

Indications, Complications, and Removal of Inferior Vena Cava Filters in a hospital in Colombia

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Summary

Introduction

Inferior Vena Cava Filters (IVCF) are endovascular devices used to reduce the risk of pulmonary embolism (PE) and death in patients with acute proximal venous thromboembolic disease (VTE) who are unable to receive anticoagulation therapy, or in patients with recurring PE despite appropriate anticoagulation therapy ¹. The problem with IVCFs apart from complications due to migration and breakage of the device is that their long-term use paradoxically increases the risk of deep venous thrombosis (DVT) ². For this reason, IVCFs should be removed as soon as anticoagulation therapy is no longer contraindicated³. However, the literature on the subject shows that a large percentage of IVCFs are left in place and never removed ⁴. Additionally, there is an increased use of IVCFs in scenarios where its use is not evidence based such as primary prophylaxis in trauma or bariatric surgery, and in patients submitted to lower limb local thrombolysis or pulmonary endarterectomy ^{5,6}. These practice exposes patients to the risk of iatrogenic thrombotic complications and increase health care costs.

No data has been published regarding the use of IVC filters in Colombia. The objective of this study is to evaluate the indications, practices, removal rates, and complications of IVC filters in a Colombian university hospital.

Materials and Methods

Design, and location of study: An observational, descriptive and retrospective study was performed at IPS Universitaria - Clínica León XIII, a level three university teaching hospital.

Patients: the study included 196 male and female hospitalized adult patients (>18 years old) who had an IVCF implanted during their hospital stay. Patients who had essential missing data that were part of the variables required for the analysis were excluded from the study.

Source of information: Patients who had an IVCF placed were identified using CUPS codes and the data base of patients who were attended by the Radiology Department between January 1st, 2010 and December 31st, 2016. The information of eligible patients was obtained from electronic medical (EMR) by doctors trained in using electronic medical records and using a predesigned form. The following data was included: demographics including age, sex, and type of patient; comorbidities; risk factors for Thromboembolic Disease; anticoagulation (type and duration); and IVCF (ordering department, indication, date of implantation, filter brand, removal attempt, date of removal, duration, and complications).

Statistical analysis: age was described as mean and standard deviation, other quantitative variables were described as medians and interquartile ranges, and the categoric variables as absolute frequency and percentages. All the calculations were carried out in MS Excel 2016.

Results

A total of 196 patients were identified as having an IVCF implanted. Of those, 134 were women (68.4%), and 62 men (31.6%). The average age at the time of implantation was 65 ± 18.1 years of age. 140 patients were considered medical (71.4%), and 56 surgical (28.6%) (Table 1). All patients had acute thromboembolic disease. None received a filter as primary prophylaxis.

The total number of IVCFs placed between 2010 and 2013 remained relatively stable [2010: 25 (12.8%), 2011: 27 (13.8%), 2012: 28 (14.3%), 2013: 32 (16.3%)], followed by a peak in 2014 (n= 42, 21.4%) but then there was a significant decline starting in the year 2015. [2015: 24 (12.2%) and 2016: 18 (9.2%)].

Indications of IVCF

The most common indications for the placement of IVCFs were the need of surgery 76/196 (38.7%), acute hemorrhage or risk of hemorrhage 73/196 (37.2%), and catheter guided local thrombolysis in lower extremities. 44/196, (22.4%) (Table 2). Not a single IVCF was implanted as a prophylactic measure, however 1 IVCFs was implanted in a patient with acute VTE but without a clear clinical indication.

Acute complications due to IVCFs

Acute complications related to the implantation of IVCFs occurred in 13 patients. The most common complication was acute inferior vena cava thrombosis (4 patients), tilting of the IVCF (4 patients), and lesion in the puncture site (2 patients) (table 3). Interestingly, there was a case of extravascular migration of the filter that became lodged in the duodenum and the patient required a laparotomy to extract the device, the patient was later discharged in a healthy state. The average length of time between the implantation of the IVCF and the development of the complication was 4 days (range 0-20 days).

Removal of IVCF

ICVF removal was considered no feasible in 40 patients (12 because of death, 28 because of device considered permanent). Of the remaining 156 patients, removal was attempted in 118

patients (75.6%), being successful in 108 patients (91.5%) and unsuccessful in 10 (8.4%), 3 of them because of thrombus lodged in the filter and 7 because of technical failure. The relative frequency of removal attempts was less than or equal to 50% between the years of 2010 and 2012 and sharply increased from 2013 to 2016. [2010: 41.2%, 2011: 50%, 2012: 50%, 2013: 72.2%, 2014: 81.5%, 2015: 81.8%, 2016: 71.4%].

Notoriously, it was found a high number of patients 38/156 (24.3%) in which removal was not attempted and there was no mention of follow up of the device in the patient records.

The average duration of IVCF use in patients where the device was successfully removed was 8 days (range: 5 – 99 days). Anticoagulation therapy was started in 104 out of 108 patients after removal of the IVCF (96.2%). Patients who did not receive a removal attempt, were significantly older than patients who had removal of the IVCF (68.2 ± 14.9 vs. 56.9 ± 18.4 years, $p < 0.01$). There was no significant difference based on gender. (females: 69.6% vs. 64.2%).

Subgroup of oncologic patients

76 oncologic patients were identified in the period of study, 55 women (72.4%) and 21 men (27.6%). The average age at the time of implantation of the IVCF was 64.2 ± 14.8 years. All patients had acute VTE. (Tabla X). The most common indications for the placement of IVCFs were the need of surgery (46/76, 60.5%) and active bleeding or high risk of bleeding, (30/76, 39.5%). There were 3 acute complications related to the IVCF implantation in this group. Surprisingly, in this group, removal attempts were carried out only in 36 patients (47.4%) (compared to the 75.6% of the total population of the study which was or not statistically significant), being successful in 32 patients (88.8%). The causes of no removal attempt were indication of permanent filter ($n=19$, 43.2%), lack of follow up ($n=13$, 29.5%), death

before removal attempt (n=6, 13.6%) and thrombus attached to the device (n=3, 6.8%). The average duration of IVCF use in patients where the device was successfully removed was 10 days (range: 1 – 80 days). Anticoagulation therapy was started in all patients after removal of the IVCF. (n=32).

Discussion

IVCFs are endovascular devices used as a temporary protecting measure, mainly in patients with acute proximal VTE and absolute contraindication to anticoagulation therapy (i.e: active bleeding, high risk of bleeding or need of surgery) to reduce the risk of PEs. In this study 149 patients (76%) had a clear indication for use of IVCF because of acute thromboembolic disease and contraindication to anticoagulation due to active bleeding, risk of bleeding or need of surgery.

One of the most common indications for use of IVCFs identified in the study, was the need of catheter guided local thrombolysis in the lower extremities. Despite of the belief that the use of the IVCF reduce the risk of PE in this context, the incidence of PE in patients without filter submitted to this procedure is extremely low, which generates controversy respect to cost effectiveness and safety of the use of the IVCF in this group of patients.^{11,12} In this study 22.4% of IVCFs were implanted for this reason and 89.7% of them were ordered by Interventional radiology. One of these patients suffered a perforation of the vena cava with migration of the device to the duodenum and need of emergent laparotomy. Given the fact that catheter guided thrombolysis has almost become obsolete with the new evidence on the topic, this indication of IVCF tends to disappear.

The use of IVCF is not indicated as a primary prophylactic measure¹. However, according to some publications, in trauma patients, the use of IVCF can be as high as 76%¹³. This could

be a significant problem due to the high costs and unnecessary complications. This study did not identify the use of any IVCs as a primary prophylactic measure which could be attributed to the high adherence to clinical guidelines and rational use of medical devices or because of the limited resources of the health system in Colombia which avoids the use of expensive medical devices in no evidence based settings.

IVCs are effective at preventing PE in the short term but this effect is offset by an increased risk of DVT distal to the filter in the long term.² For this reason, IVCs should be removed as soon as the contraindication of anticoagulation therapy is resolved, and appropriate anticoagulation therapy should be initiated which would avoid the long term complications caused by IVCs^{3,14}. In this study IVC removal was attempted in 75.6% of patients being successful in 92.6% of the cases. The lack of follow-up for any reason was the most frequent cause for not removing IVCs accounting for 24.3% of cases. Those forgotten unremoved filters, generate an opportunity for quality improvement for the institution, given that leaving them in situ is associated with medium and long term thrombotic complications.

To increase the frequency of IVCs withdrawal, it is recommended to use a “responsibility of patient follow up” strategy, where the supervising physician should be the one to determine when anticoagulation therapy is no longer contraindicated in the patient and not the interventionist who places the filter. Also, it is recommended that a nurse keep a follow-up record of patients with IVCs and notify doctors when its use is no longer necessary. Lastly, the supervising physician should leave a written discharge plan in cases where removal was not possible during the patient stay at the hospital. This note should include the reason why it was not removed and a reevaluation date¹⁵.

Strikingly, in the study was observed an improvement in the rate of filter removal in the time, being lower of 50% in the 3 first three years of the study (2010 – 2012) which increased notoriously in the following years. This could be explained by the increased awareness in the topic regarding the complications of the filters, generated for the health authorities in the last years.

Cancer is a well-known risk factor for both VTE and hemorrhagic complications related to anticoagulation use. Because of this, the use of IVCF is quite common in this subgroup, despite of a lack of evidence to support a benefit or adverse effects in this population. Currently, the indications for use of filter are similar to the patients without cancer. In this study, we identified 76 patients with filter associated to cancer. All of them had a clear indication for the use of the device. However, we identified a low rate of filter removal compared to the global population of the study, which was statistically significant compared to the total number of patients of the study??. Given the retrospective design of the study it was not possible to define the reason of this finding, but we speculate that it could be related to a greater need of permanent filters in patients with increased risk of persistent bleeding related to their debilitating illness.

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Table 1. Patient demographics and clinical characteristics

Age, Average (ICR)	65 (50 – 75)	
	n	%
Gender female	13	68.4
	4	
Primary reason for hospitalization		
Thromboembolic Disease	73	37.2
Cancer	41	30.9
Excessive hemorrhaging	22	11.2
Trauma/Fractures	17	8.7
Infection/Sepsis	14	7.1
Chronic illness	10	5.1
Cerebrovascular disease	8	4.1
Other	11	5.6
Current neoplasms		
Gynecological	25	32.9
Gastrointestinal	22	29.0
Urological	10	13.2
Pulmonary	5	6.6
Other	5	6.6
Lymphatic/hematological	4	5.3
CNS	2	2.6

Endocrine	2	2.6
Osteo-muscular	1	1.3
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Specialty that ordered IVCF		
Internal Medicine	72	36.7
Vascular	56	28.6
Interventional Radiology	41	20.9
Other	18	9.2
General surgery	3	1.5
Vascular Surgery	3	1.5
Thoracic Surgery	1	0.5
Gynecology	1	0.5
Orthopedics	1	0.5
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Filter Brand		
Temporal IGTCFS-65	14	74
	5	
G2 Express	51	26
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ICR: Interquartile Range; CNS: Central Nervous System		
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Table 2. Indication for IVCF in patients with

Thromboembolic Disease

(n=186)	n	%
Need for Surgery	73	39.8
Gynecological	12	21.8
Oncological	16	20.5
Orthopedic	16	20.5
Abdominal	11	14.1
CNS	6	7.7
Urological	4	5.3
Thorax	3	3.9
Vascular	2	2.6
Cardiac	1	1.3
Transplant	1	1.3
ENT	1	1.3
Hemorrhaging	61	31.1
GIT	31	50.8
GUT	12	19.7
CNS	12	19.7
Skin	3	4.9
Retroperitoneal	3	4.9
Fibrinolysis	43	21.9

High risk of hemorrhage	7	3.6
Failure of anticoagulation therapy	2	1
Treatment of thromboembolic disease in patients who can receive anticoagulation	0	0

ENT: Ear nose throat; CNS: Central nervous system; GIT:

Gastrointestinal tract; GUT: Genitourinary tract

Table 3. Complications associated with IVCF implantation

Complication	n	%
Complication	13	6.6
Incorrect position	1	7.7
Lesion at incision site	2	15.4
Acute thrombosis of vena cava	4	30.8
Migration (> 1 cm)	1	7.7
Penetration or erosion of vena cava	1	7.7
Inclination of filter (>10°eje)	4	30.8
Fracture of filter	1	7.7
Infection	3	23.1

IVCF: Inferior vena cava filter

Tabla 1. Características sociodemográficas y clínicas de paciente oncológicos con filtro de vena cava inferior (n = 76)

Edad, Media ± DE	64.2 ± 14.8
Genero, N (%)	
Femenino	55 (72.4)
Masculino	21 (27.6)
Sitio primario del cáncer, N (%)	
Mamas y genitales femeninos	24 (31.6)
Órganos digestivos	24 (31.6)
Tracto urinario	9 (11.8)
Órganos respiratorios	5 (6.6)
Ojo, cerebro, sistema nervioso	3 (3.9)
Linfoide o hematopoyético	3 (3.9)
Sitio no especificado	3 (3.9)
Glándulas endocrinas	2 (2.6)
Hueso, piel, mesotelio, endotelio, tejidos blandos	1 (1.3)

Labios, cavidad oral, faringe	1 (1.3)
Genitales masculinos	1 (1.3)
ETEV aguda, N (%)	72 (94.7)
TEP	21 (29.2)
TVP Distal	23 (31.9)
TVP Proximal	56 (77.8)
Uso de anticoagulación, N (%)	35 (46.1)
HBPM	33 (94.3)
HNF	2 (5.7)

ETEV: Enfermedad tromboembólica venosa; HBPM: Heparinas de bajo peso molecular; HNF: Heparina no fraccionada; TEP: Tromboembolismo pulmonar; TVP: Trombosis venosa profunda.