Optimal Time of Extraction Retrievable Inferior Vena Cava Filters in Venous Thromboembolic Treatment: Evidence Based Case Report

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Background: Inferior vena cava (IVC) filters have been proven to be significantly advantageous and clinically efficacious in the prevention of deathly venous thromboembolism, but also carry long-term risks, such as device failure, filter fracture, migration, penetration into adjacent structures, etc. Retrievable filters offer the same degree of protection, and subsequently lower those risk by removing them after they aren't needed. Unfortunately, increasing use of retrievable filters leads to one alarming trend: there's massive number of filters that are left for an extended time. Whether the time between deployment and retrieval affects filter's technical success of retrieval remains questionable. Here is a case of a 45-year old woman who had undergone retrievable IVC filter due to pulmonary embolism risk. The patient only came to clinician for routine follow-up once, one month after deployment. One year later, the patient felt abdominal pain and asked to remove the filter. After one failed attempt, the clinician decided to leave the filter in situ as permanent filter.

Method: Literature searching was conducted in several databases (ScienceDirect, EbscoHost, and ClinicalKey) using specified keywords. Six articles that had been passed exclusion and inclusion criteria, were eventually appraised and extracted.

Results: Of all six articles that are included in this study, there are no standard time of retrieval. Each study provides data regarding their attempted retrieval, successful retrieval, and dwell time. Only two articles (Uberoi et al and Glocker et al) analyze the relationship between time of retrieval and successful retrieval. Uberoi et al claims filter retrieval statistically more successful if the dwell time is less than 9 weeks, whereas Glocker et al states the procedure is considerably more successful within 3-4 months (117 days) after deployment. The reasons of retrieval failure in these studies are varied, including device angulation, filter incorporation with IVC wall, and penetration to IVC wall and adjacent structures, or significant thrombus inside the filter.

Conclusion: There are no standard time of retrieval, but clinicians could follow FDA recommendation by removing the filter when it isn't necessarily needed. However, a time span of 3-4 months between implantation and retrieval can be respectable choice to make sure the maximum chance at retrieval success.

Keywords: Inferior Vena Cava Filter, Filter Retrieval, Dwell Time, Venous Thromboembolism
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INTRODUCTION

Venous thromboembolism (VTE), manifested as deep vein thrombosis (DVT) or pulmonary embolism (PE), is a fatal disease that 5% of people are affected during their lifetime.¹ One-third of venous thromboembolism cases turn into PE, while others become DVT. Anticoagulant management of such cases, which has been applied for decades, doesn't appear to reduce the mortality rate of VTE. According to a study, one month-mortality rate of DVT is 6% and the number is doubled for PE.² Inferior Vena Cava

Filter (IVCF) has been widely recognized as alternative option when anticoagulant as the first line of therapy is deemed to be ineffective or contraindicated in several conditions. The use of IVC filter has gained popularity as a safe option in the last decades, when IVCF placement procedure grew by 25 times between 1979 and 1999.³ FDA seemingly supported this practice by authorizing retrievable filter production in early 2000s. This type of filter offers several advantages, such as time flexibility between deployment and retrieval, and long-term complications prevention. In 2012, almost 75% of IVC

Figure 1. Pre-Retrieval CTA

filters that had been placed worldwide were retrievable.⁴

Although retrievable filter is indicated for temporary placement, in reality, the retrieval rate among centers worldwide is considerably low, ranging from 10% to 50 %, with mean rate 30%.⁵ Currently, there is no guideline that communicate the optimal time of filter retrieval. Experimental studies in animal have shown that retrievable filter begins to incorporate into IVC wall after three weeks of placement. Therefore, several studies suggest retrieval procedure should be attempted in the second week.^{6,7} Longer dwell time is relatively correlated with risk and complication increase, such as IVC occlusion, perforation, filter migration, and emboli.⁵ Retrieval failure, complex retrieval, and complicated retrieval are also affected by duration of dwell time. To intervene this potentially harmful trend, FDA published a statement that recommends the filter retrieval is completed as soon as possible when it isn't no longer necessary, especially in young adults.^{8,9}

Until now, there is no guideline that show the optimal time of retrieval attempt resulting in highest possibility of successful retrieval. The purpose of this evidence based case report are the optimal time of filter retrieval could be determined, and the factors that affect failed retrieval could be identified.

CASE ILLUSTRATION

A 30-year old female reported in vascular surgery clinic with a chief complaint of swelling on her left lower extremity, accompanied by redness and tenderness. The patient was referred by Ob-Gyn because of these symptoms. The Ob-Gyn was going to perform total hysterectomy and bilateral salpingo-oophorectomy procedure on the patient due to recurrent vaginal bleeding and prolonged menstrual cycle that require blood transfusion.

From CT Angiography, there was an acute thrombosis of left iliofemoral vein, with extension to inferior vena cava. The diagnosis of DVT was confirmed by this finding, therefore anticoagulant therapy and gradual external compression were initiated to the patient. Adequate anticoagulant dosage was never reached because vaginal bleeding returned that the patient needed to be hospitalized several times. The surgeon subsequently placed IVC filter to prevent pulmonary embolism.

Four days later, the patient came to surgeon's clinic to report her symptoms. The swelling gradually reduced, but she did daily activities without any significant problems. The patient was going to be referred back to Ob-Gyn when the DVT manifestations were resolved. Two weeks later, on the second visit, the initial symptoms of swelling and tenderness were not complained. Anticoagulant was still given on adjustment dose to prevent vaginal bleeding.

In the next two months, the patient was hospitalized two times due to massive vaginal bleeding and received blood transfusion, supervised by the Ob-Gyn.

Four months after IVCF placement, the total hysterectomy and bilateral salpingo-oophorectomy procedure was performed by the Ob-Gyn. One month after this procedure, patient started to feel chest pain and palpitations. Nevertheless, the patient never came to the surgeon to consult these problems.

One year after IVCF placement, the patient came to surgeon with several complaints, such as palpitations, epigastric pain, and itching. The patient asked the IVC filter to be retrieved. The patient and her family were educated about the procedure, including complications and success rate afterwards. CT Angiography was conducted as pre-procedural management. The result showed that the filter didn't migrate, but both its hook and anchor merged into IVC wall. The surgeon explained about filter's condition and the option to leave filter in-situ as permanent type, but they refused and insisted the procedure to be continued. After several attempts, the filter was failed to retrieve. The patient and her family was informed, and they eventually agreed to leave it permanently with its associated risks (e.g. IVC thrombosis and filter migration). After the procedure, the patient returned daily life without problem

CLINICAL QUESTION

The clinical question in this article is:

"In patient that has undergone retrievable filter placement, when is the optimal time filter retrieval procedure's performed?"

METHOD

In order to answer the clinical question, a comprehensive computer-based literature search was

Table 1. Result of Article Search

No	Writer (Year)	Study Type	Sample Size	Number of Retrievable Filter Placement	Retrieval Attempt	Successful Retrieval (%)	Level of Evidence (LoE)
1	Tapson, et al (2017)	Prospective, clinical study	163	163	143/163	143/143 (100%)	II
2	Glocker, et al (2014)	Retrospective study	121	636	121/636	92/121 (76%)	II
3	Lee, et al (2018)	Retrospective study	141	141	100/141 <i>Abutting group: 37/52</i> <i>Non-abutting group: 63/89</i>	96/100 (96%) <i>Abutting group: 34/37 (92%)</i> <i>Non-abutting group: 62/63 (98%)</i>	II
4	Stavropoulos, et al (2016)	Prospective, clinical study	200	200	124/200	121/124 (97.5%)	I
5	Uberoi, et al (2013)	Retrospective study	1434	721	415/721	345/415 (83%)	II
6	Reis, et al (2016)	Retrospective study	87	87	31/87	31/31 (100%)	II

conducted on April until Mei 2019 using several databases (ScienceDirect, EBSCOHost, and ClinicalKey). This process use following keywords: ("Venous Thromboembolism" OR "Deep Vein Thrombosis" OR "Pulmonary Embolism") AND ("Retrievable Filter") AND ("Retrieval") AND ("Success Rate") AND ("Timing" OR "Time" OR "Duration"). Several inclusion criteria was applied, including text in English or Bahasa, published in the last six years, and full-text available. All abstracts and title form the initial search was reviewed thoroughly to ensure the selected articles fulfilled both inclusion and exclusion criteria. All relevant studies were appraised using critical appraisal worksheet from Center of Evidence Based Medicine (CEEEM), Oxford University. Valuable information and data from each study was extracted and compiled into one single table.

RESULT

A total of 29 studies met inclusion criteria after abstract and title screening process in literature search. After reading the full-text version of each study, 23 studies were excluded because several reasons (study design, no desirable information, etc.). In total, there are six studies included in this case report, and all of them were appraised using the criteria from Centre of Evidence-Based Medicine University of Oxford for prognostic studies. All involving studies are described in Table 1 and II.

Glocker, et al conducted a review to determine the optimal time filter retrieval, and factors related to successful procedure. This study included 121 patients that had undergone filter retrieval attempts from 2006 to 2012 in Alabama, US. From those attempted retrievals, 92 filters (76%) were successfully retrieved. 26 cases were failed to retrieve due to inability to reach the filter's hook, while another three cases were caused by the inappropriate manner of filter's release. In unsuccessful retrieval group, retrieval procedure took remarkably longer time (mean 49 minutes, SD 17 minutes) than successful retrieval group (mean 29 minutes, SD 14 minutes). Dwell time in this group was also significantly longer (162 days, 43-379 days) than the other group (105 days, 7-368 days). These data was analyzed and projected into Kaplan-Meier curve, and

it showed that 90% of successful retrieval cases had dwell time less than 117 days.

The second study was a multicenter, prospective, single-arm clinical trial from Tapson, et al that investigated filter placement in 20 *intensive care unit* (ICU) across United States. One hundred and sixty three filters were placed in critically-ill patients that met following criteria: recognized contraindications to pharmacologic thromboprophylaxis and/or confirmed acute lower extremity DVT that contra-indicated to anticoagulant therapy. Nearly all of the samples (98.2%) used IVC filter as prophylaxis of pulmonary embolism, and the filters were maintained in IVC for approximately 7 days (mean 7.2 days $\pm$ 3.8 days). Retrieval attempts were performed in 143 (88%) patients, and they were all successful. Mean procedure time was 8 minutes (IQR 4-18 minutes). Large thrombus and small thrombus occurred in 14 (8.6%) samples and 17 (10.4%) respectively.

Uberoi, et al, analyzed *British Society of Interventional Radiology (BSIR) Inferior Vena Cava Filter (IVC)* registry report from October 2007 until March 2011. This report contained data about 1434 filter placement and 400 filter retrieval procedures in 68 centers across UK. Gunther Tulip (39%) and Celect (25%) were the most frequently used filters. Retrieval filters were mainly placed in young adults, pregnant women, or patients with temporary high risk. Cordis OptEase was the filter with the shortest dwell time (median 12 days, 2-45 days), while Bard G 2 was the longest one (median 77 days, 34-154 days). Seventy hundred and twenty one filters were initially placed for temporary placement, and follow-up data was only available in 514 samples. From the remaining samples, 415 (81%) filters were retrieved with success rate went up to 83%. Cava thrombosis and clinical deterioration were the common reasons for non-retrieved filters. Successful retrieval was highly affected by dwell time. It's reported that filter placement beyond 9 weeks was significantly correlated with failed retrieval, mainly due to incorporation of the device, IVC thrombosis, or penetration by filter's legs. One of the interesting facts in this study was Bard filter had the highest success rate despite its prolonged dwelling time. IVC wall perforation, filter migration, pulmonary embolism, and lower extremity thrombosis were notable long-term complications reported.

Table 2. Characteristics of Involving Studies

Nu	Writer (Year)	Dwell Time	Factors Related to Failed Retrieval Failure
1	Tapson, et al (2017)	Mean 7.2 days $\pm$ 3.8	All filters were retrieved successfully
2	Glocker, et al (2014)	Successful retrieval: Mean 105 days (7-368 days) Unsuccessful retrieval: Mean 162 days (43-379 days)	26 cases were failed to retrieve due to inability to reach the filter's hook, while another three cases were caused by the inappropriate manner of filter's release. Filter angulation $>20^\circ$ was statistically correlated with retrieval failure, found in 7 out of 29 failed cases in this study
3	Lee, et al (2018)	Abutting group: Mean 21 days Non-abutting group Mean 23 days	There was no description on failed retrieval reason on both groups. However, the incidence of retrieval failure, complex retrieval, and complicated retrieval was statistically higher. The presence of external compression of IVC also resulted in higher number of difficult retrieval case
4	Stavropoulos, et al (2016)	Mean 200.8 days $\pm$ 156.9 (5-736 days)	The reasons of failed retrieval were filter apex hadn't been engaged successfully (2 cases) and the existence of blood clot inside the filter (1 case)
5	Uberoi, et al (2013)	Bard G: Median 77 days (34-154 days); Bard Recovery: Median 77 days (28-166 days) Cook Select: Median 32 days (18-66 days); Cook Gunther Tulip: Median 39.5 days (22-101 days) Cordis OptEase: Median 12 days (2-45 days)	There was no detailed information regarding failed retrieval cases. However, failed retrieval case that had been deployed >62 days was correlated with device incorporation with IVC wall, IVC thrombosis, and penetration of IVC wall by filter legs.
6	Reis, et al (2016)	Mean 125 days (34-324 days)	All filters were retrieved successfully

Retrospective study from Reis, et al, on Denali filter placement in Dallas, US. This specific filter was placed in 87 patients, mainly as an alternative option for patients that were contraindicated to anticoagulant. Retrieval attempts were performed in 31 (36%) patients, with mean dwell time of 125 days (34-324 days). All of the filters were successfully retrieved. Post-deployment complications were IVC wall penetration, cava thrombus and occlusion, and filter tilt.

Lee, et al, published a retrospective study on Celect filter placement in South Korea. In this study, samples were divided into two separate groups, patients with filter tip abutment and patients without it. Total retrieval attempt was 100 (71%) in both groups (37/52 in abutting group and 63/89 in non-abutting group). Higher success rate was found in non-abutting group (98%), with overall success rate was 96%. This remarkable high success rate compared to other studies was believed to have been correlated with shorter dwell time (21 days in abutting group vs 23 days in non-abutting group). Filter tilt $>15^\circ$ was the only post-deployment complication that was stated in this study.

Stavropoulos, et al, conducted a multicenter, prospective trial with 200 samples that had undergone Denali filter placement. Placement procedure success rate was 99.5%, with only one sample was failed to deploy due to technical problem. Indications for placement including current vein

thromboembolism disease (DVT or PE) or temporary high risk of PE. Retrieval procedure was performed in 124 samples, with success rate percentage went as high as 97.6% (121 out of 124). The reasons of failed retrieval were filter apex hadn't been engaged successfully and the existence of blood clot inside the filter. Mean dwell time was 200.8 days $\pm$ 156.9 (5-736 days). Almost half of the filter (46.3%) had been remained inside IVC more than 180 days. Complication that was found during follow-up included IVC wall penetration during placement and retrieval.

DISCUSSION

Retrieval Optimal Time

In recent years, the increasing use of retrievable filter in clinical practice has created several questions regarding its placement. This type of filter, originally, is designed to facilitate its retrieval procedure. In reality, there is growing trend where these filters are left in place for longer time or used as permanent filters. Many studies state that retrieval rate among centers all over the world is as low as 30%. Despite approval from FDA, this institution still recommends filter retrieval as primary choice. It is believed that extended dwell time increases post-deployment complications (filter migration, filter fracture, etc.). Therefore, interventionist should acknowledge when is the optimal time that retrievable filter removal should be performed, to ensure

minimum risk of complications or retrieval failure later.

This evidence-based case report provides 2146 samples that have undergone retrievable filter placement from six studies. Each study publishes the number of filter placement, filter retrieval attempt, successful retrieval, as well as filter's dwell time.

Prior studies never publish the standard time of filter retrieval, and neither do the studies in this report. Only two studies (Uberoi, et al, and Glocker, et al) analyze the relationship between dwell time and success rate of retrieval procedure, while remaining studies only provide data regarding their success rate and mean dwell time.

In Uberoi's study, retrieval procedure statistically more successful in the first 9 weeks (62 days). This study also provided dwell time from each type of filter that was recommended by its manufacturer (BBraun <12 weeks, Celect <67 weeks, Gunther Tulip <20 days, OptEase <23 days, Pyramed ALN <25 months). Interestingly, many retrieval failure cases occurred within the time period.³¹ Meanwhile, Glocker, et al, found that the duration of filter's placement was significantly different between successful retrieval and unsuccessful retrieval (105 days vs 162 days). This study stated that extended filter's dwell time was a predictor of filter retrieval failure in the future, other than filter angulation more than $>20^{\circ}$. Retrieval procedure prior than 117 days had success rate up to 90%.³⁰ A study in US showed that success rate could be as high as 98%, with time to retrieval interval was 4.6 months $\pm$ 4.3 months.³⁹ Another study found that dwell time >90 days was correlated with higher number of retrieval failure cases.³²

Other studies in this report had contrasting perspectives. Two studies, Tapson, et al, and Lee, et al, had shorter dwell time (<30 days) with retrieval success rates were more than 90%. Meanwhile, the other studies, Stavropoulos, et al, and Reis, et al, had similar success rates with much longer dwell time (200 days $\pm$ 156.9 and 125 days). Both studies used an exact type of filter, Denali filter that was recently launched in the market.

Based on these studies, retrieval procedure could be considered around three to four months after placement to achieve significant success rate. However, the recommendation from FDA that filter retrieval should take place as soon as possible when bleeding risk diminishes to start anticoagulant therapy, can be prioritized. One of the key reasons is to prevent loss-to-follow up cases that normally occur when dwell time is prolonged. Therefore, interventionist should design follow-up strategies that are strict yet effective. Few examples are establishing patient-based-registry and 30-days routine control program. Then, the clinician, the patient and his/her family members, can discuss the ideal time of retrieval procedure together. Furthermore, patients that don't show up during routine control, can be contacted personally after cross-checking in the registry. These methods are proven to be effective to improve patients' adherence during follow in several institutions.³⁹

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Factors Related to Retrieval Failure

Prolonged dwell time is well-known to result in several complications, such as filter fracture, IVC wall perforation, filter migration, or thrombosis. Belkin, et al, showed that filter that had been remained too long is key predictor of retrieval failure.³⁹ Prior studies have demonstrated the main reason of failed retrieval is filter tilt, when tip of the filter contacts IVC wall.³⁰ This finding is in accordance with another two respective studies in US, when filter tilt is correlated with advanced retrieval and retrieval failure.^{40,41} From studies that are included in this report, there are only four articles that have reported retrieval failure cases. Glocker, et al, showed that there was a relationship between retrieval failure and filter angulation more than 20° . Meanwhile, Stavropoulos, et al, stated that there were two factors related to retrieval failure, the inability to reach the filter due to anatomical curvature and thrombus inside the filter. Filter incorporation with IVC wall, IVC penetration, and filter thrombus were reasons in failed retrieval cases with prolonged dwell time (>62 days).

Studies that are included in this evidence-based case report have several limitations regarding filter retrieval. One of them is majority of the study doesn't set the optimal time of filter retrieval as primary outcome of the study, making it difficult to analyze two key variables (dwell time and success rate). Furthermore, studies with high number of retrieval failure don't explain in detail the reason for each case. Most of them only describe it in quite short sentences. Therefore, finding conclusion on this topic is rather difficult.

CONCLUSION

The conclusion of this evidence-based case report is six studies are matched with case illustration and clinical question based on literature search and study appraisal. They are four retrospective studies and two prospective, clinical studies. There is no single guideline that has published optimal time of filter retrieval procedure, therefore interventions should consider retrieve the filter as soon as possible when it is no longer needed, according to FDA recommendation. This report has showed that dwell time up to 4 months is still considered safe to prevent any technical failure on retrieval. The time limit can be used in terms of clinical setting when follow-up strategy is not established yet.

Factors that are known affect retrieval failure include filter tilt, filter incorporation with IVC wall, and penetration from filter component into IVC.

CONFLICT OF INTEREST

The author states the original work, and there is no conflict of interest in doing this research.

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