

# Impact of Presence of Inferior Vena Cava Filter on Iliocaval Stent Outcomes

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**Background:** The impact of presence of an IVC filter in patients undergoing stenting for symptomatic femoroiliocaval obstruction has not been explored in detail. This study attempts to fill this gap by evaluating clinical and stent-related outcomes in such patients. The incidence of deep vein thrombosis (DVT) in this setting is also analyzed.

**Methods:** A retrospective review of contemporaneously entered EMR data on initial iliocaval stents placed in patients with an indwelling IVC filter (or placed after stenting) over a 15-year period from 2000 to 2015 was performed. A separate matched cohort that underwent initial stenting during the time frame, but which did not have an IVC filter, was utilized as the control group. Clinical outcomes were evaluated through use of the venous clinical severity score (VCSS) and visual analog scale (VAS) pain scores. Incidence of deep venous thrombosis after stenting was also reviewed in both groups. The Kaplan-Meier analysis was used to assess stent patency after intervention while *t*-tests were used to examine preintervention and postintervention outcomes within and in-between groups.

**Results:** A total of 50 limbs (40 patients) underwent placement of a femoroiliocaval stent in the setting of a preexisting (49) or post-stent (1) IVC filter [filter group]. The control group had 156 limbs (155 patients). There was no difference in VCSS, VAS pain score, or grade of swelling at baseline between the 2 groups. Over the median follow-up duration (43 months—filter group; 40 months—control group), VCSS went from 6 to 4 at 12 months ( $P = 0.0001$ ) in the filter group and from 6 to 4 in the control group ( $P < 0.0001$ ). VAS pain scores went from 7 to 0 at 12 months ( $P < 0.0001$ ) in the filter group and from 5 to 0 in the control group ( $P < 0.0001$ ). There was no significant difference in the VCSS scores or VAS pain score between the 2 groups at 12 months ( $P > 0.05$ ). Overall, there was a statistically significant increase in the incidence of DVT in the filter group (10%) compared to the control group (3%) [ $P = 0.03\%$ ]. Primary, primary assisted, and secondary patencies in the filter/control groups at 48 months were 64%/65% ( $P = 0.6$ ), 100%/97% ( $P = 0.5$ ), and 100%/75% ( $P = 0.4$ ), respectively. Reintervention from in-stent restenosis was noted in 16% of patients in the filter group compared to 4% in the control group ( $P = 0.006$ ).

**Conclusions:** Patients with an IVC filter in the setting of a femoroiliocaval stent tend to have an increased rate of deep venous thrombosis on the stented side. In addition, an increased rate of reintervention secondary to in-stent restenosis was also noted. In light of this, every attempt should be made to remove the IVC filter as soon as the need for the filter no longer exists.

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## BACKGROUND AND OBJECTIVES

Increasing utilization of stenting for chronic iliac vein obstruction (CIVO) has been noted over the last several years.<sup>1–7</sup> A subset of these patients have an indwelling inferior vena cava filter (IVCF) or undergo placement of one subsequently. The impact of presence of such a filter on outcomes, both clinical and stent related, has not received much attention. This study explores the topic

**Table I.** Baseline characteristics of the filter and control groups

	Filter group	Control group	<i>P</i>
Median age	57.5 years	58.5 years	0.052
Gender	24 F/26 M	98 F/58 M	0.606
Laterality	28 L/22 R	94 L/62 R	0.064
NIVL	1 (2%)	17 (11%)	0.596
PTS	49 (98%)	139 (89%)	0.053

NIVL, nonthrombotic iliac vein lesion; PTS, post-thrombotic syndrome.

**Table II.** Baseline VCSS and VAS pain scores

	Filter group	Control group	<i>P</i>
VCSS	6	6	0.910
VAS pain score	5	6.5	0.100

including the incidence of deep vein thrombosis (DVT) in this setting.

## METHODS

### Study Design

A single-center retrospective analysis of prospectively collected data over a 15-year period from 2000 to 2015 was performed. Patient consent and hospital institutional review board approval was obtained for the study.

### Setting

The center is a tertiary center for management of venous and lymphatic disorders.

### Participants

Patients who underwent initial placement of a femoroiliacal stent in the setting of a preexisting IVCF or who subsequently underwent placement of an IVCF formed the filter group. The control group had matched patients who underwent femoroiliacal stenting during the same period but did not have or undergo placement of an IVCF during the study period. Stenting was carried out for patients presenting with disabling symptoms. These symptoms included swelling, pain, hyperpigmentation, and lipodermatosclerosis suggestive of obstructive femoroiliacal lesions. All patients underwent intravascular ultrasound (IVUS) interrogation to confirm diagnosis before stenting. Stenting was carried out either exclusively using Wallstents (Boston Scientific, Marlborough, MA) or, in the last few years, a composite stent configuration of Wallstent and Z stent (Cook Medical, Bloomington, IN) top.

Stent sizes used typically ranged from 14 to 20 mm diameter for the Wallstent and 25 to 30 mm for the Z stent. Antithrombotic therapy protocol after procedure during the study period was in the form of aspirin 81 mg that was continued indefinitely. Only patients on anticoagulation preoperatively for a prior deep venous thrombosis or thrombophilia were anticoagulated postoperatively. Details of stent technique and perioperative management have been described in prior publications.<sup>1,8,9</sup> Follow-up was in the form of venous duplex ultrasound (DUS) on day 1; 2 and 4 weeks; 3 months, 6 months, 1 year after intervention and yearly thereafter if asymptomatic without evidence of stent malfunction. Clinical appraisal was performed at every follow-up visit starting at 6 weeks.

### Measurements

The venous clinical severity score (VCSS) and visual analog scale (VAS) pain score were determined at the initial and follow-up clinic visits to assess the clinical status of the patient. In addition, the incidence of DVT after stenting was also evaluated in both groups. Stent patencies analyzed included primary, primary assisted, and secondary patencies.

### Reintervention

On follow-up, if patients had recurrence of disabling symptoms, they underwent repeat IVUS interrogation and correction of the etiology of stent malfunction. Such malfunction included stent compression (SC), in-stent restenosis (ISR), combination of SC and ISR or stent occlusion.

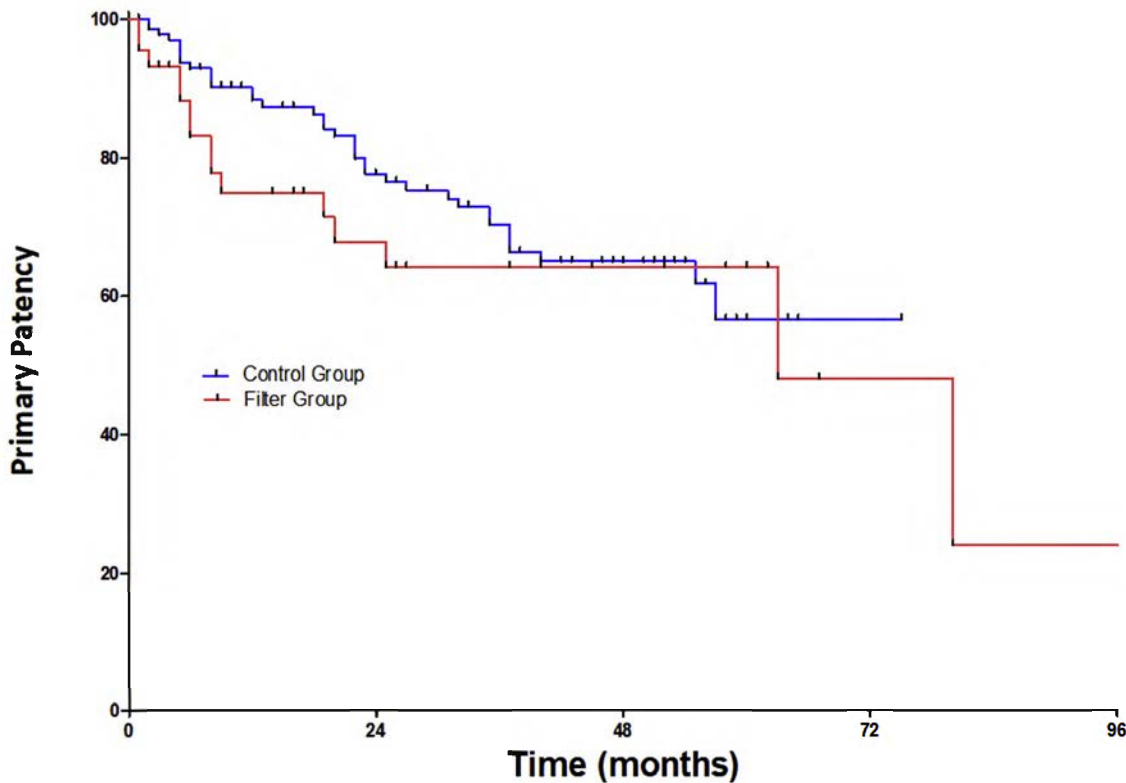


Fig. 1. Comparison of primary patency between the IVC filter and control groups.

### Statistical Analysis

Statistical analysis was performed using SPSS statistics version 24 (IBM Corp., Armonk, NY). Paired *t*-test was used to examine preintervention and post-intervention outcomes within groups, while unpaired *t*-test was used to compare the filter and control groups. The Kaplan-Meier analysis was used to assess stent patency after intervention. *P* value < 0.05 was considered significant.

### RESULTS

A total of 50 limbs (40 patients) underwent placement of a femoroiliacaval stent in the setting of a preexisting (49) or post-stent<sup>1</sup> IVC filter [filter group]. The control group had 156 limbs (155 patients). Baseline characteristics of both groups are considered in Table I. The median follow-up duration was 43 months for the filter group and 40 months for the control group. Ten patients underwent bilateral stenting in the filter group and 1 in the control group. Of the 39 patients who had an IVC filter before placement of the femoroiliacaval stent, historical filter data were available only in 10

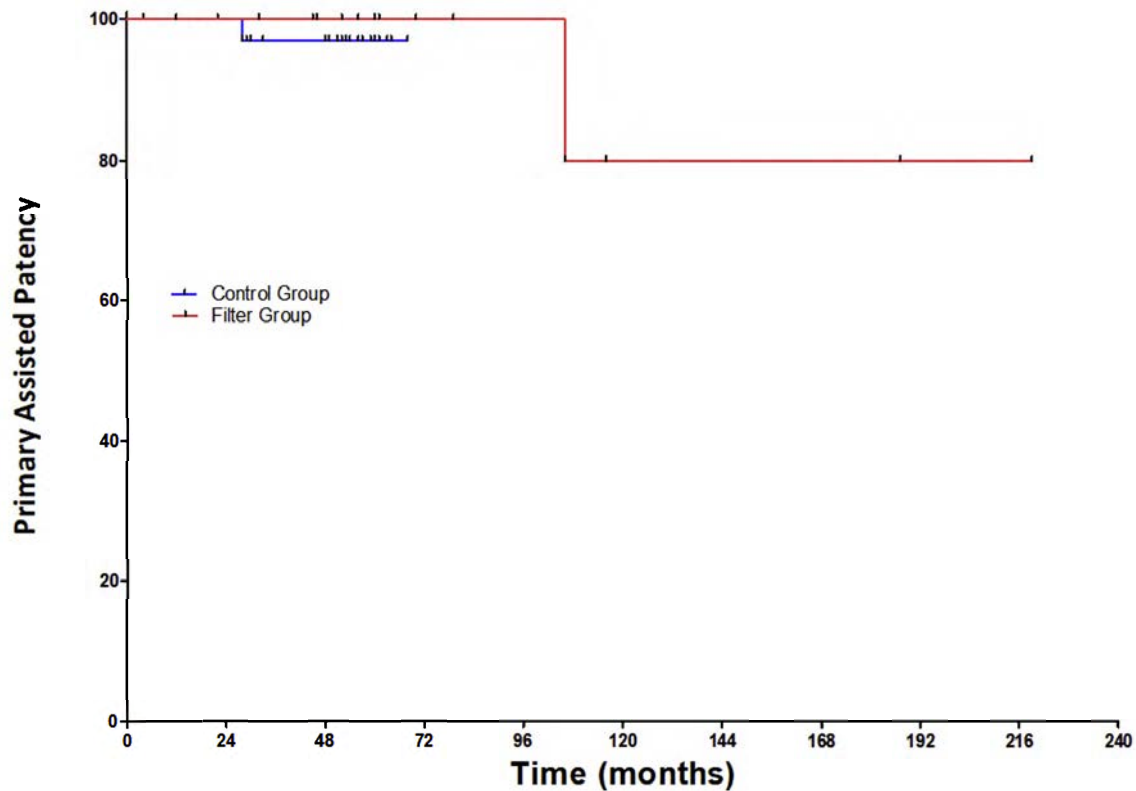
patients. Based on that information, the average duration from IVC filter placement to stenting was 51.5 months. One patient underwent IVC filter placement 3 months after stenting. Of the total 40 patients, 2 underwent IVC filter removal after stenting, one at 3 months and the other at 17 days.

### Clinical Characteristics

There was no difference in VCSS or the VAS pain score at baseline between the 2 groups (Table II). Over the median follow-up duration, VCSS went from 6 to 4 at 12 months ( $P = 0.0001$ ) in the filter group and from 6 to 4 in the control group ( $P < 0.0001$ ) as well. VAS pain scores went from 7 to 0 at 12 months ( $P < 0.0001$ ) in the filter group and from 5 to 0 in the control group ( $P < 0.0001$ ). There was no significant difference in the VCSS scores or the VAS pain score between the 2 groups at 12 months ( $P > 0.05$ ).

### Deep Vein Thrombosis

Overall, there was a statistically significant increase in the incidence of DVT in the filter group ( $n = 4$  limbs, 8%) compared to the control group ( $n = 4$



**Fig. 2.** Comparison of primary assisted patency between the IVC filter and control groups.

limbs, 2%) [ $P = 0.03\%$ ]. This included 3 (6%) on the stented side and 1 (2%) on the contralateral side in the filter group. In the control group, there were 2 instances each (overall 2%) of ipsilateral and contralateral DVTs. Although there was a significant difference in the incidence of ipsilateral DVT (stented side) ( $P = 0.0006$ ) between the 2 groups, there was not a significant difference in the incidence of contralateral DVT ( $P = 0.71$ ). Overall, only 25% of patients were on anticoagulation at the time of diagnosis of the DVT.

### Stent Patency

Primary, primary assisted and secondary patencies at 48 months in the filter group were 64%, 100% and 100% and in the control group were 65%, 97% and 75% respectively (Figs. 1–3). There was no statistically significant difference in primary ( $P = 0.6$ ), primary assisted ( $P = 0.5$ ) and secondary patencies ( $P = 0.4$ ) between the two groups.

### Reintervention

Reintervention was noted in 19/50 limbs (38%) of the filter group and 40/155 patients (26%) of the control group ( $P = 0.09$ ). The breakdown of etiology

for reintervention is considered in Table III. Of the reinterventions performed for ISR, SC, ISR + SC and stent occlusion, reintervention for ISR was noted to be statistically significant with 8 limbs (16%) undergoing reintervention in the filter group and 7 limbs (4%) undergoing reintervention in the control group ( $P = 0.006$ ).

## DISCUSSION

Over the years, the utilization of IVC filters, both temporary and permanent, has increased tremendously. Removal of filters when they are no longer required, however, has not kept pace with the placement. This has resulted in patients having an IVC filter long after the need for such filters have gone away. This period has also witnessed the emergence of femoroiliocaval stenting as the first line for treatment for symptomatic chronic iliac vein obstruction. Of the approximately 3,000 patients who underwent iliac vein stenting during the study period, 40 patients had an IVC filter (or had one placed subsequently) corresponding to  $\sim 1.3\%$ . This latter number, however, does not take into account patients who end up having chronic total occlusion of the IVC in the setting of an occluded filter

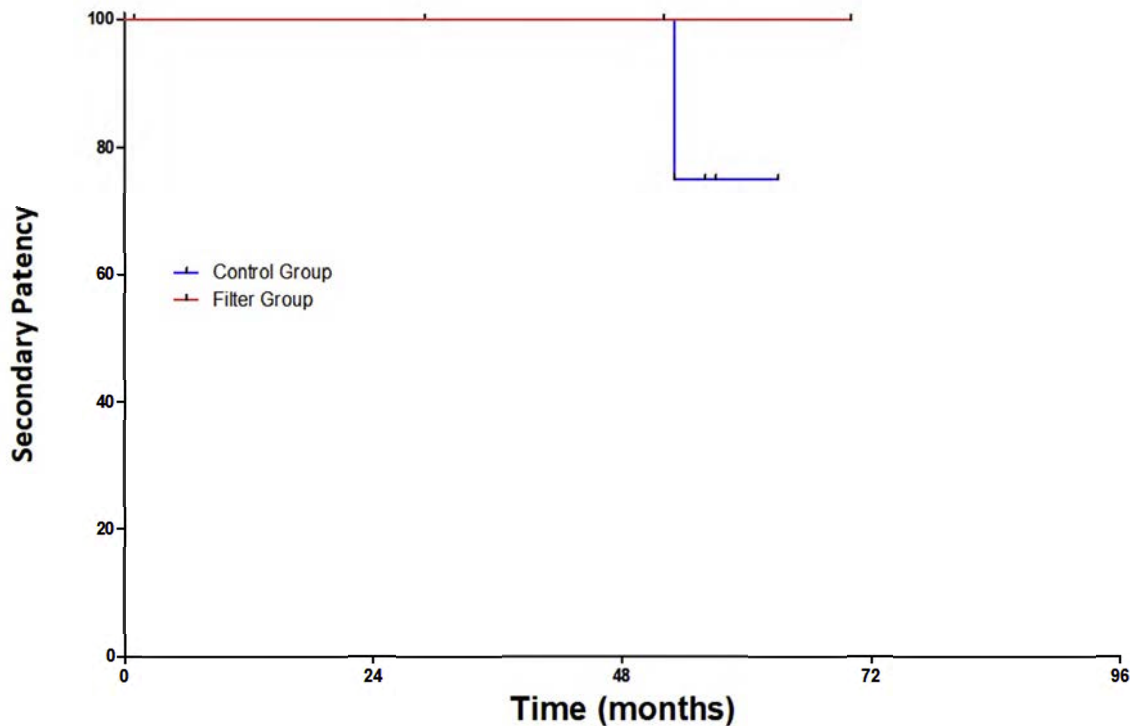


Fig. 3. Comparison of secondary patency between the IVC filter and control groups.

and who require IVC filter crushing and stenting across. The prevalence of this scenario can be as high as 21% according to previously published data.<sup>10</sup> Although the overall number of patients who end up with a filter in the setting of an iliac vein stent are small (up to 8% has been reported<sup>10</sup>), the impact of such filters on venous stents merit exploration.

#### Impact of Presence of IVC Filter in Stented Patients on Clinical Outcomes

From a clinical standpoint, the presence of an IVC filter does not impact outcomes. Both groups had improvement in VCSS and VAS pain scores at 12 months after stenting that were statistically significant. In addition, at this time point, there was no significant difference between the clinical improvement attained by the 2 groups. There however was an increase in the incidence of DVT in patients who underwent placement of a filter 10%, versus those who did not, 3%. This would be expected given that IVC filters are placed in patients who are not candidates for or those who have failed anticoagulation. In fact, overall, only 25% of patients who were diagnosed with a DVT were on anticoagulation at the time of diagnosis including 33% in the control group, and 20% in the treatment group.

#### Impact of Presence of IVC Filter in Stent Patients on Stent Outcomes

Stent patencies after femoroiliacal stenting were not significantly different if patients had an IVC filter or not. While primary patency in the filter group was 57 months, it was 53 months in the control group. There was no statistically significant difference in primary, primary assisted and secondary patencies between the filter and control groups. Overall, there was a 38% reintervention rate in the filter group, while it was 26% in the control group. When broken down based on reason for reintervention, in-stent restenosis has a higher rate for reintervention 16% in the filter group compared to 4% in the control group ( $P = 0.006$ ). This potentially could be from altered outflow hemodynamics in the presence of an IVC filter that leads to more robust ISR development than would otherwise happen. This however does not necessarily lead to stent occlusion given that there was no significant difference in the incidence of stent occlusion in the 2 groups. In addition, previously published data argue against relentless progression of ISR to stent occlusion.<sup>11</sup>

#### Case for Removal of the IVC Filter

Patients with an IVC filter undergoing iliac vein stenting or those who undergo placement of a filter

**Table III.** Breakdown of reintervention in both groups

	ISR 'n' (%)	<i>P</i>	SC <sup>a</sup> 'n' (%)	ISR + SC 'n' (%)	<i>P</i>	SO 'n' (%)	<i>P</i>
Filter group	8 (16)	0.006	0 (0)	8 (16)	0.83	3 (6)	0.52
Control group	7 (4)		4 (3)	23 (15)		6 (4)	

The statistically significant result is highlighted.

SO = stent occlusion.

<sup>a</sup>There were no reinterventions for stent compression in the filter group disallowing comparison.

subsequently have similar clinical and stent-related outcomes compared to those without a filter. Nevertheless, given the increased rate of reintervention secondary to altered hemodynamics and development of in-stent restenosis, the filter should be removed as soon as they are no longer needed.

### Limitations

The relatively small number of patients with an IVC filter represents a shortcoming as does the inherent retrospective nature of the study.

### CONCLUSIONS

Patients with an IVC filter in the setting of a femoroiliocaval stent tend to have an increased rate of deep venous thrombosis on the stented side. In addition, an increased rate of reintervention secondary to in-stent restenosis also noted. In light of this, every attempt should be made to remove the IVC filter as soon as the need for the filter no longer exists.

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