Int J Clin Exp Med 2019;12(5):5867-5873
www.ijcem.com /ISSN:1940-5901/IJCEM0085493

Original Article

Clinical efficacy and safety of a new inferior vena cava filter retrieving technique using 9-Fr long sheath combined with memorable alloy trap

Linjun Wang[1], Wei Han[1], Yangmin Dong[1], Songmao Wang[1], Huanle Jiang[1], Yanxin Guo[2]

[1]Department of Vascular Surgery, Hangzhou Third Hospital, Hangzhou 310009, China; [2]Department of Ultrasound, Hangzhou Hospital of Zhejiang Medical and Health Group, Hangzhou 310022, China

Received September 14, 2018; Accepted February 12, 2019; Epub May 15, 2019; Published May 30, 2019

Abstract: *Background:* Anticoagulant therapy is the first choice for venous thromboembolism (VTE), and the inferior vena cava (IVC) filter is implanted when the anticoagulant therapy fails or the anticoagulation contraindications exist. The retrieving of IVC filter is very important in the treatment. This study aimed to investigate the clinical efficacy and safety of a new inferior vena cava filter retrieving technique using 9-Fr long sheath combined with memorable alloy trap. *Methods:* Thirty-four VTE patients who were implanted with Cook Celect/Günther Tulip retrievable IVC filters were enrolled. They were divided into conventional retrieving group (20 cases) and long sheath + trap group (14 cases), which received the filter retrieving using the Cook MReye filter retrieving system and using 9-Fr long sheath combined with memorable alloy trap, respectively. The duration of filter in body, duration of filter retrieving surgery, radiation exposure time, intraoperative/postoperative adverse events, length of hospitalization, and treatment cost were recorded and compared in two groups. *Results:* The success rate of filter retrieving surgery was 100% in each group. The duration of filter retrieving surgery in long sheath + trap group was 29.36 ± 10.72 minutes, which was significantly shorter than 39.45 ± 15.94 minutes in conventional retrieving group ($P < 0.05$). The radiation exposure time in long sheath + trap group was 8.43 ± 1.40 minutes, which was significantly shorter than 11.80 ± 2.14 minutes in the conventional retrieving group ($P < 0.01$). The treatment cost in long sheath + trap group was 10126.79 ± 1612.17 yuan, which was significantly lower than 12226.50 ± 1182.72 yuan in conventional retrieving group ($P < 0.05$). There was no serious adverse event in surgery or postoperative follow-up in each group. *Conclusion:* The technique using 9-Fr long sheath combined with memorable alloy trap is a safe, effective and economical method for IVC filter retrieving and can be applied in the clinic.

Keywords: Inferior vena cava, filter, retrieving, 9-Fr long sheath, memorable alloy trap

Introduction

Venous thromboembolism (VTE) is a common clinical disease. According to the epidemiological survey in the United States, the incidence of VTE is as high as 422/100000 [1]. The Antithrombotic Therapy and Prevention of Thrombosis Guidelines issued by American College of Chest Physicians (ACCP) recommends that anticoagulant therapy be the first choice for VTE patients, and the inferior vena cava (IVC) filter should be implanted when the anticoagulant therapy fails or the anticoagulation contraindications exist [2]. After implantation of permanent IVC filter, with the time going on, the probability of severe adverse events such as filter displacement, fracture, perforating vascular wall and IVC obstruction is gradually increased [3]. Therefore, the retrievable IVC filters are developed. They can be timely taken out without need of filter protection, which can avoid a series of adverse events that occur later [4]. The application of retrievable IVC filters has been increasingly widespread, and they have replaced most of permanent filters. Cook Celect/Günther Tulip retrievable IVC filter (Cook Medical Corp., IN, USA) is one of the common clinical products used in our department. However, the matched Cook MReye filter retrieving system (Cook Medical Corp., IN, USA) is not incorporated into the local medical insurance catalogue in China, and the patients receiving the filter retrieving need to pay the cost of this system. 9-Fr long sheath (Cook Medical Corp.,

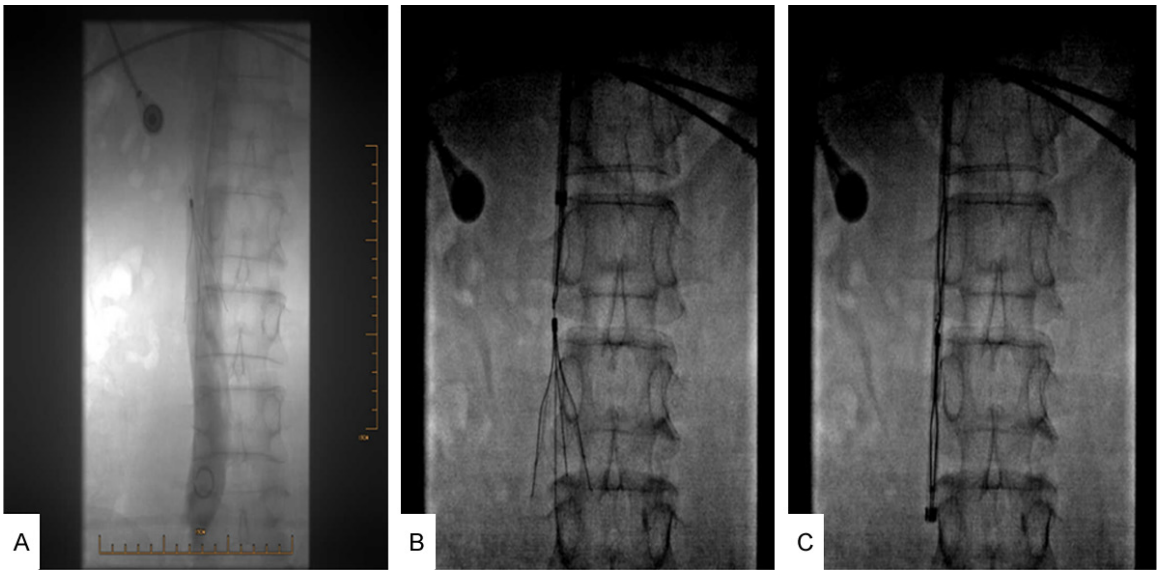

Figure 1. Inferior vena cava filter retrieving using Cook MReye filter retrieving system. A: Angiography confirmed that the inferior vena cava was unobstructed, with no obvious filling defect in the filter. B: Cook MReye filter retrieving device was inserted. The retrieving trap was adjusted to lock the tail hook of filter. C: The long sheath was pushed, and the filter was retrieved into the long sheath.

IN, USA), memorable alloy trap (SHSMA Medical Corp., Shanghai, China) and assorted single-bend catheter (Cordis Corp., FL, USA) are often used in peripheral vascular surgeries. They are incorporated into the local medical insurance catalogue in China. In order to reduce the economic burden of the patients, the filter retrieving technique using 9-Fr long sheath combined with memorable alloy trap has been developed in our department. In this study, the clinical data of patients receiving filter retrieving using 9-Fr long sheath combined with memorable alloy trap and conventional filter retrieving technique were collected, and their efficacy and safety were compared.

Patients and methods

Patients

Thirty-four VTE patients who were implanted with the Cook Celect/Günther Tulip retrievable IVC filters and received the filter retrieving in Department of Vascular Surgery, Hangzhou Third Hospital (Hangzhou, China) from January 2014 to March 2017 were enrolled in this study. According to the method of filter retrieving, the patients were divided into the conventional retrieving group (using the Cook MReye filter retrieving system, 20 cases) and the long sheath + trap group (using 9-Fr long sheath combined with memorable alloy trap, 14 cases). The choice of the filter retrieving method was based on the wish of the patients after detailed communication. This study was approved by the Ethics Committee of Hangzhou Third Hospital. Written informed consent was obtained from all participants.

Inclusion criteria and exclusion criteria

The inclusion criteria were as follows: i) all patients received thrombus clearance (catheter-directed thrombolysis/Angiojet thrombus aspiration) and implantation of the IVC filter due to the central lower extremity deep vein thrombosis (DVT); ii) the interval between filter implantation and filter retrieving was not more than 4 weeks; iii) the enhanced CT examination confirmed that the IVC was unobstructed and there was no significant thrombosis load in filter (thrombus diameter < 1 cm); iv) the filter was in normal position, or it was inclined without perforation or embedding of the end. The exclusion criteria were as follows: i) the patients used other types of filters; ii) the interval between filter implantation and filter retrieving was more than 4 weeks; iii) the enhanced CT examination showed that the filter perforated outside the IVC wall or had serious displacement; iv) the preoperative ultrasound found the right jugular vein thrombosis, anatomical variation and other abnormalities.

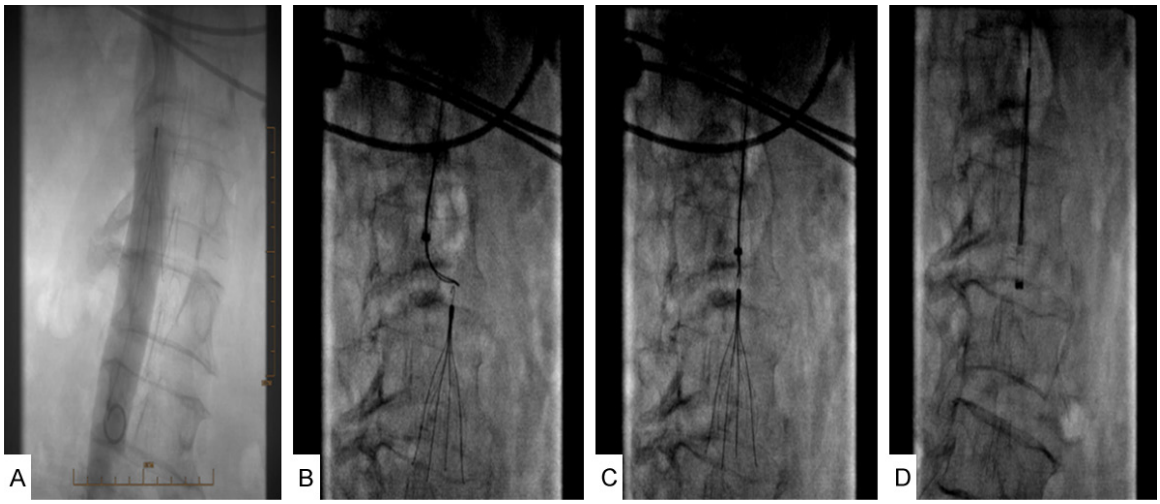

Figure 2. Inferior vena cava filter retrieving using 9-Fr long sheath combined with memorable alloy trap. A: Angiography confirmed that the inferior vena cava was unobstructed, with no obvious filling defect in the filter. B: 9-Fr long sheath was inserted, and the 5-Fr single-bend catheter containing memorable alloy trap was placed. C: The direction of memorable alloy trap was adjusted to trap the tail hook of filter. D: The long sheath was pushed, and the filter was retrieved into the long sheath.

Preoperative preparation

Before the operation, the IVC enhanced computed tomography (CT) scanning was performed to confirm the IVC patency and to understand the thrombus load in the filter. Pulmonary artery-computed tomography angiography (CTA) was performed to understand the pulmonary embolization (PE) and the embolization site. In all patients, the Cook Celect/Günther Tulip filter was retrieved through the jugular approach. The right internal jugular vein condition was evaluated by B-ultrasound. Routine blood tests were used to exclude the surgical contraindications.

Surgical methods

In the conventional retrieving group, the patient was in the supine position. The infiltration anesthesia was performed by injection with 1% lidocaine at the surface projection site of right internal jugular vein in the right carotid triangle area. Under the B-ultrasound positioning, the right internal jugular vein was punctured using Seldinger method. The 5-Fr sheath was placed. The 5-Fr pigtail catheter was guided by the guide wire to descend to the common iliac vein through the vena cava. The patency of IVC was confirmed by radiography. After confirming that there was no obvious filling defect in the filter or IVC under filter, the Cook MReye filter retrieving device was inserted by exchange. The retrieving trap was adjusted to lock the tail hook of filter. After fixing the filter with retrieving device, the filter was closed up using the long sheath of retrieving device, and then was taken into the long sheath (**Figure 1**). After the operation, radiography was performed again to confirm the patency of IVC, with no abnormal sign such as contrast agent extravasation, IVC stenosis or residual IVC wall thrombosis.

In the long sheath + trap group, the body position of patients, anesthesia method, puncture and sheathing, and IVC angiography were the same with those in conventional retrieving group. After angiography evaluation, the 9-Fr long sheath was inserted by exchange, and the 5-Fr single-bend catheter containing memorable alloy trap was placed. The direction of the trap was adjusted to trap the tail hook of filter. The single-bend catheter was pushed, and the tail hook of filter was locked. Then, the long sheath was pushed, and the filter was retrieved into the long sheath (**Figure 2**). Postoperative radiography was performed to confirm the existence of abnormal signs or not.

During surgery, all patients were given standard whole body heparinization (80-100 unit/kg heparin sodium, with addition by 18-20 unit/kg per hour). The standard anticoagulant therapy was performed during the perioperative period.

Table 1. General information of patients

Index	Conventional retrieving group	Long sheath + trap group	t/χ^2	P
n	20	14		
Gender [n (%)]			2.835	0.092
Male	13 (65.00)	5 (35.71)		
Female	7 (35.00)	9 (64.29)		
Age (years)	58.81 ± 16.92	57.93 ± 13.33	0.162	0.872
DVT site [n (%)]			2.072	0.150
Left side	16 (80.00)	8 (57.14)		
Right side	4 (20.00)	6 (42.86)		
Combined PE [n (%)]			2.505	0.113
Yes	6 (30.00)	8 (57.14)		
No	14 (70.00)	6 (42.86)		
Combined LIVS [n (%)]	2 (10.00)	4 (28.57)	1.954	0.162
DVT clearance method [n (%)]			3.603	0.058
CDT	15 (75.00)	6 (42.86)		
Angiojet thrombus aspiration	5 (25.00)	8 (57.14)		

DVT, Deep vein thrombosis; PE, pulmonary embolism; LIVS, left iliac venous stenosis; CDT, catheter-directed thrombolysis.

The oral administration of warfarin or rivaroxaban was selected according to the patient's economic conditions and wishes. The pulmonary artery CTA was reexamined on the second day after the surgery.

Follow-up

After 1, 2, and 4 weeks from surgery, ultrasound examination was performed on the jugular vein and IVC to confirm whether there were puncture point hematoma, thrombosis or stenosis in jugular vein, thrombosis in IVC, and exudation or hematoma beside IVC.

Data collection

The general data of all patients were collected, including gender, age, VTE site, combined pulmonary embolism (PE), VTE clearance method, etc. In addition, the duration of filter in body (from filter implantation to retrieving), duration of filter retrieving surgery, radiation exposure time, intraoperative/postoperative adverse events (filter retrieving failure, IVC injury, postoperative residual IVC stenosis, residual wall thrombosis, intraoperative/postoperative new PE, puncture site complications, etc.), length of hospitalization and treatment cost were recorded.

Statistical analysis

All statistical analysis was carried out using SPSS 22.0 software (SPSS Inc., Chicago, IL, USA). The enumeration data are presented as number and rate, and were compared using χ^2 test. The measurement data are presented as mean ± SD, and were compared using t test. $P < 0.05$ was considered as statistically significant.

Results

General information of patients

In 34 patients, the average age was 58.4 ± 15.3 years. There were 18 males (52.94%) and 16 females (47.06%). Twelve patients (35.29%) were implanted with Cook Celect retrievable filter and 22 patients (64.71%) were implanted with Günther Tulip retrievable filter. The duration of filter in the body was 8-28 days.

In the conventional retrieving group, there were 20 cases using Günther Tulip retrievable filter and 0 case using Cook Celect retrievable filter, respectively. In the long sheath + trap group, there were 2 cases using Günther Tulip retrievable filter and 12 cases using Cook Celect retrievable filter, respectively. There was no significant difference of gender, age, DVT site, combined PE, combined left iliac venous stenosis or DVT clearance method between the two groups (**Table 1**).

Efficacy of two filter retrieving methods

In each group, the success rate of filter retrieving surgery reached 100%. The duration of filter

Table 2. Efficacy of two filter retrieving methods

Index	Conventional retrieving group	Long sheath + trap group	t	P
Duration of filter in body (day)	22.55 ± 13.48	22.50 ± 9.22	0.012	0.990
Duration of filter retrieving surgery (min)	39.45 ± 15.94	29.36 ± 10.72	2.060	0.047
Radiation exposure time (min)	11.80 ± 2.14	8.43 ± 1.40	5.158	< 0.001
Length of hospitalization (days)	1.75 ± 0.79	1.57 ± 0.65	0.702	0.488
Treatment cost (yuan)	12226.50 ± 1182.72	10126.79 ± 1612.17	4.387	< 0.001

retrieving surgery in long sheath + trap group was 29.36 ± 10.72 minutes, which was significantly shorter than 39.45 ± 15.94 minutes in the conventional retrieving group ($P < 0.05$). The radiation exposure time in long sheath + trap group was 8.43 ± 1.40 minutes, which was significantly shorter than 11.80 ± 2.14 minutes in the conventional retrieving group ($P < 0.01$). In addition, the treatment costs of filter retrieving surgery in conventional retrieving group and long sheath + trap group were 12226.50 ± 1182.72 yuan and 10126.79 ± 1612.17 yuan, respectively. Even without considering the incorporation of medical insurance reimbursement, the treatment cost in long sheath + trap group was significantly lower than that in conventional retrieving group ($P < 0.05$) (**Table 2**). This helped to reduce the economic burden of the patients.

Safety of two filter retrieving methods

There was no serious adverse event (postoperative new PE or recurrent PE, death, filter retrieving failure, IVC rupture, residual IVC stenosis, residual IVC wall thrombosis, puncture site complications, etc.) in each group. In the long sheath + trap group, there was 1 patient (7.14%) in which the filter was difficult to be retrieved due to the serious filter inclining and filter tail hook sticking to vena cava wall. In this case, the Loop technique was added to the 9-Fr long sheath combined with memorable alloy trap, and then the filter was successfully taken out. In each group, no serious adverse event occurred in the postoperative follow-up.

Discussion

VTE can lead to the high disability and high mortality [5]. The DVT of lower extremity and PE are the most common forms of VTE [6]. The implantation of IVC filter is an important supplementary technique in treatment of VTE, which can reduce the risk of PE in DVT patients [7]. Although it has been reported that, in the DVT treatment there is no significant differences in PE incidence, VTE recurrence or thrombus formation between using permanent filter and retrievable filter [8], the time prolongation of filter in body can increase the probability of implantation related complications [3, 9]. The complications after the implantation of the IVC filter include IVC thrombosis, filter penetration into IVC wall, filter displacement, filter fracture, etc. [10]. Some literature [11, 12] has reported that the filter can migrate to right atrium and pulmonary artery, perforate duodenum and small intestine, and even the filter reversely can migrate to the rectum. The incidence of the above complications will increase with the increase of the duration of filter in body [13, 14]. Therefore, FDA clearly suggests that, if the protective effect of temporary filter on PE is no longer obvious, it should be taken out as soon as possible [12].

In treatment of VTE, the implantation of temporary filters or retrievable filters and retrieving them as early as possible has become a consensus in current clinical practice. Adopting the retrievable devices equipped by the manufacturer is the currently internationally used method. However, it has been found that, the dissatisfaction of retrieving rate of recoverable filter is related to the postoperative loss of visit and the use of conventional retrieving methods [15]. Even it has been reported that, more than 15% of patients suffer from filter retrieving failure due to using the conventional filter retrieving method [16].

In clinical practice, our experiences in using the conventional filter retrieving method and long sheath + trap method are as follows: (i) As the trap of the Cook MReye retrieving device is not memorable, the strangling is easy to happen during the hook process, which leads to the dif-

ficulty in trapping the tail hook of filter, even sometimes the trap needs to be taken out for reshaping. The memorable alloy trap can effectively ensure the elliptical shape when it is working. The operator can conveniently adjust the direction of trap so as to trap the tail hook. In addition, the working area of the memorable alloy trap is larger than that of Cook MRey device. This also greatly facilitates the trapping of filter tail hook. (ii) The Cook MReye device has straight head long sheath, which lacks direction orientation for the inclined and adherent filter. However, the 9-Fr long sheath can freely select the straight head or bended head, and even the Fustar adjustable sheath can be used as one of the options. Even without considering the head shape of the long sheath, the single-bend catheter can be controlled and rotated freely. This greatly increases the intraoperative manipulation and shortens the trapping time. In this study, the duration of filter retrieving surgery and radiation exposure time in long sheath + trap group were significantly shorter than those in conventional retrieving group, respectively. This indicates that, the 9-Fr long sheath combined with the memorable alloy trap can effectively shorten the length of operation, thus reducing the radiation exposure time. (iii) The external diameter of the Cook MReye filter retrieving device is 11-Fr. Compared with Cook MReye device, the 9-Fr long sheath system can reduce the damage to the approach-involved vessels, and the complications of the puncture point.

In addition, in this study, even without considering the incorporation of medical insurance reimbursement, the treatment cost in long sheath + trap group was significantly lower than that in conventional retrieving group ($P < 0.05$). If the medical insurance reimbursement was considered, the treatment cost of the patients used the new retrieving method will be greatly reduced, compared with patients using conventional retrieving method. A further detailed cost-benefit analysis on the total treatment cost and cost of simple surgical consumables will be done in the future. It is believed that, the long sheath with memorable alloy trap is of great benefit for the reduction of the total economic burden of patients.

In conclusion, in filter retrieving surgery, the technique using 9-Fr long sheath combined with memorable alloy trap is superior to the technique using conventional Cook MReye filter retrieving device in duration of surgery, radiation exposure time, and treatment cost. In addition, this technique has no serious intraoperative or postoperative complications. This suggests that, the technique using 9-Fr long sheath with memorable alloy trap is a safe, reliable and economical technique for retrieving the IVC filter. It has bright application prospects in clinic. This study still has some limitations. The sample size of this study is relatively small, which may affect the persuasiveness of the results. In our follow-up studies, the sample size will be further increased for obtaining more satisfactory outcomes.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Wei Han, Department of Vascular Surgery, Hangzhou Third Hospital, 38 West Lake Avenue, Hangzhou 310009, China. Tel: +86-571-87823126; E-mail: hw9453@sina.com

References

[1] Deitelzweig SB, Johnson BH, Lin J, Schulman KL. Prevalence of clinical venous thromboembolism in the USA: current trends and future projections. Am J Hematol 2011; 86: 217-220.

[2] Kearon C, Akl EA, Comerota AJ, Prandoni P, Bounameaux H, Goldhaber SZ, Nelson ME, Wells PS, Gould MK, Dentali F, Crowther M, Kahn SR. Antithrombotic therapy for VTE disease: antithrombotic therapy and prevention of thrombosis, 9th ed: American college of chest physicians evidence-based clinical practice guidelines. Chest 2012; 141: e419S-e496S.

[3] Brown JD, Raissi D, Han Q, Adams VR, Talbert JC. Vena cava filter retrieval rates and factors associated with retrieval in a large US cohort. J Am Heart Assoc 2017; 6.

[4] Doody O, Given MF, Kavnoudias H, Street M, Thomson KR, Lyon SM. Initial experience in 115 patients with the retrievable cook celect vena cava filter. J Med Imaging Radiat Oncol 2009; 53: 64-68.

[5] Heit JA. Epidemiology of venous thromboembolism. Nat Rev Cardiol 2015; 12: 464-474.

[6] Tagalakis V, Patenaude V, Kahn SR, Suissa S. Incidence of and mortality from venous thromboembolism in a real-world population: the Q-VTE study cohort. Am J Med 2013; 126: 832.e13-21.

[7] Malhotra A, Kishore S, Trost D, Madoff DC, Winokur RS. Inferior vena cava filters and prevention of recurrent pulmonary embolism. Semin Intervent Radiol 2018; 35: 105-107.

[8] Ghatan CE, Ryu RK. Permanent versus retrievable inferior vena cava filters: rethinking the "One-Filter-for-All" approach to mechanical thromboembolic prophylaxis. Semin Intervent Radiol 2016; 33: 75-78.
[9] Ayad MT, Gillespie DL. Long-term complications of inferior vena cava filters. J Vasc Surg Venous Lymphat Disord 2019; 7: 139-144.
[10] Caplin DM, Nikolic B, Kalva SP, Ganguli S, Saad WE, Zuckerman DA. Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2011; 22: 1499-1506.
[11] Bardin F, Bernard D, Coudert M. Duodenal perforation: a rare complication of ALN Optional® vena cava filter. Diagn Interv Imaging 2016; 97: 943-945.
[12] Chen JX, Montgomery J, McLennan G, Stavropoulos SW. Endobronchial forceps-assisted and excimer laser-assisted inferior vena cava filter removal: the data, where we are, and how it is done. Tech Vasc Interv Radiol 2018; 21: 85-91.
[13] Milovanovic L, Kennedy SA, Midia M. Procedural and indwelling complications with inferior vena cava filters: frequency, etiology, and management. Semin Intervent Radiol 2015; 32: 34-41.
[14] Andreoli JM, Lewandowski RJ, Vogelzang RL, Ryu RK. Comparison of complication rates associated with permanent and retrievable inferior vena cava filters: a review of the MAUDE database. J Vasc Interv Radiol 2014; 25: 1181-1185.
[15] Goodin A, Han Q, Raissi D, Brown JD. A review of interventions to increase vena cava filter retrieval rates. Ann Vasc Surg 2018; 51: 284-297.
[16] Kuo WT, Cupp JS, Louie JD. Complex retrieval of embedded IVC filters: alternative techniques and histologic tissue analysis. Cardiovasc Intervent Radiol 2012; 35: 588-597.