrieval failure	Denali	50	M	24.8	12.9	6.3	10.2	None	10	Entrapped thrombus
Advanced retrieval	Celect	24	M	24.3	2.8	4.4	20.9	Abutment	27	Urokinase + balloon assisted
Advanced retrieval	Celect	64	M	27.0	7.2	5.7	13.9	Penetration	14	Balloon assisted
Advanced retrieval	Denali	23	M	27.6	3.1	7.5	38.7	Penetration	34	Balloon and forceps assisted
Complicated retrieval	Celect	64	M	26.9	5.6	6.1	16.5	Abutment	14	Concealed IVC rupture
Complicated retrieval	Celect	67	M	23.2	3.4	5.5	2.1	None	15	Concealed IVC rupture
Complicated retrieval	Celect	71	F	21.3	7.2	6.4	10.9	Abutment	21	Concealed IVC rupture

IVC, inferior vena cava.

allow matching of multiple variables in two different groups. In our study, age, sex, IVC long diameter, proximity to the renal vein insertion site, and IVC angulation were entered in the propensity model. These variables can potentially influence the tilting of the IVC filter because each individual's IVC morphology is different and can change according to age. In our study, before matching, the filter tip proximity to the renal vein insertion level was significantly different between the two groups. After propensity score one-to-one matching, 31 patients were finally selected in each group and matched for multiple input variables.

The mean degree of filter tilt was greater in the Celect group both before and after the propensity score matching. This result is similar with a previous study [5]. In our study, we evaluated not only the filter tilt but also the number of filter tip abutments or penetrations of the IVC wall in each filter group. We hypothesized that the abutted filter tip to the IVC wall can be a potential risk of epithelialization of the filter tip and result in difficult retrieval or retrieval failure. After propensity matching, 39% (12/31) of the patients in the Celect group and 13% (4/31) of those in the Denali group showed filter tip abutment in the postprocedural CT analysis. In short-term follow-up CT analysis, our results showed that the degree of filter tilt was greater and the incidence of tip abutment to the IVC wall was higher in the Celect group than in the Denali group both before and after propensity score matching.

In the filter retrieval outcome analysis, retrieval was attempted for most Denali filters (93% [41/43] before propensity matching and 94% [29/31] after propensity matching). However, in the Celect group, retrieval of 71% of the filters were attempted both before and after matching. This difference may be due to the increased will of physicians

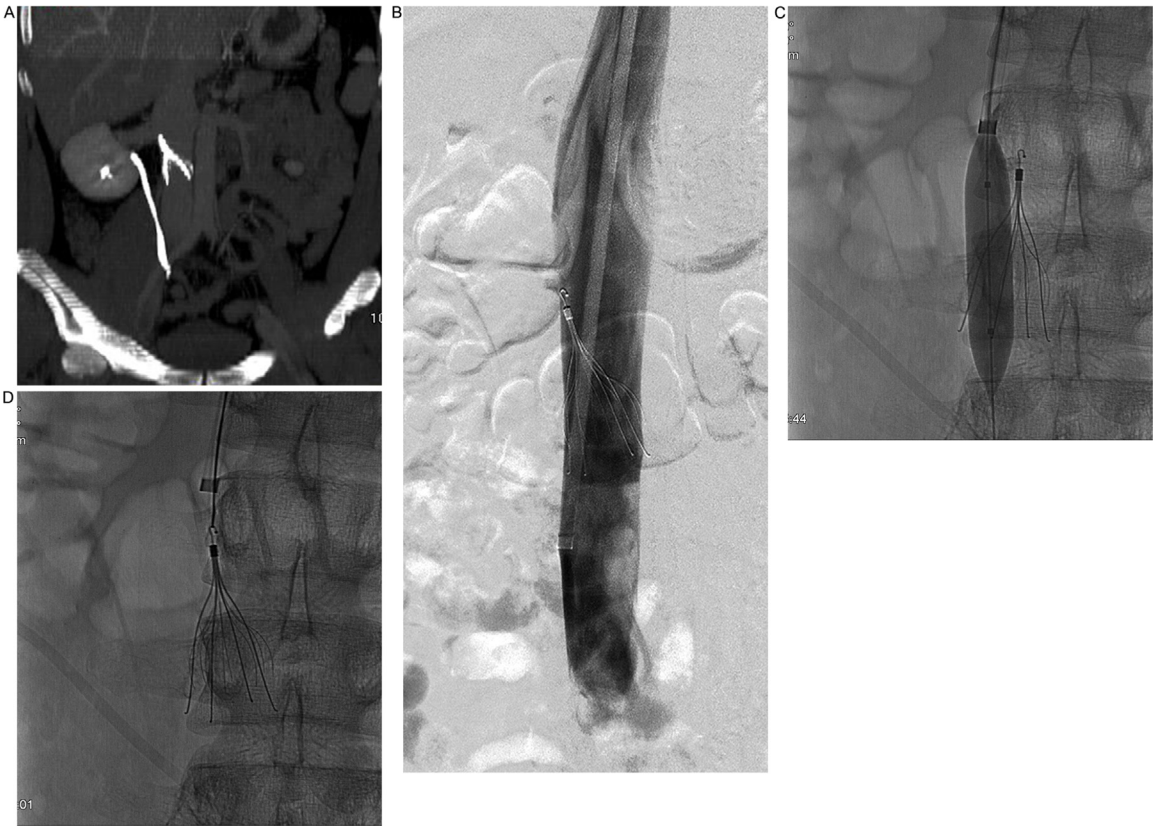

Fig. 2. Twenty-four-year–old male patient shows IVC filter tilting. A, B. Coronal reformatted computed tomography and venography show IVC filter abutment to the IVC wall. C. A 12-mm balloon catheter was used for reposition of the tilted filter tip. D. Finally, IVC filter was successfully captured with endovascular snare.

regarding the importance of IVC filter retrieval over time. It is interesting that the retrieval success rate decreased in the Celect group after propensity score matching (from 96% [96/100] before to 71% [21/31] after propensity matching). However, from the viewpoint of retrieval data, propensity score-matching analysis reduced the number of cases and limited the evaluation of the overall retrieval outcome. Previous larger case series also showed higher retrieval rates and lower complication rates for the Denali IVC filter [5,7].

Although no statistically significant differences were found, retrieval failure and the need for an advanced technique to retrieve the filter or complicated retrieval were more common in the Celect group. Three of four cases of retrieval failure of the Celect filter were due to the filter tip abutted to the IVC wall or penetration of the IVC wall, with a mean degree of filter tilt of 12.2° ± 5.5°. The remaining case had no filter tilt but had thrombotic occlusion of the IVC.

Our study has several limitations. First, two different IVC filters were inserted by two radiologists. In addition, the proximity of the filter to the renal vein insertion level was significantly different between the two filter groups. These differences were compensated by propensity score adjustment. Second, the venous access site was significantly different between the two groups. Most Celect filters were inserted via right internal jugular access. By contrast, transfemoral access was preferred for the Denali filter. The transfemoral approach usually has a wider angulation between the IVC and the delivery sheath, which is considered a risk factor of filter tilting [14]. Thus, a modified technique was introduced to avoid filter tilting [16]. In our results, although the Denali filter was mainly inserted via the transfemoral access, it showed less tilt than the Celect filter, which was mainly inserted via the right internal jugular approach. Third, our data showed a shorter indwelling time of the IVC filter than those reported in other studies [5,6].

In conclusion, the Denali IVC filter showed less tilt and lower rate of filter tip abutment to the IVC wall after propensity score-matching analysis. The retrieval rate was not significantly different in the short-term filter indwelling setting. More large-scale, long-term follow-up studies are needed to verify these results.

Conflict of interest statement

All authors (Jae Heung Bae and Sang Yub Lee) declare that they have no conflicts of interest.

Acknowledgments

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