Original Article

Efficacy and safety of a novel vena cava filter on pulmonary embolism prophylaxis: a prospective, multicenter, randomized, parallel, positive-controlled, noninferiority clinical trial

Maofeng Gong[1#], Boxiang Zhao[1#], Jianlong Liu[2], Gaojun Teng[3], Caifang Ni[4], Hao Xu[5], Zhen Li[6], Shuiting Zhai[7], Yanrong Zhang[8], Hua Xiang[9], Weizhu Yang[10], Jianping Gu[1]

[1]Department of Interventional and Vascular Radiology, Nanjing First Hospital, Nanjing Medical University, Nanjing, China; [2]Department of Vascular Surgery, Beijing Jishuitan Hospital, Beijing, China; [3]Center of Interventional Radiology & Vascular Surgery, Department of Radiology, Zhongda Hospital, Medical School, Southeast University, Nanjing, China; [4]Department of Interventional Radiology, The First Affiliated Hospital of Soochow University, Suzhou, China; [5]Department of Interventional Radiology, The Affiliated Hospital of Xuzhou Medical University, Xuzhou, China; [6]Department of Endovascular Surgery, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China; [7]Department of Vascular and Endovascular Surgery, Henan Provincial People's Hospital, People's Hospital of Zhengzhou University, Zhengzhou, China; [8]Department of Vascular Surgery, the Third Hospital of Hebei Medical University, Shijiazhuang, China; [9]Department of Interventional Radiology and Vascular Surgery, Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University), Changsha, China; [10]Department of Interventional Radiology, Fujian Medical University Union Hospital, Fuzhou, China

Contributions: (I) Conception and design: All authors; (II) Administrative support: J Liu, G Teng, C Ni, H Xu, Z Li, S Zhai, Y Zhang, H Xiang, W Yang, J Gu; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: M Gong, B Zhao; (V) Data analysis and interpretation: M Gong, B Zhao, J Gu; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Jianping Gu, MD. Department of Vascular and Interventional Radiology, Nanjing First Hospital, Nanjing Medical University, Changle Road, Nanjing 210006, China. Email: cjr.gujianping@vip.163.com.

Background: There are different types of vena cava filter (VCF) available in clinical practice. However, limited data exist to determine whether one type is superior to another, and no single VCF is universally recommended in clinical guidelines. The objective of this study was to investigate the safety and efficacy of a novel VCF, Octoparms, for the prevention of pulmonary embolism (PE) and to compare it with the Celect filter.

Methods: This multicenter, randomized, open-label, parallel, positive-controlled, noninferiority trial was conducted in 10 centers across 6 provinces in China from October 2017 to March 2019. Patients who had confirmed lower extremity deep vein thrombosis or PE or who were at risk of PE with a clinical indication for VCF placement due to contraindication to or failure of anticoagulant therapy were included in the trial. The sample size for this trial was based on the assumption that the clinical success rate would be 95% and the noninferiority margin would be 10% for both filters. Each patient underwent baseline testing and was randomized using a web-based central system. Any additional interventions or standard treatments patients received along with the VCF placement were recorded. The primary endpoint was the overall clinical success rate, including technical and clinical success of filter placement and retrieval. The secondary endpoint was the safety of filter placement and retrieval, encompassing procedure-related and filter-related complications.

Results: A total of 188 patients were included and were divided into two groups: the Octoparms group (n=94) and the Celect group (n=94). Baseline characteristics and demographics were comparable between the two groups (P>0.05). Technical and clinical success rates for filter placement were achieved in 100% (188/188) of patients. The median dwelling time was 12.0 days (range, 4–190 days). Ten VCFs were left *in situ* as permanent devices. Of the remaining 178 patients, technical success and clinical success rates for filter

retrieval were both achieved in 100% of cases (178/178). Clinical success rates were 92.6% (87/94) for the Octoparms group and 96.8% (91/94) for the Celect group, with a difference of –4.2% (hazard ratio 2.441, 95% confidence interval 0.612–9.741; P=0.206). The lower limit was greater than the noninferiority margin of –10%. Eight patients experienced a total of eight procedure-related complications. No filter-related complications, such as migration, deformation, inferior vena cava (IVC) penetration, peripheral organ damage, or IVC stenosis/occlusion, were observed (P>0.05).

Conclusions: The Octoparms filter exhibited a high rate of clinical success and a low rate of complications during placement and retrieval, demonstrating noninferiority to the Celect filter.

Keywords: Pulmonary embolism (PE); inferior vena cava (IVC); vena cava filter (VCF); treatment outcome; safety

Submitted Apr 29, 2024. Accepted for publication Aug 08, 2024. Published online Sep 14, 2024.
doi: 10.21037/qims-24-879
View this article at: https://dx.doi.org/10.21037/qims-24-879

Introduction

Pulmonary embolism (PE), with a mortality rate of up to 9.4%, is a common and preventable condition resulting from lower extremity deep vein thrombosis (LEDVT) (1,2). Besides the pharmacologic strategy of anticoagulants, which are the mainstay management for DVT, the inferior vena cava filter (VCF) is a mechanical strategy devised to prevent PE by trapping thrombi within metal struts in high-risk patients who have absolute contraindication or for whom anticoagulation has been ineffective (3,4). Over the past few decades, various types of VCFs have emerged, including permanent and retrieval filters (4). Permanent VCFs have been shown to reduce the initial risk of PE and provide long-term, sometimes lifelong protection. However, they have inherent risks, such as recurrent LEDVT and complications related to indwelling devices, including inferior vena cava (IVC) stenosis/occlusion, strut perforations, or filter fracture (1,5,6).

Concerns regarding the scenario described above have driven the development of various types of retrievable VCFs, particularly for patients who only temporarily require a filter, as it can be removed when clinically feasible, potentially eliminating the long-term risks of permanent filters. Currently, there are different types of VCF available in clinical practice (3). However, limited data exist to determine whether one type is superior to another, and no single VCF is universally recommended in clinical guidelines (3). The choice of filter is largely influenced by operator preference, economic considerations, and device availability at different institutions. Each VCF features a unique design aimed at maximizing retrievability and minimizing complications associated with long-term indwelling (6). The development of new VCFs continues to expand the range of available options, although this area remains underexplored.

This paper reports the results of a multicenter, randomized, parallel positive-controlled, noninferiority trial conducted in 10 hospitals across 6 provinces in China between October 2017 and March 2019. The trial was designed to evaluate the placement and retrieval of a new VCF, Octoparms, in patients with identified LEDVT, PE, or a temporarily increased risk of PE requiring filter placement. The Octoparms VCF was compared with the Celect filter (7) in terms of filter placement, retrieval, and indwelling complications. We present this article in accordance with the CONSORT (for noninferiority or equivalence randomized trial) reporting checklist (available at https://qims.amegroups.com/article/view/10.21037/qims-24-879/rc).

Methods

Trial design and oversight

This was a multicenter, randomized, parallel, positive-controlled, noninferiority trial conducted in 10 hospitals across 6 provinces in China, but it was not registered on any registration platform. This study was performed in accordance with Declaration of Helsinki (as revised in 2013) and was reviewed and approved by the institutional review board of Nanjing First Hospital (No. QX20170714-02). All participating hospitals were informed and agreed with the study. Written informed consent was obtained from every patient or their legal surrogates. An independent data and safety monitoring committee provided oversight throughout the study. The Center for Statistics in Medicine

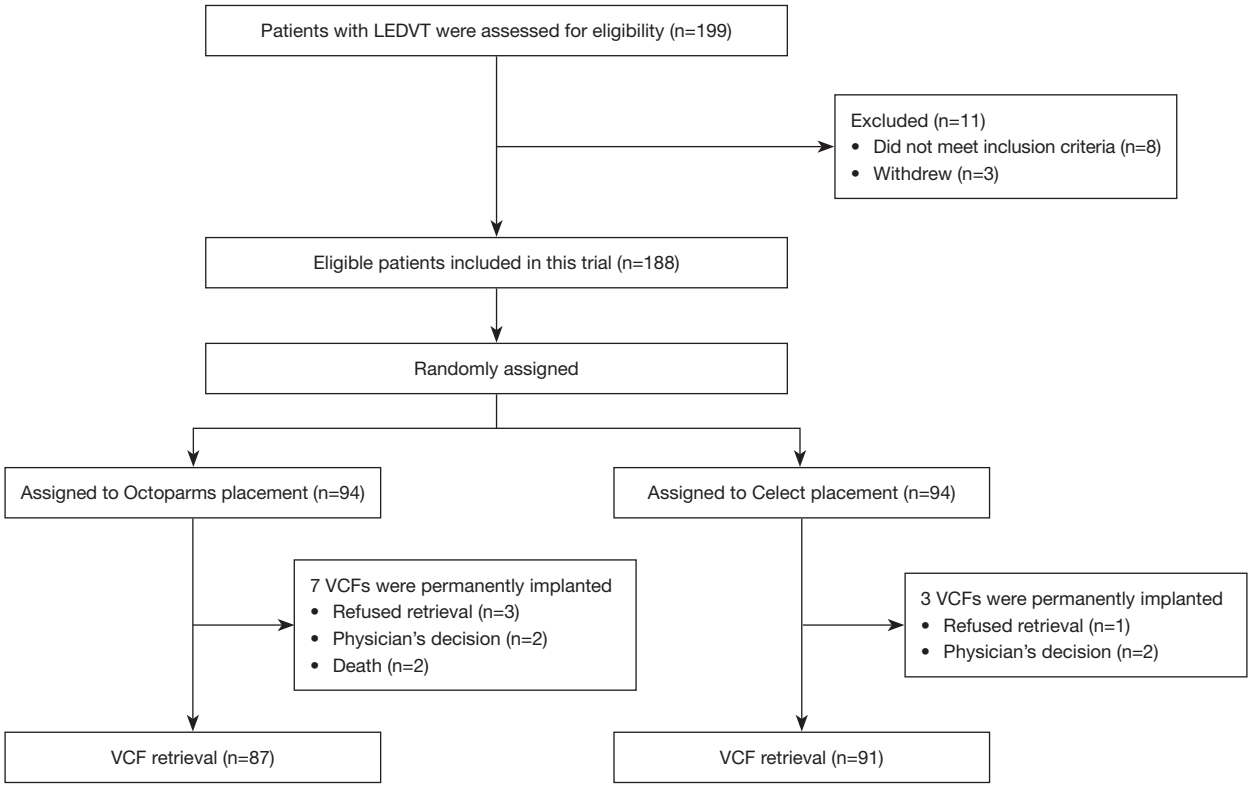

Figure 1 The study flowchart of the inclusion and exclusion of patients with LEDVT who received VCFs. LEDVT, lower extremity deep vein thrombosis; VCF, vena cava filter.

at Nanjing First Hospital maintained the web-response randomization portal, updated the clinical database, and conducted all analyses independently from the investigators. The authors vouch for the completeness and accuracy of the data and ensure the adherence of the trial to the project. The Octoparms filter received regulatory approval from the National Meidical Products Administration in 2021.

Trial sample size, population, and randomization

Based on previous clinical research results of venous filters, the primary effective indicator, clinical success rate, was determined to be 95% when compared to the control product. A noninferiority margin of 10% was established through collaboratively between statistical and clinical experts. This margin was used to define the sample size and to evaluate the noninferiority of the Octoparms filter compared to the Celect filter in this study.

The sample size for this trial was based on the assumption that the clinical success rate would be 95% and the noninferiority margin would be 10% for both filters. Using PASS statistical software (NCSS, Kaysville, UT, USA), it was calculated that 94 participants per group, accounting for a 20% dropout rate, would be required to achieve a power of 0.80 and a significance level of 0.05 to detect differences between the two groups. The inclusion and exclusion criteria are listed in Table S1, and the study flowchart is shown in *Figure 1*. Between October 2017 and March 2019, 188 patients who had confirmed LEDVT or PE or who were at risk of PE with a clinical indication for VCF placement due to contraindication to or failure of anticoagulant therapy were included in the trial. Before enrollment, each patient underwent baseline testing, including routine hematological tests, electrocardiography, Doppler and compression ultrasonography of the legs, and computed tomography pulmonary artery (CTPA). Non-menopausal women additionally underwent a negative pregnancy test. For patients without contraindication, anticoagulant treatment was initiated immediately when thrombosis was identified. Eligible patients were randomly assigned to receive either a new VCF [Octoparms, Kosell MedTech (Suzhou) Co., Ltd., Suzhou, China] or an existing

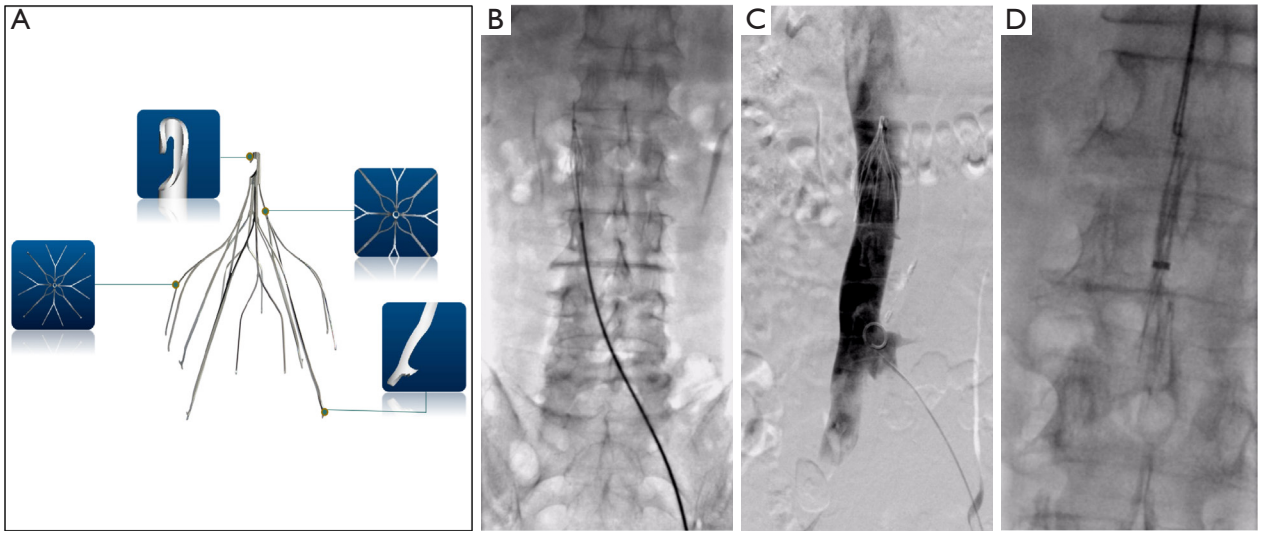

Figure 2 A schematic representation of the Octoparms filter and the procedure of its placement and retrieval. (A) Schematic of the design and structure of the Octoparms filter, showcasing its key features and components. (B) The filter is placed into the designated location. (C) Venography following the filter placement showing a well-performed placement and an unobstructed blood flow. (D) Retrieval procedure.

VCF (Celect, Cook Medical Inc., Bloomington, IN, USA) at a 1:1 ratio using a web-based central system. Ultimately, 94 patients were assigned to the Octoparms group and 94 to the Celect group.

The new VCF device and procedures

The novel VCF, Octoparms, is depicted in *Figure 2*. Constructed from a nickel-titanium alloy, it features a conical-shaped mesh structure with four pairs (eight) curved balancing arms and four support rods. The torsion-type fixed rivet at the end of each support rod attaches the filter to the IVC wall after placement. The retrieval hook is designed with a 360° configuration, allowing it to pass through a 0.035-inch guidewire.

Octoparms filters are available in two diameter options, 34 and 40 mm, suitable for IVCs with diameters of 12–20 and 15–30 mm, respectively. The training and standardization procedures for clinicians performing the VCF placement and retrieval were performed to ensure consistency across sites. Following IVC venography, the filter introducer sheath was percutaneously inserted via either the femoral vein or the internal jugular vein approach. Using a pusher, the filter was advanced through the sheath, positioned within the IVC by unsheathing and deploying it. The procedure is illustrated in *Figure 2*. Once the placement was completed, anterior-posterior and lateral venography of the IVC was performed to confirm the proper positioning of the filter. The decision and timing for filter removal were individualized by the referring interventional radiologist based on the patient's condition, with factors such as the resolution of PE risk or the patient's ability to tolerate anticoagulation being considered. Before filter retrieval, additional anterior-posterior and lateral venography of the IVC was obtained. The VCF was then retrieved using a 10- to 12-Fr filter retrieval sheath.

Endpoints and safety

The primary endpoint of the study was the clinical success rate as a composite endpoint, including both technical and clinical success of filter placement and retrieval. Technical success of filter placement or retrieval was defined as the filter being placed or retrieved completely intact without any immediate complications. Clinical success of filter placement was determined by evaluating whether the filter was appropriately positioned in the IVC to provide sufficient mechanical interruption to prevent incident symptomatic PE and by the absence of adverse events related to filter placement. These adverse events included filter migration, fracture, titling, IVC occlusion, filter- or procedure-related death, or failure of filter placement. Clinical success of filter retrieval was achieved when the filter was successfully and completely removed without requiring complex techniques

or the encountering of complications that necessitated further intervention (8).

The definitions for incident PE, filter migration, fracture, penetration, and tilt were in accordance with the Society of Interventional Radiology guidelines (8). Incident PE was defined as the occurrence of PE after filter placement as confirmed by CTPA or an altered ventilation/perfusion lung scan. Filter migration was defined as a significant change in the filter position of more than 20 mm (cranial or caudal direction) compared with the baseline deployed position as assessed by radiography, computed tomography, or venography. Filter fracture was defined as a loss of structural integrity of the filter (i.e., breakage or separation of filter components) as detected through imaging or autopsy. Filter penetration was defined as penetration of a filter leg or arm more than 3 mm outside the IVC wall as measured by computed tomography, ultrasound, or venography, or identified during autopsy. Filter tilt was categorized as greater than 15° based on the angle between the longitudinal axis of the target vein and the filter. Presence of filter thrombosis, indicated by a filling defect within the filter on venography, was recorded but not considered a clinical failure.

Adverse events, defined as untoward medical occurrences to the procedure or device, were recorded by the study investigators. The secondary endpoint of the study was the safety of filter placement and retrieval, with a focus on both procedure-related and filter-related complications; the former was associated with the procedure process, including bleeding at the access site or inflammation, while the latter was related to filter migration, deformation, vessel wall penetration, bleeding, peripheral organ damage, and IVC stenosis/occlusion. New or worsening LEDVT or IVC thrombosis was defined as the extension of LEDVT to a new venous segment in patients with documented evidence of thrombosis at baseline.

Statistical analysis

Statistical analyses were performed using SPSS 23 (IBM Corp., Armonk, NY, USA) and R statistical language software version 4.2.1 (The R Foundation for Statistical Computing, Vienna, Austria). Normality and homogeneity of variances were determined using the Shapiro-Wilk test and the Levene test. Continuous data are presented as the mean ± standard deviation (SD) and as the median and 25^{th} and 75^{th} percentiles, while categorical data are expressed as counts and percentages. To assess correlations between two groups and compare continuous data (e.g., age, circumference, IVC diameter, tilt angle, and time to filter retrieval), a *t*-test or Wilcoxon rank-sum test was used. Significance of categorical data was evaluated using the chi-square test or the Fisher exact test. Ranked data were assessed with the Wilcoxon rank-sum test or the Cochran-Mantel-Haenszel (CMH) test. The relationship between filter tilt during placement and retrieval was evaluated with a pairing graph using R software. Findings with $P<0.05$ (two-tailed) were deemed statistically significant.

Results

Patients and baseline characteristics

Between October 2017 and March 2019, a total of 188 eligible patients were enrolled and randomized into two groups based on the filter types: the Octoparms group (n=94) and the Celect group (n=94). The mean age of the patients was 58.4 years, and 52.1% (98/188) were male. The majority of patients were of Han ethnicity (96.8%). A body mass index (BMI) ≥28 kg/m^2 was observed in 17.0% (32/188) of patients. Regarding symptoms and signs of LEDVT, 64.9% (122/188) reported limb pain and 90.4% (170/188) reported limb swelling, with the mean circumference of the involved limb being 46.9 cm. Approximately 20.7% (39/188) had a D-dimer value ≥10 μg/mL (reference value <0.5 μg/mL). Concerning the thrombus distribution, a majority of the included patients experienced proximal LEDVT (85.1%) and involvement of the left limb (64.4%). Concurrent PE identified by CTPA was present in 49.5% (93/188) of patients. The most prevalent comorbidities and risk factors among patients with LEDVT were hypertension (30.3%) and trauma (29.8%). Baseline characteristics were comparable between the two groups ($P>0.05$). The demographics, LEDVT presentation, laboratory examinations, thrombus characteristics, concurrent PE, comorbidities, and risk factors for LEDVT in patients who received VCFs are summarized in *Table 1*.

Procedure and primary endpoints

Technical success of filter placement was achieved in 100% (188/188) of the patients enrolled in the study. VCFs were placed in the infrarenal vein (97.9%) and suprarenal vein (2.1%) via the access site of internal jugular vein (22.9%) or femoral vein (77.1%). There were no statistically significant differences observed in filter locations or access

Table 1 Baseline demographics, presentation of LEDVT, laboratory examination, thrombus characteristics, concurrent PE, comorbidities, and risk factors for LEDVT in patients who received VCFs

Characteristic	All patients (n=188)	Octoparms filter group (n=94)	Celect filter group (n=94)	P value
Age (years)	58.4±15.0	57.5±16.0	59.2±14.0	0.445
Gender				0.243
Male	98 (52.1)	53 (56.4)	45 (47.9)	
Female	90 (47.9)	41 (43.6)	49 (52.1)	
Ethnicity				>0.999
Han ethnicity	182 (96.8)	91 (96.8)	91 (96.8)	
Other ethnicity	6 (3.2)	3 (3.2)	3 (3.2)	
BMI[†]				>0.999
≥28 kg/m^2	32 (17.0)	16 (17.0)	16 (17.0)	
Symptoms and signs				
Dyspnea	8 (4.3)	1 (1.1)	7 (7.4)	0.065
Limb pain	122 (64.9)	63 (67.0)	59 (62.8)	0.541
Limb swelling	170 (90.4)	85 (90.4)	85 (90.4)	>0.999
Circumference (cm)	46.9±11.3	46.8±10.4	47.0±12.1	0.955
D-dimer value				0.208
≥10 μg/mL	39 (20.7)	23 (24.5)	16 (17.0)	
<10 μg/mL	149 (79.3)	71 (75.5)	78 (83.0)	
Thrombus limbs				
Left	121 (64.4)	62 (66.0)	59 (62.8)	0.648
Right	44 (23.4)	21 (22.3)	23 (24.5)	0.730
Bilateral	22 (11.7)	10 (10.6)	12 (12.8)	0.650
IVC involved	11 (5.9)	5 (5.3)	6 (6.4)	0.756
Isolated IVC	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Thrombus segments				0.682
Proximal DVT[‡]	160 (85.1)	79 (84.0)	81 (86.2)	
IDDVT[§]	28 (14.9)	15 (16.0)	13 (13.8)	
Concurrent PE	93 (49.5)	47 (50.0)	46 (48.9)	0.885
Comorbidities				
Hypertension	57 (30.3)	27 (28.7)	30 (31.9)	0.637
Diabetes mellitus	22 (11.7)	8 (8.5)	14 (14.9)	0.173
CAD	13 (6.9)	6 (6.4)	7 (7.4)	0.774
CVD	20 (10.6)	11 (11.7)	9 (9.6)	0.636
Hyperlipemia	5 (2.7)	1 (1.1)	4 (4.3)	0.368*
Lung infection	19 (10.1)	11 (11.7)	8 (8.5)	0.468
Disc herniation	10 (5.3)	8 (8.5)	2 (2.1)	0.051

Table 1 (*continued*)

Table 1 (*continued*)

Characteristic	All patients (n=188)	Octoparms filter group (n=94)	Celect filter group (n=94)	P value
Risk factors for LEDVT				
Trauma	56 (29.8)	26 (27.7)	30 (31.9)	0.524
History of major surgery	50 (26.6)	24 (25.5)	26 (27.7)	0.741
Autoimmune diseases	9 (4.8)	6 (6.4)	3 (3.2)	0.305
Previous VTE	22 (11.7)	12 (12.8)	10 (10.6)	0.650
Previous cancer	17 (9.0)	6 (6.4)	11 (11.7)	0.204
History of smoking	33 (17.6)	16 (17.0)	17 (18.1)	0.848

Continuous data are presented as the mean ± standard deviations; categorical data are presented as the count (percentage). *, Fisher exact test; †, 34 patients lacked BMI data; ‡, proximal DVT included thrombus in the common iliac vein, external iliac vein, common femoral vein, proximal and distal segments of the femoral vein, and/or popliteal vein; §, IDDVT included thrombus in the distal veins, including the anterior tibial vein, posterior tibial vein, peroneal vein, gastrocnemius muscle vein, and soleus muscle vein. LEDVT, lower extremity deep vein thrombosis; PE, pulmonary embolism; VCF, vena cava filter; BMI, body mass index; IVC, inferior vena cava; DVT, deep vein thrombosis; IDDVT, isolated distal deep vein thrombosis; CAD, cardiologic artery disease; CVD, cerebral venous disease; VTE, venous thromboembolism.

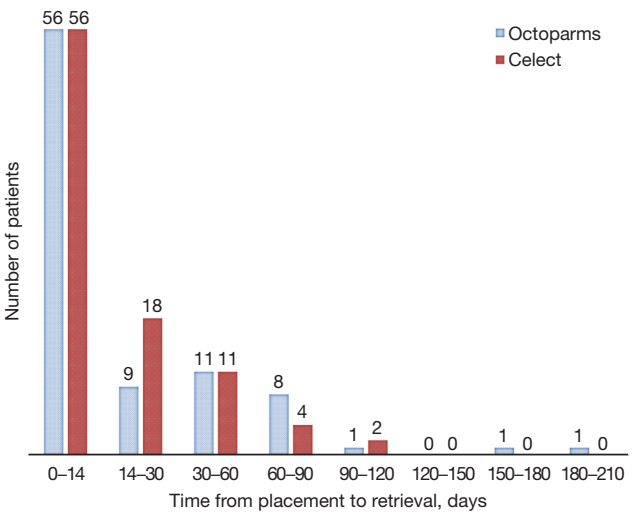

Figure 3 Dwelling time before VCF retrieval. VCF, vena cava filter.

sites (P>0.05). The mean IVC diameter at the site of filter placement was 20.3±3.3 mm. Thus, the 40-mm Octoparms and the 65-mm Celect filter types were selected. Clinical success of VCF placement was achieved in 100% (94/94) of patients in both the Octoparms group (94/94) and the Celect group (94/94).

There was a median dwelling time of 11.0 days (range, 4–190 days) in the Octoparms filter group and of 12.0 days (range, 4–113 days) in the Celect filter group (P>0.05) as shown in *Figure 3*. Ten VCFs were left *in situ* as permanent devices due to patient refusal (n=4), physician's decision due to severe illness (n=4), or non-filter-related death (n=2). The access site of filter retrieval for the remaining 178 patients was primarily via the right internal jugular vein (97.8%). Retrieval attempts were successfully completed in all cases, representing a 100% (178/178) technical success rate of filter retrieval. Clinical success rates of filter retrieval were also 100% in both groups (P>0.05). Filters were removed intact in all successful retrieval cases. Prior to filter retrieval, one patient (1/82, 1.22%) in the Octoparms group and two (2/82, 2.44%) in the Celect group were identified as incident PEs by CTPA, and all patients were asymptomatic. No new LEDVT or IVC thrombus were noted following venography at retrieval. No death was noted. Clinical successes of the two groups were 92.6% (87/94) for the Octoparms group and 96.8% (91/94) for the Celect group, with a difference of –4.2% [hazard ratio (HR) 2.441, 95% confidence interval (CI): 0.612–9.741; P=0.206]. The lower limit was lower than the noninferiority margin of –10%, indicating that the clinical success rate of the Octoparms group was noninferior to that of the Celect group.

Secondary endpoints

Eight patients experienced a total of eight procedure-related complications, including infection, sepsis, hypersensitivity reactions, fever, constipation, nausea, and lower abdominal pain, which are detailed in *Table 2*. The differences between the two groups were not statistically significant (P>0.05). During follow-up, two out-of-hospital deaths occurred in

the Octoparms group due to an unknown cause (3 weeks after placement) and esophageal cancer (7 months after placement). With respect to VCF-related complications, no instances of filter migration, deformation, IVC penetration, peripheral organ damage, or IVC stenosis/occlusion were observed. Moreover, 24 patients (27.6%) in the Octoparms group and 34 in the Celect (37.4%) group experience VCF thrombosis during IVC venography prior to retrieval (P>0.05). Two patients in the Celect group had massive clots necessitating the relinquishing of the VCFs as permanent

Table 2 Placement and retrieval procedure and clinical success of filter placement and retrieval for patients who received the Octoparms or Celect filters

Characteristic	All patients (n=188)	Octoparms filter group (n=94)	Celect filter group (n=94)	P value
Placement procedure				
Technical success of placement	188 (100)	94 (100)	94 (100)	NA
IVC diameter at placed sites (mm)	20.3±3.3	20.4±3.4	20.2±3.1	0.739
Vascular accesses for placement				
Right-side FV	118 (62.8)	55 (58.5)	63 (67.0)	0.227
Left-side FV	27 (14.4)	14 (14.9)	13 (13.8)	0.835
Right-side IJV	43 (22.9)	25 (26.6)	18 (19.1)	0.224
Filter location				0.621*
Infrarenal vein	184 (97.9)	93 (98.9)	91 (96.8)	
Suprarenal vein	4 (2.1)	1 (1.1)	3 (3.2)	
Filter tilt angle at the time of placement				
Title angle (°)	4.0 (2.3,7.0)	3.4 (2.2, 6.2)	4.6 (2.7, 7.4)	0.135
≥15°	2 (1.1)	1 (1.1)	1 (1.1)	>0.999*
Clinical success of filter placement	188 (100)	94 (100)	94 (100)	NA
Retrieval procedure				
Permanent VCF	10 (5.3)	7 (7.5)	3 (3.2)	0.194
Filter removal	178 (94.7)	87 (92.6)	91 (96.8)	0.194
Technical success of retrieval	178 (100)	87 (100)	91 (100)	NA
Vascular access for retrieval				
Right-side IJV	174 (97.8)	87 (100)	87 (95.6)	0.141
Left-side IJV	3 (1.7)	0 (0)	3 (3.3)	0.260
Right-side SCV	1 (0.6)	0 (0)	1 (1.1)	>0.999*
Time from VCF placement to retrieval (days)	12.0 (7.0, 22.0)	11.0 (7.0, 31.0)	12.0 (7.0, 20.3)	0.196
Filter tilt angle at the time of retrieval				
Title angle (°)	3.1 (2.0, 6.0)	3.3 (2.0, 5.1)	3.0 (2.0, 6.2)	0.502
≥15°	2 (1.1)	0 (0)	2 (2.2)	0.497*
Clinical success of filter retrieval	178 (100)	87 (100)	91 (100)	NA
PE incidence (n=164)	3 (1.8)	1 (1.2)	2 (2.4)	>0.999*
Clinical success rate	178 (94.7)	87 (92.6)	91 (96.8)	0.194

Table 2 (*continued*)

Table 2 (*continued*)

Characteristic	All patients (n=188)	Octoparms filter group (n=94)	Celect filter group (n=94)	P value
Procedure-related complications				
Infection	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Sepsis	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Hypersensitivity	1 (0.5)	0 (0)	1 (1.1)	>0.999*
Fever	1 (0.5)	0 (0)	1 (1.1)	>0.999*
Death	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Constipation	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Nausea	1 (0.5)	1 (1.1)	0 (0)	>0.999*
Lower abdominal pain	1 (0.5)	0 (0)	1 (1.1)	>0.999*
Filter-related complications	n=178	n=87	n=91	
Thrombosis in filter	58 (32.6)	24 (27.6)	34 (37.4)	0.164
Filter fracture	0 (0)	0 (0)	0 (0)	NA
Filter migration	0 (0)	0 (0)	0 (0)	NA
IVC penetration	0 (0)	0 (0)	0 (0)	NA

Continuous data are presented as the mean ± standard deviation; data with a nonnormal, negatively skewed distribution are presented as the median (P25, P75); categorical data are presented as the count (percentage). *, Fisher exact test. NA, not applicable; IVC, inferior vena cava; FV, femoral vein; IJV, internal jugular vein; VCF, vena cava filter; SCV, subclavian vein; PE, pulmonary embolism.

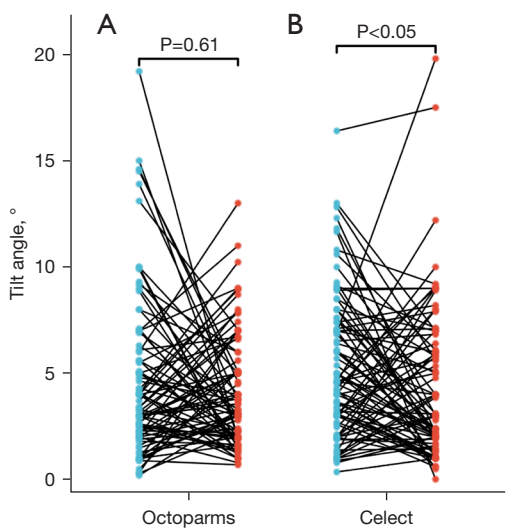

Figure 4 The distributions of filter tilt angle at the time of placement and retrieval for both groups. (A) In the Octoparms group, there was no statistically significant difference between filter tilt angles at the time of placement and the time of retrieval (P=0.61). (B) In the Celect group, there was statistically significant difference between filter tilt angles at the time of placement and the time of retrieval (P<0.05).

devices under physician's decision. Clots in Octoparms were small and nonfloating, exerting minimal impact on the IVC hemodynamics and not impeding filter retrieval. The distributions of filter tilt angle at placement and retrieval are shown in *Figure 4*. Two cases in the Octoparms group and one in the Celect group lacked tilt data at retrieval; however, the difference in filter tilt between the groups was not significant (P>0.05). During placement, one patient (1/94, 1.06%) in each group exhibited a tilt >15°. Tilt angle in the Octoparms group decreased from 19.2° to 1.9°, and thus there were no cases of tilt >15° in the Octoparms group. In the Celect group, one case showed an increase to 17.5°, and another case exhibited an increase to 19.8°, resulting in a total of two cases (2/90, 2.22%) with a tilt >15°.

Discussion

Over the past half a century, VCF research and development has progressed and has been investigated in a number of prospective studies and applied in a variety of clinical practices (5-7,9-13). Conical VCFs, in various forms, have advanced significantly from the introduction of the Greenfield filter in 1973 to the more recent Denali filter in 2014. These

innovations have catalyzed substantial improvements in various aspects of filter technology. However, each filter has distinct advantages and disadvantages, and prospective comparative studies on different types of filters remain limited (1,3,6). Data on the retrieval characteristics of different filter types will be instrumental in guiding VCF selection in clinical practice (6). In our study, we compared the Octoparms filter with the Celect filter based on two primary factors. First, the Octoparms filter shares several characteristics with the Celect filter, including a similar morphological structure, characterized by a conical shape with four support struts and a four-paired inverted Y-shape balance arms; for another, the Celect filter is widely available in China and has been extensively used among the conical VCFs, with reports indicating its efficacy and safety.

In our study, among the 188 patients who received VCFs, the clinical success rate was 92.6% for those who received the Octoparms filter, compared to 96.8% for those who received the Celect filter. This slightly lower rate for the Octoparms filter may be attributable to a conservative definition of clinical success, which comprehensively evaluated both technical and clinical success from placement to retrieval. However, the success rate of the Octoparms filter was noninferior (within the established threshold value of −10%) to that of the Celect filter. Among the 10 patients classified as clinical failures, the filters were left *in situ* as permanent devices, resulting in a failure to meet the primary endpoint. Apart from these 10 cases, the remaining 178 patients who underwent intended filter retrieval experienced complete clinical success.

In this study, preoperative compressive ultrasonography confirmed the presence of LEDVT in all 188 patients. Among these patients, 49.5% were found to have PE according to CTPA, which is consistent with the 58.9% incidence rate reported in a previous study (14). The higher morbidity rates of PE observed in our study and that of Jin *et al.* (14) likely stemmed from the increased use of CTPA for detection. However, in most clinical cases, CTPA is typically performed only patients with LEDVT and symptomatic PE, potentially leading to an underestimation of PE and missed diagnoses in asymptomatic patients with LEDVT. These findings suggest that patients with LEDVT may have a higher propensity for silent PEs during the disease course, highlighting the clinical implications of CTPA in these patients. The potential risk of incident PE arises from clots escaping even after filter placement (6). The incident PE rate reported in previous filter trials ranges from 1% to 6% (6,9-13), which is in line with the results of our study. The rates were comparable between the two filter types (1.22% *vs.* 2.44%; P>0.05). Fortunately, all three cases with incident PEs were asymptomatic, likely due to the small volume of clots captured by the filter and distal branch embolism of the pulmonary artery. Additionally, these patients had good cardiopulmonary fitness, reducing the risk of symptomatic PE.

The overall retrieval rate of retrievable filters is reported to be 20–50%, primarily due to concerns over the risks associated with permanent placement and the lack of a planned follow-up for patients (6). In our study, 94.7% of participants returned to the outpatient clinic and underwent clinical and imaging assessments for filter retrieval, in accordance with the study procedure. This indicated the paramount effectiveness of a dedicated VCF program and a patient planned follow-up by implanting physicians or clinicians in improving overall filter retrieval rates. Of the 178 patients who underwent filter retrieval attempts, all had their filters successfully retrieved without the need for any complex technique or experiencing complications requiring intervention. No instances of filter migration, deformation, IVC penetration, bleeding, peripheral organ damage, or IVC stenosis/occlusion were observed between the time of filter placement and retrieval, supporting the safety of the Octoparms filter.

As previously reported, the incidence of IVC thrombosis is 4–15%. However, the incidence of IVCF thrombosis is more variable, ranging from 1.6% to 33% across different studies (15). In our present study, the overall incidence of IVCF thrombosis with conical VCFs was 32.6%, which is lower than that reported previously (15). This may be partly attributable to the improved design of the VCFs and the lower inherent thrombogenicity, as demonstrated in other study (16). The incidence of VCF thrombosis was 27.6% for the Octoparms filter and 37.4% for the Celect filter. It is possible that the thrombi detected were either formed at the insertion site or were intercepted from LEDVT migration by the filter, but these possibilities were not adequately explored. Notably, the definition of VCF thrombosis in this study was conservative, as patients with filling defects in the filter on venography were considered to have thrombosis. This may have led to an overestimation of the incidence. A more accurate CT-based diagnosis for filter thrombosis was not used in our study.

It is worth noting that a filter tilt >15° is considered to be risk factor for increased filter hook embedment and the need for complex filter retrieval techniques (17). In the study by Bos *et al.* (12), the complex retrieval rate was 18.9% in the

Celect group. Although two patients in our study exhibited anterior-posterior angulation >15° in preretrieval according venography imaging, nonstandard filter retrieval techniques such as forceps retrieval or the loop-snare technique were not required. It is well-established that prolonged indwell time, along with filter tilt, is a recognized risk factor for complex retrieval, leading to higher rates of penetration, tilt, and filter tip embedment. The discrepancy between our findings and those of Bos *et al.* (12) may be explained by the prolonged indwelling time of 128.2 days in their study compared to the shorter indwelling time (12 and 105 days) in our study. This highlights the importance of retrieving the filter as early and as decisively as possible when clinically appropriate.

Although the relationship between vascular access and filter tilt has been previously documented (18,19), the impact of vascular access on VCF placement remains controversial. In a retrospective cohort study of 78 patients, Choi *et al.* (18) reported no significant difference in filter tilt between the vascular access of internal jugular veins and femoral veins. In a larger study that involved 13,003 patients in which the association between internal jugular vein and femoral vein access was evaluated, Grullon *et al.* (19) found that the internal jugular vein approach might allow for more precise placement and less tilt. In our study, the selection of vascular sites was comparable between the two groups. The incidence of filter tilt angle >15° at the time of placement was 1.1% for the Octoparms filter and 1.1% for the Celect filter. Prior to filter retrieval, no tilt angle >15° was observed in the Octoparms group, and the reduction in angulation from prefilter retrieval to postplacement seemed be for pronounced in the Octoparms group than in the Celect group. A potentially clinically relevant finding of this trial was a slightly higher self-adjustment and self-centering capacity of the Octoparms filter.

This involved several limitations that merit discussion. First, as a manufacturer-sponsored device trial, inherent bias might have affected the interpretation of results and should be considered. Second, although this trial was prospective in nature, its design including a comparison with the Celect filter rather than with other types of VCFs may introduce certain limitations. Third, the use of CTPA imaging both pre-VCF placement and pre- or post-VCF retrieval might have resulted in an increased radiation dose compared with other IVC filter trials. In addition, the high incidence of filter thrombosis observed in this study needs further explanation (20). It is possible that the detected thrombi were either formed at the insertion site or intercepted from LEDVT migration by the filter, but these possibilities were not thoroughly explored. Furthermore, the sample size in this study was relatively small for comprehensive assessment. The short duration of filters being left *in situ* could have reduced the statistical power to demonstrate any potential differences in complications between the two types of filters. In addition, the costs of the filters and the radiological procedural time were not reported. Future studies with larger sample sizes are necessary to address these limitations and provide a more robust understanding of this new filter.

Conclusions

The Octoparms filter exhibited a high rate of clinical success with a low rate of complications during placement and retrieval, demonstrating noninferiority to the Celect filter. The Octoparms filter may provide an option for VCFs in patients requiring PE prophylaxis due to LEDVT.

Acknowledgments

We would like to thank all the investigators from 10 centers who prepared and executed the trial (https://cdn.amegroups.cn/static/public/qims-24-879-1.docx).

Funding: This work was supported by the Jiangsu Medical Association Special Fund Project (No. SYH-3201140-0088[2023035]), the Nanjing Medical Science and Technology Development Project (No. YKK23116), and the Nanjing Medical University Science and Technology Development Fund Project (No. NMUB20230163).

Footnote

Reporting Checklist: The authors have completed the CONSORT (for noninferiority or equivalence randomized trial) reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-24-879/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-24-879/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was

performed in accordance with Declaration of Helsinki (as revised in 2013) and was reviewed and approved by the institutional review board of Nanjing First Hospital (No. QX20170714-02). All participating hospitals were informed and agreed with the study. Written informed consent was obtained from every patient or their legal surrogates.

References

1. Kaufman JA, Barnes GD, Chaer RA, Cuschieri J, Eberhardt RT, Johnson MS, Kuo WT, Murin S, Patel S, Rajasekhar A, Weinberg I, Gillespie DL. Society of Interventional Radiology Clinical Practice Guideline for Inferior Vena Cava Filters in the Treatment of Patients with Venous Thromboembolic Disease: Developed in collaboration with the American College of Cardiology, American College of Chest Physicians, American College of Surgeons Committee on Trauma, American Heart Association, Society for Vascular Surgery, and Society for Vascular Medicine. J Vasc Interv Radiol 2020;31:1529-44.
2. Bikdeli B, Wang Y, Jimenez D, Parikh SA, Monreal M, Goldhaber SZ, Krumholz HM. Pulmonary Embolism Hospitalization, Readmission, and Mortality Rates in US Older Adults, 1999-2015. JAMA 2019;322:574-6.
3. Sheahan KP, Tong E, Lee MJ. A review of inferior vena cava filters. Br J Radiol 2023;96:20211125.
4. Jia Z, Wu A, Tam M, Spain J, McKinney JM, Wang W. Caval Penetration by Inferior Vena Cava Filters: A Systematic Literature Review of Clinical Significance and Management. Circulation 2015;132:944-52.
5. Decousus H, Leizorovicz A, Parent F, Page Y, Tardy B, Girard P, Laporte S, Faivre R, Charbonnier B, Barral FG, Huet Y, Simonneau G. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. Prévention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. N Engl J Med 1998;338:409-15.
6. Ahmed O, Sheikh S, Tran P, Funaki B, Shadid AM, Navuluri R, Van Ha T. Inferior Vena Cava Filter Evaluation and Management for the Diagnostic Radiologist: A Comprehensive Review Including Inferior Vena Cava Filter-Related Complications and PRESERVE Trial Filters. Can Assoc Radiol J 2019;70:367-82.
7. Lyon SM, Riojas GE, Uberoi R, Patel J, Lipp ME, Plant GR, De Gregorio MA, Günther RW, Voorhees WD, McCann-Brown JA. Short- and long-term retrievability of the Celect vena cava filter: results from a multi-institutional registry. J Vasc Interv Radiol 2009;20:1441-8.
8. Caplin DM, Nikolic B, Kalva SP, Ganguli S, Saad WE, Zuckerman DA; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2011;22:1499-506.
9. Johnson MS, Nemcek AA Jr, Benenati JF, Baumann DS, Dolmatch BL, Kaufman JA, Garcia MJ, Stecker MS, Venbrux AC, Haskal ZJ, Avelar RL. The safety and effectiveness of the retrievable option inferior vena cava filter: a United States prospective multicenter clinical study. J Vasc Interv Radiol 2010;21:1173-84.
10. Smouse HB, Mendes R, Bosiers M, Van Ha TG, Crabtree T; RETRIEVE Investigators. The RETRIEVE trial: safety and effectiveness of the retrievable crux vena cava filter. J Vasc Interv Radiol 2013;24:609-21.
11. Clements W, Moriarty HK, Paul E, Goh GS. Stratification of Pre-procedure Risk Factors Associated with Difficult-to-remove Inferior Vena Cava (IVC) Filters: A 6-year Retrospective Analysis at a Tertiary Center. Cardiovasc Intervent Radiol 2020;43:238-45.
12. Bos AS, Tullius T, Patel M, Leef JA, Navuluri R, Lorenz JM, Van Ha TG. Indwelling and Retrieval Complications of Denali and Celect Infrarenal Vena Cava Filters. J Vasc Interv Radiol 2016;27:1021-6.
13. Zhu X, Tam MD, Bartholomew J, Newman JS, Sands MJ, Wang W. Retrievability and device-related complications of the G2 filter: a retrospective study of 139 filter retrievals. J Vasc Interv Radiol 2011;22:806-12.
14. Jin S, Sun Z, Li X, Jian T, Jin X, Li S, Wang G, Ma C, Cui K, Xu P. May-Thurner syndrome and the risk of pulmonary embolism in patients with acute deep venous thrombosis. J Vasc Surg Venous Lymphat Disord 2018;6:433-440.e1.
15. Angel LF, Tapson V, Galgon RE, Restrepo MI, Kaufman J. Systematic review of the use of retrievable inferior vena cava filters. J Vasc Interv Radiol 2011;22:1522-1530.e3.
16. Mismetti P. Randomized trial assessing the efficacy of the

partial interruption of the inferior vena cava by an optional vena caval filter in the prevention of the recurrence of pulmonary embolism. PREPIC 2 trial: prevention of embolic recurrences by caval interruption (prospective, multicentric, randomised, open trial). Rev Pneumol Clin 2008;64:328-31.
17. Glocker RJ, Novak Z, Matthews TC, Patterson MA, Jordan WD, Pearce BJ, Passman MA. Factors affecting Cook Gunther Tulip and Cook Celect inferior vena cava filter retrieval success. J Vasc Surg Venous Lymphat Disord 2014;2:21-5.
18. Choi SJ, Lee SY, Ryeom HK, Kim GC, Lim JK, Lee SM, Kim WH. Femoral versus jugular access for Denali Vena Cava Filter placement: Analysis of fluoroscopic time, filter tilt and retrieval outcomes. Clin Imaging 2018;52:337-42.
19. Grullon J, Qato K, Bahroloomi D, Nguyen N, Conway A, Leung TM, Pamoukian V, Giangola G, Carroccio A. Effect of access site choice on inferior vena cava filter angulation and outcomes. J Vasc Surg Venous Lymphat Disord 2023;11:326-30.
20. Gong M, Liu Z, Kong J, Zhao B, Jiang R, He X, Wang T, Gu J. Incidence and risk factors for inferior vena cava filter thrombosis detected at time of filter retrieval in patients with lower extremity deep vein thrombosis: a multicenter retrospective cohort study. Quant Imaging Med Surg 2023;13:8313-25.

Cite this article as: Gong M, Zhao B, Liu J, Teng G, Ni C, Xu H, Li Z, Zhai S, Zhang Y, Xiang H, Yang W, Gu J. Efficacy and safety of a novel vena cava filter on pulmonary embolism prophylaxis: a prospective, multicenter, randomized, parallel, positive-controlled, noninferiority clinical trial. Quant Imaging Med Surg 2024;14(10):7073-7085. doi: 10.21037/qims-24-879