Retrievable inferior vena cava filters (rIVCFs) were developed to provide temporary protection from pulmonary embolism while minimizing the risk of filter-related deep venous thrombosis associated with permanent inferior vena cava filters. In practice, however, the majority of rIVCFs are left in place permanently, with historic retrieval rates as low as 8.5%. Although poor clinical follow-up of patients with these devices plays an important role, prolonged filter implantation has been associated with retrieval failure rates as high as 43%. Furthermore, prolonged rIVCF dwell time is associated with device-related complications, including fracture, migration, organ penetration, and increased risk of deep venous thrombosis. These concerns were mirrored in a 2014 safety communication issued by the US Food and Drug Administration urging rIVCF retrieval once no longer indicated.

The development of advanced retrieval techniques has had a significant impact on rIVCF retrieval rates, particularly for devices that are in place for extended periods of time or are embedded. However, there is currently no specific definition of what rIVCF dwell time requires increased use of advanced retrieval techniques. We aim to define prolonged retrievable inferior vena cava filters dwell time by determining the inflection point when the risk of standard retrieval technique failure increases significantly, necessitating advanced retrieval techniques to maintain overall technical success of retrieval.

Methods

Study Setting and Population
Our study cohort included all patients referred to our department for rIVCF retrieval from January 2009 to April 2015. The study was
WHAT IS KNOWN

- Historically, retrievable inferior vena cava filters with extended implantation times were difficult or impossible to remove.
- The development of advanced retrieval techniques has greatly improved retrieval rates, particularly of embedded filters with prolonged dwell time.

WHAT THE STUDY ADDS

- Now that retrieval failure is rare, prior definitions of extended dwell time based on retrieval failure no longer apply.
- We have found that the likelihood of standard technique failure, and, therefore, the necessity for advanced retrieval techniques to maintain overall retrieval success, increases significantly at 7 months.
- We have defined this as the inflection point, a potential new definition for extended implantation time.
- Knowledge of the inflection point may improve overall retrieval rates by prompting referral of patients with retrievable inferior vena cava filters and prolonged dwell times to centers with advanced retrieval expertise.

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institutional review board approved and complied in accordance to the Health Insurance Portability and Accountability Act. All subjects provided written informed consent.

Data Collection

Data on patient age/sex, filter dwell time (months), procedural technical success, the use of advanced retrieval techniques, and procedure-related adverse events were collected from a prospectively acquired database. Adverse events were classified as major or minor according to the Society of Interventional Radiology guidelines.

rIVCF Retrieval Procedures

All retrieval procedures were performed by board-certified interventional radiologists, with >90% of procedures performed by 1 of the 3 operators: R.J.L., R.K.R., or K.R.D. Filter retrieval was performed when the rIVCF was no longer indicated for mechanical caval prophylaxis from lower extremity deep venous thrombosis. Technical success is defined as successful endovascular removal of the rIVCF. Standard filter retrieval techniques were initially attempted for all retrieval procedures, consisting of coaxial inner and outer vascular sheaths (Flexor; Cook Medical, Bloomington, IN) with a trilooop endovascular snare device (12- to 20-mm EnSnare; Merit Medical Systems, Inc, South Jordan, UT), under conscious sedation per previously published protocols. Advanced techniques were used when standard techniques failed to successfully remove the rIVCF. These techniques included directed inner sheath use (7F 55-cm Flexor sheath with Ansel 2 modification; Cook Medical, Bloomington, IN), loop wire snare technique, balloon disruption/displacement, microdissection with endobronchial forceps (Lymol Medical, Woburn, MA), and photothermal fibrinolysis using an Excimer laser sheath (Spectranetics Corp, Colorado Springs, CO).

Statistical Analysis

Descriptive statistics are reported as means with SD, whereas overall dwell time is reported as a median with 25th and 75th percentiles. Device-specific dwell times are reported as means with SD. Categorical data are expressed as number and percentages. Univariable logistic regression was performed to determine the independent factors associated with failure of standard retrieval technique. Log odds with 95% confidence intervals are reported. Spline logistic regression was used to explore the relationship between dwell time and failure of standard retrieval technique. We first plotted an LOESS curve (locally weighted scatterplot smoothing) of log odds of standard retrieval technique failure versus dwell time; a dwell time of <1 month was used as the reference group. From the LOESS curve, we identified that spline regression was the appropriate regression model. Proper splines (knots) were visually identified. Standard retrieval technique failure was restricted as monotonously increasing with dwell time. Using spline regression, the risk of standard retrieval technique failure was calculated at different time points. Statistical significance was determined at the level of 0.05. Statistical analysis was performed with R software (R Core Team, version 3.3.2; Vienna, Austria).

Results

From January 2009 to April 2015, 762 retrieval procedures were performed. Mean age of patients in the study cohort was 56 years (SD, 16), and 49% were men. Median rIVCF dwell time across the entire cohort was 1.9 months (25th percentile, 1.2 months; 75th percentile, 3.2 months; range, 0–108.3 months). Filters encountered are listed in Table 1 with mean (SD) dwell times and include the Gunther Tulip, Celect, Celect Platinum (all Cook Medical, Bloomington, IN), Option, Option Elite (both Argon Medical Devices, Inc, Plano, TX), G2, G2X/express, Meridian, Eclipse, Denali (all Bard Peripheral Vascular, Inc, Tempe, AZ), OptEase (Cordis Corp, Miami Lakes, FL), Crux (Volcano Corp, San Diego, CA), and ALN (ALN Implants Chirurgicaux, Ghisonaccia, France).

Standard retrieval techniques were successful in 82% of procedures (n=626). Advanced retrieval techniques were necessary 18% of the time (n=138). With the use of advanced retrieval techniques, the overall technical success rate increased to 98% (n=745). Univariable logistic regression revealed that dwell time was associated with failure of standard retrieval techniques, thereby increasing necessity of advanced techniques to maintain overall retrieval success (odds ratio, 1.08; 95% confidence interval, 1.05–1.10; P<0.001). Table 2 summarizes the findings from univariable analysis.

Table 1. Filter Types

<table>
<thead>
<tr>
<th>Filters</th>
<th>N</th>
<th>Mean Dwell Time, mo</th>
<th>SD</th>
</tr>
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<tbody>
<tr>
<td>Celect</td>
<td>430</td>
<td>3.6</td>
<td>8.3</td>
</tr>
<tr>
<td>Celect Platinum</td>
<td>3</td>
<td>2</td>
<td>1.6</td>
</tr>
<tr>
<td>Tulip</td>
<td>89</td>
<td>8.2</td>
<td>19.4</td>
</tr>
<tr>
<td>ALN</td>
<td>75</td>
<td>2.1</td>
<td>2</td>
</tr>
<tr>
<td>Meridian</td>
<td>2</td>
<td>15.8</td>
<td>18.7</td>
</tr>
<tr>
<td>Denali</td>
<td>15</td>
<td>2.9</td>
<td>3.5</td>
</tr>
<tr>
<td>Eclipse</td>
<td>11</td>
<td>9.4</td>
<td>21.9</td>
</tr>
<tr>
<td>G2</td>
<td>28</td>
<td>17.4</td>
<td>31.4</td>
</tr>
<tr>
<td>OptEase</td>
<td>18</td>
<td>9.2</td>
<td>9.4</td>
</tr>
<tr>
<td>Option</td>
<td>87</td>
<td>2.9</td>
<td>2.6</td>
</tr>
<tr>
<td>Option Elite</td>
<td>1</td>
<td>1.6</td>
<td>NA</td>
</tr>
<tr>
<td>Crux</td>
<td>3</td>
<td>4.1</td>
<td>4.2</td>
</tr>
<tr>
<td>Total</td>
<td>762</td>
<td>4.6</td>
<td>11.7</td>
</tr>
</tbody>
</table>

NA indicates not available.
An LOESS scatter plot of the log odds of standard retrieval technique failure versus dwell time was constructed (Figure). From the LOESS curve, we identified 2 splines (dwell times of ≈7 and 30 months). A spline linear function was constructed to describe the relationship between dwell time and the log odds of standard technique failure. The first change in slope was identified at 7 months; the risk of standard technique failure at this point was 40.9%. After 7 months, the risk of standard technique failure remained high and continued to increase, as expected. Characterization of the 30-month spline is limited because of the distribution of the data: in this cohort, the longest dwell time was 108 months. However, >90% of the patients had dwell time <10 months. Second, as shown in the Figure, all patients with dwell time >56 months (black dots) failed standard retrieval technique. Therefore, the right tail of the LOESS curve may not be accurate.

Adverse Events
A total of 18 procedure-related adverse events (3 major and 15 minor) occurred during the study period, at an overall rate of 2%. Three major events occurred during the study period. One occurred in a patient with a Celect filter in place for 5.9 months. During retrieval, 2 filter struts fractured and remained embedded in the caval wall. These filter struts could not be retrieved and were left in place. The second occurred during retrieval of an OptEase filter with a dwell time of 11.4 months. This device required retrieval from a femoral approach, with subsequent groin hematoma requiring 2 days of inpatient hospitalization for observation but no further treatment. The third occurred in a patient with a Celect filter in place for 0.5 months. During retrieval, significant force, along with dual jugular and femoral venous access, was necessary to collapse and remove the filter, resulting in injury to the inferior vena cava with extravasation. This resolved with a short period of balloon tamponade. However, the patient required 3 additional days of inpatient hospitalization because of a groin hematoma. The remaining adverse events were minor, with most being venous access site issues that required nominal or no therapy.

Discussion
In the present study, we have found that after a 7-month rIVCF dwell time, the likelihood of standard retrieval technique failure is high, with a calculated risk of 40.9%, and continues to increase with dwell time. Therefore, after 7 months, advanced filter retrieval techniques are necessary to maintain high overall rates of retrieval technical success.

Given that a large proportion of rIVCFs remain in situ indefinitely, it is particularly troubling that there have been increasing reports of complications associated with these devices, including filter fracture, migration, organ penetration, and increased risk of deep venous thrombosis. In a review of the Food and Drug Administration’s own Manufacturer and User Facility Device Experience database, Andreoli et al reported that ≈87% of user-reported adverse events were associated with rIVCFs, as opposed to ≈13% associated with permanent inferior vena cava filters. Similarly, a retrospective review by Desai et al found a complication rate of 9% in a series of 449 rIVCFs. Furthermore, studies have demonstrated that device-related rIVCF complications are positively associated with dwell time. Devices that have been in place for extended periods of time potentially encounter prolonged exposure to multivector respiration-based caval biomechanics, resulting in metal fatigue, thereby increasing the risk of fracture and en bloc or component migration/embolization. Thus, because of low retrieval rates, any potential benefit of a device optimally designed for limited use may be offset by the increased risk of complications associated with prolonged or often indefinite implantation.

Prolonged rIVCF implantation poses a significant challenge for retrieval. Several studies have identified prolonged filter dwell time as an independent negative predictor for successful rIVCF retrieval. In a series of 200 patients using 3 different rIVCF devices, Geisbusch et al described a dwell time of >90 days as being associated with retrieval failure, similar to results reported by Averginos et al and Marquess et al. Glockner et al found that Cook Celect and Tulip filters with dwell times of >117 days correlated with rIVCF retrieval failure. Of note, these studies except for Marquess et al reported the use of various advanced retrieval techniques when standard techniques were insufficient; however, these techniques were limited to balloon disruption, use of multiple endovascular snares, snare-over-guidewire techniques (similar to loop wire technique), or filter displacement with a reverse curve catheter. Reported successful retrieval rates from these studies ranged from 76% to 92%. In the present study, similar

Table 2. Univariable Analysis of Factors Associated With Failure of Standard Retrieval Techniques

<table>
<thead>
<tr>
<th>Variables</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>0.99 (0.98–1)</td>
<td>0.2</td>
</tr>
<tr>
<td>Men</td>
<td>0.48 (0.61–1.28)</td>
<td>0.5</td>
</tr>
<tr>
<td>Dwell time</td>
<td>1.08 (1.05–1.10)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

CI indicates confidence interval.
techniques along with the use of rigid endobronchial forceps and Excimer laser sheath-assisted photothermal ablation allowed an overall 98% retrieval success rate in a large cohort.

The development of advanced retrieval techniques has had a significant impact on overall rIVCF retrieval rates. In a series of 50 patients, Kuo et al13 demonstrated that complex retrieval methods could retrieve filters with 100% success where conventional methods had previously failed. Recent studies have demonstrated that the ability to successfully remove rIVCF is independent of filter dwell time and is positively impacted by the use of advanced retrieval techniques when necessary.33 However, attempts at quantifying the time period that constitutes prolonged dwell time have thus far been largely device specific,32 making generalizations about optimal retrieval windows difficult. Furthermore, previous descriptions of prolonged dwell time were limited to retrieval failure. In the present study, we have defined prolonged dwell time as the time when standard retrieval techniques fail at high rates; thereby requiring advanced retrieval techniques to maintain overall retrieval success. At 7 months, while encountering a variety of rIVCF, the calculated risk of standard technique failure (and, therefore, requirement of advanced retrieval techniques) is 40.9%. This relationship continues to increase with dwell time. Filters with prolonged dwell times often require complex procedures and the use of multiple advanced techniques. Thus, attempts at retrieval of these devices at centers with limited experience in these techniques may be predisposed to fail.

Previously published studies have reported higher procedure-related adverse event rates when using advanced techniques. Al-Hakim et al4 reported a complication rate of 5.3% when using advanced retrieval techniques. In the present study, our overall complication rate was 2%; in a previous analysis, we found no association between adverse event rates and filter dwell time or use of advanced techniques on multivariable analysis.13 With clinical experience, it seems that rIVCF retrieval procedures have an excellent safety profile.

There are limitations to this study. The use of specific advanced techniques was based on operator preference and was not objectively assigned. Another limitation is the single-center nature of our experience, thereby limiting broader clinical application. However, as demonstrated in our analysis and previously published studies, retrieval of rIVCF with prolonged dwell time often requires complex techniques and optimally should be performed in a center with a high level of experience in these procedures. The distribution of the data set is not normal; >90% of the cohort had an rIVCF in place for ≤10 months. Therefore, characterization of the second spline at a 30-month dwell time is limited. Further study is necessary to characterize dwell time in patients with prolonged dwell times (eg, >10 months). Finally, multiple types of rIVCF were encountered in the study period. The technical challenges encountered during a retrieval procedure vary by device33; as a result, the data may vary by device type. In the current cohort, comparisons of the impact of device subtype on the inflection point would be potentially confounded because of the disparate number of filters encountered. As further data are gathered, future studies could be performed to examine the inflection point for necessity of advanced retrieval techniques by device subtype.

Conclusions

Retrieval of rIVCF with prolonged dwell time is historically unsuccessful because of lack of expertise in advanced retrieval techniques. Based on our data, we have defined prolonged dwell time as 7 months, where there is significant risk of standard technique failure, thereby requiring advanced techniques to maintain a high rate of technical success. Knowledge of this inflection point may be particularly useful in guiding referral of patients to centers with expertise in advanced retrieval techniques, where rIVCF with extended implantation times can be safely removed. As data on the potential risks of prolonged dwell rIVCFs continue to mount, it is important to optimize opportunities to remove rIVCFs that are no longer indicated.

Disclosures

Dr Desai is on the Speaker’s Bureau for Cook Medical, Inc, and Dr Ryu is a paid consultant at Spectranetics, Inc. The other authors report no conflicts.

References


Defining Prolonged Dwell Time: When Are Advanced Inferior Vena Cava Filter Retrieval Techniques Necessary?: An Analysis in 762 Procedures

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