



Clinical Outcomes of a Preoperative Inferior Vena Cava Filter in Acute Venous Thromboembolism Patients Undergoing Abdominal-Pelvic Cancer or Orthopedic Surgery

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Purpose: Surgery is the most common risk factor for pulmonary embolism (PE) in patients with a recent venous thromboembolism (VTE). This study reviewed clinical outcomes of preoperative inferior vena cava filter (IVCF) use in patients with acute VTE during abdominal-pelvic cancer or lower extremity orthopedic surgeries.

Materials and Methods: We retrospectively analyzed 122 patients with a recent VTE who underwent IVCF replacement prior to abdominal-pelvic cancer or lower extremity orthopedic surgery conducted between January 2010 and December 2016. Demographics, clinical characteristics, postoperative IVCF status, risk factors for a captured thrombus, and clinical outcomes were collected for these subjects.

Results: Among the 122 study patients who were diagnosed with acute VTE in the prior 3 months and underwent preoperative IVCF replacement, 70 patients (57.4%) received abdominal-pelvic cancer surgery and 52 (42.6%) underwent lower extremity orthopedic surgery. There were no perioperative complications associated with IVCF in the study population and no cases of symptomatic PE postoperatively. A captured thrombus in the filter was identified postoperatively in 16 patients (13.1%). Logistic regression analysis indicated that postoperative anticoagulation within 48 hours significantly reduced the risk of a captured thrombus (odds ratio [OR], 0.28; 95% confidence interval [CI], 0.08-0.94; P=0.032).

Conclusion: A captured thrombus in preoperative IVCF was identified postoperatively in 16 patients (13.1%). Postoperative anticoagulation within 48 hours reduces the risk of captured thrombus in these cases.

Key Words: Venous thromboembolism, Inferior vena cava filter, Pulmonary embolism, Surgery

Received September 1, 2018

Revised October 18, 2018

Accepted October 26, 2018

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Conflict of interest: None.

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Vasc Spec Int 2018;34(4):103-108 • <https://doi.org/10.5758/vsi.2018.34.4.103>

INTRODUCTION

A venous thromboembolism (VTE) is a potentially fatal complication during a perioperative period. In addition

to the surgery itself, the other general risk factors for VTE include older age, immobilization, fracture, malignancy, chemotherapy, obesity and neurologic disease. A prior history of VTE and major surgery are also significant risk fac-

tors for this condition [1]. In perioperative patients at a high risk of VTE, current guidelines recommend perioperative prophylactic anticoagulation as a preventative measure [2]. Although an inferior vena cava filter (IVCF) is currently only recommended for VTE patients showing a contraindication for anticoagulants or who develop recurrent pulmonary embolism (PE) with these drugs, several reports have suggested that this device shows prophylactic efficacy with or without anticoagulation in perioperative patients at high risk [3–6]. Thus consideration should be given to using perioperative prophylactic anticoagulation or/and IVCF in patients undergoing major surgery and with high risk factors for VTE.

In patients with an acute VTE onset within the prior 3 months, major surgeries should include anticoagulation bridging if they cannot be delayed until a 3-month treatment has been completed for the VTE [2]. However, in some cases this bridging needs to be delayed for 48 hours because of the risk of postoperative bleeding. Hence, an IVCF is suggested for preventing perioperative PE following major surgeries in patients with acute VTE. We have here reviewed the clinical outcomes of prophylactic IVCF during high risk surgeries in patients with acute VTE, including abdominal-pelvic cancer and lower-extremity orthopedic procedures.

MATERIALS AND METHODS

This retrospective observational study was performed via a medical record review. The study protocol was approved by the Institutional Review Board of Asan Medical Center (2014-0425). This study was a retrospective study that did not cause any harm to the study subjects; therefore, the requirement of informed consent was waived by the board. Between January 2010 and December 2016, 122 consecutive patients underwent abdominal-pelvic cancer surgery or lower-extremity orthopedic surgery at our hospital whilst receiving anticoagulation therapy for acute VTE (PE and/or deep vein thrombus [DVT] on lower extremity) that had arisen within the prior 3 months. These patients underwent a retrieval IVCF insertion for the prevention of perioperative PE. The abdominal-pelvic cancer surgery cases included trans-peritoneal abdominal or pelvic organ procedures and the orthopedic surgery group included cases of fracture fixation, arthroplasty and excision of a malignant mass in the lower extremity. All instances of VTE in this cohort had been identified preoperatively via lower extremity ultrasonography or venographic computed tomography (CT) for a DVT and by chest CT for PE. Anticoagulation treatment was defined as use of unfractionated heparin, low molecular weight heparin (LMWH), warfarin

or direct oral anticoagulant (DOAC). In accordance with the American College of Chest Physicians guidelines [2], the administration of LMWH had been recommended in all patients until 12 hours preoperatively with anticoagulation (LMWH or DOAC) restarted within 48 hours if there was no risk of postoperative bleeding from using these drugs. The timing of the perioperative anticoagulation therapy was determined by the clinician with consideration of the bleeding risk.

A retrievable IVCF was inserted through the jugular vein and deployed into the IVC above or below the renal vein junction before surgery to avoid the thrombus. The IVCF types used were Celect (Cook Medical, Bloomington, IN, USA) in 119 patients and OptEase (Cordis Endovascular; a Johnson & Johnson Company, Warren, NJ, USA) in 3 cases. The insertion procedures were performed in the Department of Radiologic Intervention. Retrieval was attempted within at least 2 months of an anticoagulation restart if there was no postoperative bleeding risk and no captured thrombus on radiologic images, including a percutaneous venogram or CT. If percutaneous retrieval was not possible within 2 months, the IVCF was placed permanently without surgical removal.

We analyzed the clinical features and outcomes in our subject patients, including perioperative IVCF-related complications and instances of a captured thrombus in the IVC. A captured thrombus was confirmed by percutaneous venogram or CT within postoperative 2 months. Proximal DVT was defined as the thrombus between femoral vein and IVC, and recurred VTE was defined as new thrombus formation after the end of anticoagulation therapy for previous VTE. We stratified our patients into two groups, by thrombus capture or not, and analyzed the risk factors for this capture. Categorical data were recorded as counts and percentages and continuous data as means and ranges. To compare continuous and categorical variables, we used the student t-test, the chi-square test, or Fisher's exact test. A logistic regression model was used to identify independent risk factors for a captured thrombus. All statistical analyses were performed using PASW Statistics ver. 18.0 software (IBM Co., Armonk, NY, USA), with a P-value of ≤ 0.05 indicating significance.

RESULTS

Of the 122 patients in our study cohort who had been diagnosed with acute VTE within the prior 3 months and underwent a preoperative IVCF insertion, 70 patients (57.4%) underwent abdominal-pelvic surgery and 52 patients (42.6%) received lower extremity orthopedic surgery. VTE was diagnosed in the total study population at

a mean of preoperative 16.7 days (range, 1-81 days) and the IVCF was inserted preoperatively at a mean of 1.9 days (range, 1-12 days). There were no perioperative complications associated with IVCF insertion such as hematoma, IVC tear and IVCF migration, and there was no postoperative symptomatic PE. A perioperative transfusion was needed in 82 of the study patients (67.2%), but there were no re-exploration surgeries for postoperative bleeding. There was one perioperative death in our study cohort due to aspiration pneumonia after a total hip replacement surgery. A captured thrombus at the IVCF was identified in 16 patients

(13.1%) on postoperative CT (10 patients) and percutaneous venography (6 patients). Captured thrombus was diagnosed at a mean of postoperative 12.2 days (range, 1-48 days). Table 1 compares the clinical characteristics between the thrombus capture and non-capture groups and no significant differences were found.

All patients were evaluated for PE and lower extremity DVT. The characteristics of the VTE and perioperative anticoagulation therapy are presented in Table 2. Eighty one patients (66.4%) developed PE and 101 cases (82.8%) had lower extremity DVT. Sixty one patients (50.0%) received

Table 1. Patient characteristics

Variable	Total (n=122)	Thrombus not captured (n=106)	Thrombus captured (n=16)	P-value
Female	69 (56.6)	59 (55.7)	10 (62.5)	0.607
Age	61.9±16.5	61.9±16.9	62.0±14.1	0.987
Diabetes	21 (17.2)	18 (17.0)	3 (18.8)	1.000
Hypertension	46 (37.7)	40 (37.7)	6 (37.5)	0.986
Smoking	41 (33.6)	37 (34.9)	4 (25.0)	0.434
CAD	8 (6.6)	5 (4.7)	3 (18.8)	0.069
COPD	15 (12.3)	13 (12.3)	2 (12.5)	1.000
CVA	5 (4.1)	5 (4.7)	0 (0.0)	1.000
BMI	23.0±3.7	23.2±3.8	21.8±3.2	0.169
Surgery				0.657
Abdomino-pelvic	70 (57.4)	60 (56.6)	10 (62.5)	
Orthopedic	52 (42.6)	46 (43.4)	6 (37.5)	
Malignancy	56 (45.9)	47 (44.3)	9 (56.3)	0.373
Neoadjuvant chemotherapy	13 (10.7)	12 (11.3)	1 (6.3)	1.000
Perioperative transfusion	82 (67.2)	70 (66.0)	12 (75.0)	0.477
Preoperative antiplatelet	22 (18.0)	18 (17.0)	4 (25.0)	0.486
Preoperative d-dimer	15.2±21.1	15.5±22.4	11.5±8.2	0.508

Values are presented as number (%) or mean±standard deviation.

CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; BMI, body mass index.

Table 2. Characteristics of acute VTE and perioperative anticoagulation therapy

	Total (n=122)	Thrombus not captured (n=106)	Thrombus captured (n=16)	P-value
Pulmonary embolism	81 (66.4)	73 (68.9)	8 (50.0)	0.136
Lower extremity DVT	101 (82.8)	86 (81.1)	15 (93.8)	0.301
IVC thrombus	9 (7.4)	8 (7.5)	1 (6.3)	1.000
Proximal DVT	61 (50.0)	52 (49.1)	9 (56.3)	0.592
Recurred VTE	6 (4.9)	6 (5.7)	0 (0.0)	1.000
Preoperative anticoagulation ^a	61 (50.0)	54 (50.9)	7 (43.8)	0.592
Postoperative anticoagulation ^b	61 (50.0)	57 (53.8)	4 (25.0)	0.032

Values are presented as number (%).

VTE, venous thromboembolism; DVT, deep vein thrombosis; IVC, inferior vena cava.

^aAdministration of low molecular weight heparin (LMWH) until 12 hours preoperatively, ^bRestarting of anticoagulation (LMWH or direct oral anticoagulant) within 48 hours post-surgery.

an anticoagulation agent until 12 hours preoperatively. There was no significant difference found between the two study groups. Sixty one patients also (50.0%) were restarted on anticoagulating agents within 48 hours postoperatively, indicating that this intervention significantly reduces the risk of a captured thrombus ($P=0.032$).

There were 16 cases (13.1%) of a captured thrombus in our current study series. The mean long axial diameter of the captured thrombi was 28.3 mm (range, 10.1-75.3 mm) and the short axial diameter was 12.8 mm (range, 6.5-23.0 mm). We analyzed the risk factors associated with a captured thrombus and present these findings in Table 3. By logistic regression analysis, postoperative anticoagulation within 48 hours significantly reduced the risk of a captured thrombus (odds ratio, 0.28; 95% confidence interval, 0.08-0.94; $P=0.032$). The IVCF could only be removed safely in 6 captured thrombus cases, i.e., without complications after anticoagulation therapy. The mean induration time of the IVCF in these cases was 28 days (range, 11-57 days). IVCF retrieval could not be attempted in the other 10 cases due to persistent thrombus after anticoagulation therapy.

IVCF retrieval was attempted in 96 patients and was successful in 90 cases (a 93.7% success rate). The cause of the retrieval failure was the inability to capture the filter due to tilting. There were no recorded complications related to IVCF retrieval in 90 patients. The IVCF remained permanently in 30 of the study patients after surgery. The reasons for this permanent placement are described in Table 4 with the most common reason being a large thrombus capture postoperatively. In 10 cases of contraindication for anticoagulation and progression of DVT, the clinician decided to maintain IVCF because of concern about PE risk. Three patients with poor cancer prognosis refused IVCF removal. There was one perioperative death on the 11th day after

total hip replacement. The cause of death was aspiration pneumonia and IVCF removal was not performed in this patient. In 30 permanent IVCF patients, one IVC occlusion below IVCF was observed at postoperative 9 months and no other IVCF-related late complications were found during 22.2 months follow-up period.

DISCUSSION

IVCF was introduced as a vascular device for DVT patients to prevent PE, a condition that can have fatal consequences. The more recent development of a retrievable filter has encouraged the use of IVCF as these devices are easier to insert and can subsequently be removed [7,8]. Although the currently accepted clinical practice is to use IVCF only in patients with a contraindication for anticoagulation therapy [2], several studies have reported the efficacy of prophylactic IVCF in patients at high risk of VTE [3-6]. Wilhelm et al. [3], published a systemic review of 8 retrospective studies on the efficacy of prophylactic IVCF insertion prior to bariatric surgery (gastric bypass) and concluded that the incidence of PE in patients without prophylactic IVCF was higher. Decousus et al. [6] also reported from a randomized trial that there are initial beneficial effects of prophylactic IVCF on the prevention of acute PE in high-risk patients with a proximal DVT, although there was the observed excess rate of recurrent DVT in permanent IVCF (PREPIC study). Perioperative prophylactic anticoagulation and/or IVCF should therefore be considered in patients undergoing major surgery that show high risk factors for VTE.

Patients with acute VTE that arose within the prior 3 months should undergo anticoagulation bridging if major surgery is needed before a 3 month treatment for this condition has concluded [2]. However, surgeries to treat cancer and certain orthopedic procedures can be difficult to delay and it can be problematic to administer proper anticoagulation in such cases due to the high risk of postoperative

Table 3. Risk factors for thrombus capture by the IVCF

	P-value	Odds ratio (95% confidence interval)
Pulmonary embolism	0.136	0.45 (0.15-1.30)
Lower extremity DVT	0.301	0.34 (0.43-27.97)
Proximal DVT	0.592	1.33 (0.46-3.84)
Abdominal pelvic surgery	0.657	1.27 (0.43-3.77)
Malignancy	0.373	1.61 (0.55-4.65)
Neoadjuvant chemotherapy	1.000	0.52 (0.06-4.31)
Preoperative anticoagulation ^a	0.592	0.74 (0.26-2.15)
Postoperative anticoagulation ^b	0.032	0.28 (0.08-0.94)

IVCF, inferior vena cava filter; DVT, deep vein thrombosis.

^aAdministration of low molecular weight heparin (LMWH) until 12 hours preoperatively, ^bRestarting of anticoagulation (LMWH or direct oral anticoagulant) within 48 hours post-surgery.

Table 4. Causes of permanent IVCF placement

	Permanent IVCF placement (n=30)
Thrombosis of IVCF	10 (33.3)
Failure of filter capture due to tilting	6 (20.0)
Contraindication for anticoagulant therapy	5 (16.7)
Progression of DVT during anticoagulation	5 (16.7)
Poor cancer prognosis	3 (10.0)
Perioperative death	1 (3.3)

Values are presented as number (%).

IVCF, inferior vena cava filter; DVT, deep vein thrombosis.

bleeding [9,10]. Our present study is the first to investigate the efficacy of IVCF in patients requiring high risk surgery but already receiving anticoagulation therapy to treat acute VTE that had occurred within the previous 3 months. The surgeries in our patient cohort included abdominal-pelvic cancer and lower extremity orthopedic procedures. We found that a captured thrombus from an IVCF placement occurred in 13.1% of our study patients and that there was no case of postoperative symptomatic PE in this cohort. The mean long axial diameter of the captured thrombi was 28.3 mm (range, 10.1-75.3 mm), with a mean short axial diameter of 12.8 mm (range, 6.5-23.0 mm). IVCF are designed to reduce the frequency of significant PE by trapping emboli arising in the DVT before reach the lungs. These thrombi mean that it could have caused symptomatic or non-symptomatic PE. Our findings thus suggest that perioperative IVCF is a useful preventative measure against PE and bleeding during high risk surgery for patients with an existing acute VTE.

Early retrieval of the IVCF following the administration of anticoagulation therapy is recommended to avoid retrieval failure and possible long-term complications related to the use of this device, such as filter migration, embolization, fracture, vena cava thrombosis and perforation [11]. Notably, advanced retrieval devices and improved techniques have improved the success rate of filter retrieval and reduced the incidence of filter-related complications [12,13]. In our present study series, there were no recorded complications of an IVCF placement and subsequent retrieval and a high retrieval success rate was achieved (in 90/96 patients; 93.8%) within 2 months. The cause of retrieval failure in our present cohort was tilting of the filter in each case. A higher success rate of filter removal could likely be achieved therefore with a more careful insertion.

This study had some limitations of note. First, because of its retrospective observational design and relatively small cohort of patients, selection and information biases may have been present. Second, the perioperative administration of anticoagulation agents was not strictly controlled in accordance with current guidelines because this therapy was determined in each patient by the clinician with consideration of the bleeding risk. Third, it is possible that some of the captured thrombi were not embolized from the distal venous system but had newly arisen in situ on the filter.

In conclusion, a captured thrombus in preoperative IVCF was identified postoperatively in 16 patients (13.1%). This result suggests that preoperative IVCF insertion is helpful for preventing PE during high risk surgeries in patients with a recent VTE. Postoperative anticoagulation within 48 hours reduces the risk of captured thrombus in these cases.

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