Safety and Success Rates of Excimer Laser Sheath–Assisted Retrieval of Embedded Inferior Vena Cava Filters

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Abstract

IMPORTANCE Despite historically high rates of use, most inferior vena cava (IVC) filters are not retrieved. The US Food and Drug Administration safety communications recommended retrieval when the IVC filter is no longer indicated out of concern for filter-related complications. However, failure rates are high when using standard techniques for retrieval of long-dwelling filters, and until recently, there have been no devices approved for retrieval of embedded IVC filters.

OBJECTIVE To evaluate the safety and success of excimer laser sheath–assisted retrieval of embedded IVC filters.

DESIGN, SETTING, AND PARTICIPANTS A retrospective, multicenter, clinical cohort study of excimer laser sheath–assisted IVC filter retrievals from 7 US sites was conducted between March 1, 2012, and February 28, 2021, among 265 patients who underwent IVC filter retrieval using the laser. Patients were stratified between a high-volume single center and a multicenter data set. A blinded physician committee adjudicated reported complications and their association with use of the laser.

EXPOSURES Retrieval of IVC filters using excimer laser sheath.

MAIN OUTCOMES AND MEASURES The primary safety end point was device-related major complication rate (Society of Interventional Radiology categories C to F, which included any adverse event associated with morbidity or disability that increases the level of care, results in hospital admission, or substantially lengthens the hospital stay). The primary success end point was technical success of IVC filter retrieval. The primary end points were compared with literature-derived, meta-analysis–suggested target performance goals.

RESULTS The single-center experience included 139 participants (mean [SD] age, 52 [16] years; 78 female participants [56.1%]), and the multicenter experience included 126 participants (mean [SD] age, 52 [16] years; 75 female participants [59.5%]). The device-related major complication rate was 2.9% (4 of 139; 95% CI, 0.8%-7.2%; P = .001) for the single-center experience and 4.0% (5 of 126; 95% CI, 1.3%-9.0%; P = .01) for the multicenter experience, both of which were significantly lower than the primary safety performance goal (10%). No major complications were considered to be definitively associated with use of the laser. The technical success rate was 95.7% (133 of 139; 95% CI, 90.8%-98.4%; P = .007) for the single-center experience and 95.2% (120 of 126; 95% CI, 89.9%-98.2%; P = .02) for the multicenter experience, both of which were significantly higher than the primary performance goal (89.4%).

CONCLUSIONS AND RELEVANCE This cohort study demonstrated high technical success and low complication rates of excimer laser sheath–assisted retrieval of embedded IVC filters in centers with (continued)
variable case volume and experience, which suggests a wide applicability of the technique with proper training. The excimer laser sheath offers physicians a valuable tool for retrieval of challenging embedded IVC filters.

Introduction

Inferior vena cava (IVC) filters are indicated primarily for the prevention of pulmonary embolism (PE) in patients with acute lower-extremity deep vein thrombosis (DVT) or PE with a contraindication to therapeutic anticoagulation.1 The use of IVC filters has steadily increased,2 largely due to expanded uses, including prophylaxis. Annually, approximately 38,000 IVC filters were placed in the United States, but only approximately 22.1% were retrieved.3 The reasons for the low retrieval rates are multifactorial; in addition to historically poor follow-up of patients,4 devices with extended times of implant are often not amenable to retrieval with standard endovascular techniques.5 Furthermore, patients with IVC filters that have extended implant times are at increased risk of developing filter-related complications, including filter fracture, component embolization, caval perforation or penetration, and caval occlusion.6 Given concerns for device malfunction, particularly for IVC filters that are no longer indicated, the US Food and Drug Administration (FDA) issued safety communications in 20107 and 20148 guiding all physicians caring for patients with IVC filters to consider removing the filter as soon as protection from PE is no longer needed.

The excimer laser sheath (SLS II or GlideLight; Philips) was initially approved for the extraction of long-term implanted pacemaker or defibrillator leads. Tissues surrounding cardiac leads are ablated using 308-nm UV laser energy to facilitate lead extraction from vascular and cardiac binding sites. The device has also been used for retrieval of embedded IVC filters in an off-label, physician-directed manner. During the past decade, many physicians have reported successful off-label use of the laser sheath for IVC filter retrieval in single-center studies.9-15 Similar to lead management procedures, the laser sheath allows for ablation of fibrous tissue surrounding the IVC filters, thus requiring less force to retrieve the filter.9 However, all studies were single-center reports, thus limiting general applicability of their results. We present clinical safety and success outcomes from a retrospective multicenter cohort study on excimer laser sheath-assisted retrieval of embedded IVC filters using clinical evidence to further demonstrate the wide applicability of the technique.

Methods

Study Design

In this cohort study, a multicenter retrospective medical record review and analysis were performed to assess the safety and success of the excimer laser sheath among a cohort of patients undergoing retrieval of embedded IVC filters. All investigators for this study obtained institutional review board approval (Northwestern University institutional review board, Aura institutional review board-The University of Chicago, Oregon Health & Science University institutional review board-Research Integrity Office, Trinity Health Mid-Atlantic institutional review board, WIRB-Copernicus Group institutional review board, Colorado Multiple institutional review board, and University of Minnesota institutional review board) for the clinical study prior to study initiation in conformance with the International Conference on Harmonisation Good Clinical Practice Guideline and all applicable laws and regulations. Data from March 1, 2012, to February 28, 2021, were deidentified and collected by review of electronic medical records under a waiver of informed consent. The study was conducted under the principles of the World Medical Association Declaration of Helsinki, the International Conference on Harmonisation Good Clinical Practice Guidelines, and the International Standards
This report followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Study data were presented as 2 separate clinical experiences: a single-center, 3-operator clinical experience of IVC filter retrieval cases using the laser sheath at Northwestern University in Chicago, Illinois (n = 139) and a multicenter clinical experience from study centers with variable case volumes and practitioner experience (n = 126 from 6 sites). All patients who underwent IVC filter retrieval using the excimer laser sheath were included in the study. An IVC filter retrieval procedure that did not use a laser sheath resulted in exclusion from the study population.

The multicenter data were collected retrospectively between October 1, 2012, and February 28, 2021, from 6 clinical sites: University of Chicago, Chicago, Illinois (n = 20); Oregon Health & Science University, Portland (n = 47); Oklahoma Heart Hospital, Oklahoma City (n = 25); University of Colorado, Aurora (n = 25); Saint Francis Healthcare, Wilmington, Delaware (n = 4); and University of Minnesota, Minneapolis (n = 5). The single-center data set included cases prospectively collected between March 1, 2012, and June 30, 2019. Because the original end points collected from the single-center experience did not align directly with those collected from the multicenter study, the unavailable variables were presented as null values, and those data were analyzed separately.

Data analysis included comparison with prespecified target performance goals based on a weighted mean rate of safety (10%) and of technical success (89.4%) using a meta-analysis of published experiences of laser sheath–assisted IVC filter retrieval (details in the Statistical Analysis subsection and the eMethods in Supplement 1).

**Study End Points and Definitions**

The primary safety end point was the device-related major complication rate. The classification of major complications was based on Society of Interventional Radiology (SIR) classification categories C to F, which included any adverse event associated with morbidity or disability that increases the level of care, results in hospital admission, or substantially lengthens the hospital stay.

The primary success end point was technical success of IVC filter retrieval using an excimer laser sheath. The technical success of IVC filter retrieval was determined by the site physician who performed the retrieval procedure and was defined as retrieval of filter body and any fragments deemed retrievable of the lumen based on the clinical judgment of the practitioner.

**Safety End Point Adjudication**

Two independent physicians served as the Clinical Events Committee for the study. Adjudicators were assigned randomly to perform blinded review of complications entered in the database. The adjudicators classified each complication as major or minor per SIR classification criteria. Site-reported grading was compared by the study monitor with the Clinical Events Committee adjudication. Site-reported SIR grades were not available for the single-center experience because the data set did not align directly with the variables used for the multicenter study. Thus, the single-center SIR grades were directly assigned by the adjudicators. Adjudicators also provided their assessment on the association of each complication with the use of the laser. The association of each complication with the use of the laser was defined as definitely, probably, possibly, or not associated. The site did not provide any data on the association of each complication with the use of the laser; this was determined solely by the adjudicator.

**Statistical Analysis**

To set performance goals for safety and success, a literature search was conducted to review clinical outcomes from published experiences (eMethods in Supplement 1). In brief, a total of 8 published studies using the laser for IVC filter retrieval were identified and reviewed. A random-effect model meta-analysis was performed combining the results of the identified studies to estimate the weighted mean of treatment effects for safety and success separately. Meta-analysis results were...
considered to make recommendations for the primary safety and success performance goals (eTables 5 and 6 in Supplement 1).

Data analysis was conducted using SAS Life Science Analytics Framework, version 5.1.2 or later (SAS Institute Inc). The hypothesis for the primary safety end point was that the upper confidence limits of the device-related major complication rate would be less than the performance goal of 10%. The hypothesis for the primary success end point was that the lower confidence limits of the technical success rate would be greater than the performance goal of 89.4%. All hypothesis tests were evaluated under a 1-sample, 1-sided exact binomial test with \( P < .03 \) considered statistically significant. Descriptive statistics for continuous variables were summarized using the number of nonmissing observations, the mean (SD) values, and the 95% CIs for the mean values. Categorical variables were summarized using the percentage of participants in each category along with the numerator and denominator of that percentage and the 95% CI for the percentage.

The justification for pooling all the data to estimate a common effect across study centers requires the homogeneity of response across study centers. To assess whether the single-center and multicenter data differed with respect to clinical outcomes, a poolability analysis using the Fisher exact test was conducted to evaluate whether any heterogeneity existed between the single-center data and the multicenter data. Heterogeneity of the age, gender, and filter type subgroups was also analyzed using the Fisher exact test.

**Results**

A total of 139 IVC filter retrievals using the laser sheath were included in the single-center clinical experience. The mean (SD) age of the patients in the single-center clinical experience at the time of IVC filter retrieval was 52 (16) years, and 56.1% (78 of 139) were women (Table 1). In the single-center clinical experience, 85.2% of the participants (92 of 108) had a history of DVT, and 62.6% of the participants (57 of 91) had a history of PE. Prophylactic indication for filter placement was present in 26.6% of patients (37 of 139) in the single-center clinical experience.

In the multicenter experience, 126 IVC filter retrieval procedures were identified. The mean (SD) age of the patients in the multicenter experience at the time of IVC filter retrieval was 52 (16) years, and 59.5% (75 of 126) were women (Table 1). In the multicenter experience, 89.7% of the participants (104 of 116) had a history of DVT, and 62.1% of the participants (72 of 116) had a history of PE. In the multicenter experience, venous thromboembolism was present at the time of filter placement for 67.5% of the participants (85 of 126), and filter placement was prophylactic for 57.1% of the participants (72 of 126). The single-center and multicenter patient demographic characteristics and medical history are summarized in Table 1.

**Table 1. Demographic Characteristics and Medical History**

<table>
<thead>
<tr>
<th>Variablea</th>
<th>Participants, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single-center study (n = 139)</td>
</tr>
<tr>
<td>Age at time of procedure, mean (SD), y [No.]</td>
<td>52 (16) [138]</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>78 (56.1)</td>
</tr>
<tr>
<td>Male</td>
<td>60 (43.2)</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
</tr>
<tr>
<td>Venous thromboembolism at any time, No./total No. (%)</td>
<td>119 (85.6)</td>
</tr>
<tr>
<td>DVTb</td>
<td>92/108 (85.2)</td>
</tr>
<tr>
<td>Pulmonary embolismb</td>
<td>57/91 (62.6)</td>
</tr>
<tr>
<td>Venous thromboembolism at filter placement</td>
<td>3/132 (2.3)</td>
</tr>
<tr>
<td>Prophylactic filter placement</td>
<td>37 (26.6)</td>
</tr>
</tbody>
</table>

Abbreviation: DVT, deep vein thrombosis.

a Each variable is reported for available data, excluding null values.
b Multiple medical conditions occurred for a participant and were inclusively reported.
Preprocedural Information
A total of 89.2% of IVC filters (124 of 139) in the single-center clinical experience and 83.3% of IVC filters (105 of 126) in the multicenter data set were retrievable (eTable 1 in Supplement 1). Most of the retrievable filters were Gunther Tulip (Cook Medical), OptEase (Cordis), Option (Rex Medical), and Celect (Cook Medical). The details of filter types and models are shown in eTable 1 in Supplement 1. The mean (SD) filter dwell time was 57.1 (51.8) months (median time, 40 months [IQR, 1.0-186.0 months]) in the single-center data and 69.7 (62.0) months (median time, 64 months [IQR, 1.0-261.0 months]) in the multicenter data (Table 2). The need for the use of the laser for retrieval was at the discretion of the operator at the time of the procedure. A prior failed retrieval attempt was reported for 50.0% of patients (69 of 138) in the single-center data and 42.1% of patients (53 of 126) in the multicenter data. Additional preprocedural information is summarized in Table 2.

Safety End Points
The meta-analysis results suggested an expected device-related major complication rate of 3.0% (eMethods in Supplement 1). After applying for a margin of 7%, the primary safety performance goal was set to be 10%. The primary safety end point of device-related major complication rate for the study was met and was found to occur in 2.9% of procedures (4 of 139; 95% CI, 0.8%-7.2%; P = .001) in the single-center experience and 4.0% of procedures (5 of 126; 95% CI, 1.3%-9.0%; P = .01) in the multicenter experience (Table 3).

Of the 42 total complications from the single-center study, there were no major or minor complications that were deemed definitively associated with the use of the laser sheath. There were 2 events classified as probably associated with laser use. Twenty-four complications were possibly
associated with laser sheath use, and the rest were not associated with laser sheath use. The 4 major complications (grade C) associated with laser sheath use were filter fracture with embolization (2), filter penetration (1), and IVC perforation (1).

All site-reported complications from the multicenter study were adjudicated by the Clinical Events Committee. In the multicenter study, 23 participants had a total of 24 complications. The rate of device-related minor complications was 11.1% (14 of 126). One complication (minor) was adjudicated as definitely associated with laser use (IVC injury with extravasation), 4 were probably associated with use of the laser, 9 were possibly associated with use of the laser, and 5 were not associated with laser use. In the multicenter group, there was 100% agreement between site- and adjudicator-reported complications. The 5 major complications (grade C or D) associated with laser use included IVC injury (2), hemorrhage (1), and hematoma (2). Details of all the complications are shown in eTable 2 in Supplement 1.

Primary Performance End Points

The meta-analysis results suggested a technical success rate of 96.4% (eMethods in Supplement 1). After applying a margin of 7%, the primary performance goal was determined to be 89.4%. The primary performance end point of technical success for IVC filter retrieval with the laser sheath was met in the the single-center study (95.7% [133 of 139]; 95% CI, 90.8%-98.4%; \( P = .007 \)) and in the multicenter study (95.2% [120 of 126]; 95% CI, 89.9%-98.2%; \( P = .02 \))(Table 3). Reasons for technical failure included failure to capture filter apex, failure to ablate tissue or free filter from caval wall, and large acute luminal thrombus. Table 3 shows the primary safety and success end point results from the single-center and multicenter clinical data.

Filter Retrieval Information

For the single-center filter retrievals, the mean (SD) laser activation time was 33.8 (46.8) seconds and was recorded in 23 procedures (Table 4). The mean (SD) procedure fluoroscopy time was 23.3 (20.8) minutes, recorded in all 139 procedures. In addition to the laser, 63.0% of cases (87 of 138) also used other techniques, such as the loop or wire snare technique and rigid endobronchial forceps. Repositioning of filter with a balloon was used in 1 case.

In the multicenter clinical experience, the most commonly used laser sheath size was 14F with an introducer sheath median size of 16F (Table 4). The mean (SD) laser activation time was 42.6 (54.1) seconds, and the mean (SD) filter retrieval time under fluoroscopy was completed in 29.7 (24.4) seconds.
minutes. In addition to the laser, 70.6% of retrievals (89 of 126) also used other techniques, including the loop or wire snare technique, rigid endobronchial forceps, and balloon repositioning of filter. Long-term anticoagulation was used at the time of the procedure in 93 cases (73.8%), and additional intraprocedural anticoagulation was used in 84 cases (66.7%). Additional procedural information is summarized in Table 4.

**Poolability Analyses of Primary End Points**

To assess if there were differences in clinical outcomes between the single-center and multicenter experiences, the Fisher exact test was conducted. There was no statistically significant difference between the multicenter and single-center experience of device-related major complication rates (4.0% vs 2.9%; \( P = .74 \)) or technical success rates (95.2% vs 95.7%; \( P = .86 \)). In addition, there was no statistically significant difference in the device-related major complication rate (eTable 3 in Supplement 1) or the technical success rate (eTable 4 in Supplement 1) among different age or gender subgroups for both multicenter and single-center data sets. Therefore, the safety profiles and success benefits were consistently observed across clinical sites and different age and gender subgroups.

Subgroup analysis was also conducted on filter types (permanent vs retrievable) to assess whether there was an association between filter type and primary end points. Although the permanent filters were associated with slightly higher major complication rates and lower technical success rates for both the single-center and multicenter clinical experiences, there was no statistically significant difference in primary end points between permanent and retrievable filters (eTable 3 and eTable 4 in Supplement 1).

**Discussion**

Most IVC filters can be retrieved using standard retrieval techniques. However, with a prolonged implant time, IVC filters can become difficult or impossible to retrieve with standard techniques alone. In addition to being associated with device-related complications, such as component fracture, prolonged dwell time has been demonstrated to lead to filters embedding in the IVC wall due to component incorporation. Many patients with indwelling filters routinely undergo therapeutic anticoagulation, subjecting them to bleeding risk from long-term anticoagulation. Retrieval of these filters may prevent risks from a prolonged implant time and may potentially eliminate the need for long-term anticoagulation. The FDA has recommended retrieval when the filter is no longer indicated. However, to date, there have been no purpose-built devices for IVC filter retrieval. The use of the laser sheath and other alternative techniques has provided an advantage for filters previously considered irretrievable. These advanced tools or techniques have had a significantly positive effect on IVC filter retrieval procedural success.

Although the use of advanced techniques raises the possibility of a higher procedural risk, it is likely that such techniques are used in more complex cases, which may inherently be associated with increased procedural risk. There have been conflicting reports of safety with the use of advanced techniques for IVC filter retrieval. Apart from the excimer laser sheath, advanced techniques, including rigid endobronchial forceps, the sling technique, and center techniques using balloons or flossing, have been used for complex filter retrievals. Endobronchial forceps can be used for embedded filter apices as well as for incorporated filter components. The use of the excimer laser sheath has been demonstrated to reduce the force necessary to retrieve embedded filters and may improve the overall safety profile of these procedures relative to other techniques. Access site complications are largely due to the size of the access sheath required for advanced retrieval techniques, which is similar for laser sheath and other techniques. It was reassuring to see a low rate of filter fracture and embolization of the filter components reported in the clinical evidence.

The excimer laser uses UV laser energy to facilitate the detachment of the filter from the IVC wall. The filter then collapses partially within the laser sheath and entirely within the introducer.
sheath (Figure). At 308-nm wavelength, the excimer laser penetrates 50 to 100 μm, which may allow for precise tissue ablation while reducing risk of collateral tissue damage. Histopathologic analysis of tissue from filters retrieved by laser revealed a predominance of neointimal hyperplasia and fibrosis along filter attachment sites, suggesting that the risk of significant vessel wall injury during filter retrieval is limited. In a recent large single-center study by Kuo et al., laser-assisted retrieval of IVC filters from 500 patients was associated with a procedure-related major complication rate of 2%. This study also demonstrated that the use of a laser sheath significantly decreased the force during retrieval, thereby decreasing possible mechanical complications, such as fracture and embolization of filter components.

The excimer laser sheath has recently been cleared by the FDA for the ablation of tissue in the retrieval of IVC filters that have failed a previous retrieval method based on the present study. To our knowledge, it is the first multicenter, clinical study to evaluate the safety and success of the use of an excimer laser to retrieve a variety of embedded IVC filters. The results have demonstrated homogeneity between the 2 groups, suggesting that the use of the excimer laser sheath for IVC filter retrieval is applicable across wider populations and various levels of operator experience. The excimer laser sheath should provide physicians with a valuable tool for the retrieval of challenging IVC filters and potentially help reduce complications for patients.

Limitations
There are limitations to the study. First, the retrospective nature of this study may introduce bias. The cohort per institution was relatively small for the multicenter data set. The technique was for off-label use during the study time frame. Since the clearance of the excimer laser for IVC filter retrieval in late 2021, we are expecting a larger amount of patient data to become available in the near future. Other advanced techniques were used during some procedures; a direct comparison with other filter retrieval techniques is also limited. In addition, standardized long-term follow-up was not possible to understand the prognosis of patients after filter retrieval. Future studies that include larger patient groups across more study sites, comparative cohorts, and long-term follow-up may be valuable.
Conclusions

The results of this multicenter, clinical evidence cohort study support the use of the excimer laser sheath for retrieval of embedded IVC filters refractory to standard retrieval methods. This technique was safe and successful in retrieving a variety of embedded filters and potentially reducing long-term risks from long-term implanted IVC filters.
through an electronic case-report form via a database managed by the sponsor. Data management and site monitoring were performed by the sponsor. All statistical analyses for regulatory submission and scientific publication were performed by a biostatistician employed by the sponsor but had no other role in the project. The investigators made recommendations of additional analysis to be performed for scientific publication.

Data Sharing Statement: See Supplement 2.

Additional Contributions: The authors would like to acknowledge Nancy Jin, MS, Philips North America LLC, who provided biostatistical support; she was not compensated for her contributions to this project. The authors thank all investigators and institutions participating in the Philips CavaClear study. The authors also acknowledge Man Hon, MD (NYU Winthrop Hospital), and Timothy E. Yates, MD (South Beach Vascular, PLLC), who served as the Clinical Events Committee and were compensated for their role in the project.

REFERENCES


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SUPPLEMENT 2.
Data Sharing Statement