2018

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Philip Craven

Ciara Daly

Randall Oates

Nisha Sikotra

Tim Clay

See next page for additional authors

This article was originally published as:
Craven, P., Daly, C., Oates, R., Sikotra, N., Clay, T., & Gabbay, E. (2018). Inferior vena cava filters (IVCFs): A review of uses and application to international guidelines at a single Australian center; implications of venous thromboembolism associated with malignancy. *Pulmonary Circulation, 8* (2).

Original article available here:
https://doi.org/10.1177/2045894018776505

Authors
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Research Article

Pulmonary Circulation

Inferior vena cava filters (IVCFs): a review of uses and application to international guidelines at a single Australian center; implications of venous thromboembolism associated with malignancy

Philip Craven[1], Ciara Daly[2], Randall Oates[3], Nisha Sikotra[4], Tim Clay[2] and Eli Gabbay[1,5]

[1]Department of Respiratory Medicine, St John of God Healthcare, Subiaco, WA, Australia; [2]Department of Medical Oncology, St John of God Healthcare, Subiaco, WA, Australia; [3]SKG Radiology, Subiaco, WA, Australia; [4]Research Department, St John of God Healthcare, Subiaco, WA, Australia; [5]The University of Notre Dame, Fremantle, WA, Australia

Abstract

Venous thromboembolism (VTE) is a potentially lethal event. Anticoagulation is the cornerstone of treatment. Inferior vena cava filters (IVCFs) may be used in circumstances when anticoagulation is contraindicated or as an adjunct to anticoagulation. IVCF use is not without controversy due to concerns over their safety profile, differences in guidelines from international societies, and a limited randomized control trial evidence. We retrospectively undertook a review of IVCF use over a three-year period (2014–2016) at our center, which has a large oncology service but no trauma unit. There were 44 patients with successful IVCF insertion and one patient with an unsuccessful attempt. Indications for insertion included: a contraindication to anticoagulation (n = 28); recurrent VTE on anticoagulation (n = 10); and extensive VTE (n = 7). There were 13 retrieval attempts, of which ten were successful. There were five documented IVCF complications (tilting: n = 2, IVC thrombus: n = 3) with one episode of IVCF failure and two episodes of deep vein thrombosis during the follow-up period. Of the patients, 71% had an active malignancy (of whom 71% had metastatic disease). Seventeen patients died due to progressive malignancy during the study period. There were no life-threatening VTEs or IVCF-associated mortalities. Adherence with published international guidelines was variable. Patients with malignancy were less likely to undergo IVCF retrieval and had a reduced rate of retrieval success. None of the international guidelines comment on the use of IVCFs in patients with malignancy despite being commonly used. IVCF use may be an underappreciated tool in this group.

Keywords

venous thromboembolism, oncology, malignancy, inferior vena cava filters

Date received: 16 January 2018; accepted: 21 April 2018

Pulmonary Circulation 2018; 8(2) 1–9
DOI: 10.1177/2045894018776505

Venous thromboembolism (VTE) was responsible for 7% of all Australian hospital deaths in 2008.[1] Anticoagulation is the cornerstone of the management of VTE. Inferior vena cava filters (IVCF) were first inserted in 1973 and are used to prevent propagation of thrombi from the deep venous systems of the lower limbs to the pulmonary vasculature, where they have the potential to be fatal.[2,3] Common situations in which IVCFs are inserted include:

- patients with documented VTE where a contraindication to anticoagulation exists (either transient or permanent);
- patients that have undergone an anticoagulation failure, e.g. recurrent VTE on therapeutic anticoagulation, or propagation of an existing thrombus on therapeutic anticoagulation;

Corresponding author:
Philip Craven, St John of God Hospital, Suite 304, 25 McCourt Street, Subiaco, WA 6008, Australia.
Email: philipcraven@hotmail.com

- patients with extensive VTE disease, e.g. large pulmonary embolus (PE) and residual deep venous thrombosis (DVT);
- patients without prior documented VTE who are considered to be at very high risk of developing VTE and have a contraindication to anticoagulation, e.g. trauma patients.

Currently the majority of IVCFs inserted are retrievable.[4] Most IVCFs are inserted in patients with VTE who have a transient contraindication to anticoagulation.[5] IVCF use in oncology patients is of particular relevance, with an estimated 30,000–40,000 used annually in the United States in patients with malignancy.[6] Oncological patients are both at an increased risk for the development of VTE and are a group in whom anticoagulation may be at times problematic due to the development of acute contraindications, e.g. thrombocytopaenia, bleeding and invasive surgical management.

There are conflicting international guidelines on the use of IVCFs, with relatively few randomized controlled trials (RCT) to guide their use and concerns over their long-term safety.[7–10] We conducted a single-center retrospective observational study looking at IVCF use at St John of God Subiaco Hospital (SJGH) over a three-year period. We examined indications and appropriateness of insertion, retrieval rates, complication rates, and long-term outcomes of their use.

Methods

Study setting

SJGH is a 578-bed private hospital in Western Australia with 20 dedicated operating theatres and two Cardiovascular Interventional Labs (CVIL) where IVCFs are placed. Services provided include Interventional Radiology (IR), Cardiology, Respiratory Medicine, Medical Oncology, Hematology, Neurosurgery, Gynecologic Oncology Surgery, Colorectal, Orthopedic, and Vascular Surgery. There is no Trauma Unit at SJGH.

Study design

Ethics approval was obtained from the SJGH Human Research Ethics Committee for this single-center, retrospective observational study. We reviewed medical records of all patients who either had an IVC filter inserted or retrieved between 1 January 2014 and 31 December 2016. Patients were identified using the Medicare Benefit Schedule (MBS) item numbers (standard Australian codes for medical and healthcare interventions) for insertion of an IVCF (35330) and for IVCF retrieval (35331).

Data collection

We reviewed the medical records for each patient and examined demographic details, current clinical history, reason(s) for inserting the IVCF, documentation of previous VTE, thrombophilia status (unknown, negative, or positive with type of thrombophilia), IVCF insertion date, IVCF retrieval date when attempted, clinical specialty who inserted the IVCF, and the type of IVCF.

We categorized patients into three broad groups based on the documented indication for IVCF insertion as per established guidelines (American College of Chest Physicians [ACCP], Society of Interventional Radiology/American College of Radiology [SIR/ACR], American Heart Association [AHA], the British Committee for Standards in Haematology [BCSH], and the Cardiovascular and Interventional Radiology Society of Europe [CIRSE]). Patients in Group 1 had a contraindication to anticoagulation, Group 2 had a recurrent VTE, and Group 3 had an extensive VTE. Group 1 was subdivided into patients who had a contraindication to anticoagulation due to planned surgery and those with a contraindication due to bleeding. Bleeding was classified as either a ''major bleed'' or a ''clinically relevant non-major bleed'' (CRNMB), based on the International Society on Thrombosis and Haemostasis.[11] Major bleeding is defined as ''fatal bleeding, symptomatic bleed in a critical organ or site, bleeding cause a hemoglobin fall > 2 g/L or bleeding leading to a transfusion of two or more units of packed red blood cells,'' whereas CRNMB is bleeding not meeting the criteria of a major bleed but required unscheduled medical attention.[5]

Results

'Forty –five patients underwent insertion of an IVCF between January 2014 and December 2016. Of 45 insertions, 44 were successful (98% success rate). The types of IVCFs used included 41 Cook Celect® filters (93%) (Cook Medical, IN, USA), two OptEase® filters (5%) (Cordis, CA, USA), and one Option Elite® filter (2%) (Argon Medical, TX, USA). All IVCFs were retrievable. Forty-one (93%) were inserted by interventional radiologists and three (7%) by vascular surgeons; all three of these occurred during endovascular procedures (Fig. 1). All IVCFs were deployed infrarenally.

Thirty-two (71%) of the patients had VTE related to a confirmed malignancy, with 23 patients having metastatic disease. Sites of origin of malignancy included 12 gynecologic cancers (one patient had synchronous endometrial and rectal adenocarcinoma), 11 gastrointestinal cancers, four genitourinary cancers, two breast cancers, one cutaneous cancer, one glioblastoma, and one diffuse large B cell lymphoma. Six patients (14%) had VTE related to orthopedic procedures; three were diagnosed preoperatively and three were diagnosed postoperatively (Table 1).

Indications for insertion

Contraindication to anticoagulation. In total, 28 (62%) patients had a contraindication to therapeutic anticoagulation.

Table 1. Patient demographics.

	n = 45
Patient characteristics	
Male	18
Female	27
Age (years) (± SD)	64.4 (± 15.3)
Median age (range)	66 (21–92)
Risk factors	
Hx of VTE	12
Thrombophilia screen performed	17
Known thrombophilia	8
Factor V Leiden	3
Protein C deficiency	2
Hyperhomocysteinemia	2
Anti-phospholipid syndrome	1
VTE status	
PE only	15
DVT only	14
Both DVT and PE	13
Neither PE or DVT	3
Background	
Malignancy (metastatic)	32 (23)
Vascular-related	3
Orthopedic-related	6
Trauma	1
Other	3

Planned surgery. Eighteen patients had a VTE and a contraindication to anticoagulation due to risk of bleeding intraoperatively and postoperatively. Two patients had their index VTE diagnosed elsewhere so could not be included in index event to IVCF insertion analysis.

Median time from diagnosis of VTE to surgery was 46 days (range = 3–181 days). The median time from IVCF insertion to surgery was two days (range = 0–77 days). The median time from index VTE to IVCF insertion was 18.5 days (range = 1–181 days). The median time which therapeutic anticoagulation was interrupted was five days (range = 2–22 days). Therapeutic anticoagulation was resumed in all patients and the majority of patients received prophylactic anticoagulation in the time they were off therapeutic anticoagulation with a median time off all anticoagulation of two days (range = 0–7 days).

Bleeding. Ten patients had a contraindication to anticoagulation because of bleeding. Six reached the criteria for major bleeding and four were classified as having CRNMB. Two patients had bleeding at the time of diagnosis of VTE and never received anticoagulation, with the remaining eight all being on therapeutic anticoagulation at the time of bleeding. (Three of these eight patients developed VTE postoperatively and started on therapeutic anticoagulation.)

The median time from initiation of anticoagulation to developing bleeding was 7.5 days (range = 1–60 days). The median time from bleeding to IVCF insertion was two days (range = 0–5 days). Three patients never recommenced therapeutic anticoagulation after IVCF insertion. The remaining patients had therapeutic anticoagulation recommenced with a median time off anticoagulation of ten days (range = 8–38 days).

Recurrent VTE. Ten patients had a recurrent VTE while on therapeutic anticoagulation. All these patients had malignancy, with nine having metastatic disease at the time of diagnosis of VTE.

The median time from initial VTE to the recurrent VTE event was 87.5 days (range = 9–1121 days) and the median time from VTE recurrence to IVCF insertion was two days (range = 1–8 days). At the time of recurrence, eight patients were on low molecular weight heparin (LMWH). Seven on Dalteparin, average daily dose of 11,250 IU (range = 7500–15,000 IU), and one on Enoxaparin 80 mg daily. Two were on direct oral anticoagulants (DOACs) at the time of recurrence (Rivaroxaban 20 mg, Xarelto®, Bayer), despite this not being recommended for cancer-associated thrombosis.

Two of the patients on LMWH had had their anticoagulation withheld due to upcoming invasive procedures. In these patients, the diagnosis of VTE occurred two and five days after interruption of anticoagulation, respectively. Anticoagulation was recommenced immediately after IVCF insertion.

Following IVCF insertion, all patients resumed or switched to LMWH. There was one failed attempt at insertion of an IVCF due to significant clot burden in the inferior vena cava. This patient remained on LMWH and subsequently died from metastatic cervical cancer 43 days after the attempted insertion.

Extensive VTE. Seven patients had IVCF inserted because of extensive VTE without any of the previously noted indications. Three of these patients had a documented malignancy.

In this group, four patients had their filter inserted on the day of discovery of extensive VTE (range = 0–3 days for group as a whole). All patients commenced therapeutic anticoagulation after IVCF insertion (Table 2).

Outcomes

Death. Seventeen patients died during follow-up, all as a consequence of progressive malignancy. No deaths were attributed to VTE or IVCF complications. Fifteen patients (88%) died with their IVCF in situ. One patient had previously had their IVCF retrieved before death and one patient had a failed attempt at IVC insertion. The median time from IVCF insertion to death was 118 days (range = 10–526 days).

Retrievals. There were 13 attempted retrievals (30%), in whom retrieval was successful in ten (23%). Failed retrievals

Table 2. Indications for insertion.

Indications for insertion	
Contraindication to anticoagulation	28
Planned surgery	18
Malignancy (metastatic)	12 (7)
Gynecological	6
Gastrointestinal	3
Genitourinary	2
Lymphoma	1
Orthopedic	3
Vascular	2
TLH/BSO for benign pathology	1
Active bleeding	10
Malignancy (metastatic)	7 (5)
Gynecological	3
Gastrointestinal	2
Genitourinary	1
Breast cancer	1
Orthopedic	1
Trauma	1
Lower body/thigh lift	1
Recurrent VTE	10
Malignancy (Metastatic)	10 (9)
Gastrointestinal	6
Gynecological	3
Glioblastoma	1
Extensive VTE disease	7
Malignancy (Metastatic)	3 (2)
Breast	1
Cutaneous	1
Gastrointestinal	1
Orthopedic	2
Vascular	1
Unprovoked PE	1

occurred due to IVCF tilting (two patients) and in filter thrombus (one patient). The median time from insertion to attempted retrieval was 73 days (range = 13–203 days). Failed retrievals occurred at 68, 158, and 213 days. All IVCFs inserted by the vascular surgeons were successfully retrieved with a median time of retrieval of 56 days (range = 17–168 days). Sixteen of the patients with an in situ IVCF were alive at the time of writing. Of 16, 14 had resumed therapeutic anticoagulation and in all of these patients we could not find any documentation of future planned IVCF retrieval.

IVCF-associated complications. There were three documented cases of recurrent VTE post IVCF insertion. Two episodes of lower limb DVT, both patients were in the bleeding group, and therefore were not on anticoagulation at the time of recurrence. There was one episode of recurrent PE while the patient was on 1.5 mg/kg daily enoxaparin.

Table 3. Patient outcomes.

Outcome	n	Median
Death	17	118 (10–526)
Retrieval attempt	13	73 (13–203)
Successful	10	68.5 (13–168)
Failed	3	158 (68–203)
Not deceased and no documented retrieval attempt	16	
IVCF no anticoagulation	2	
IVCF with anticoagulation	14	
Complications	8	
IVCF tilting	2	
In filter thrombus	3	
Recurrent DVT	2	
Recurrent PE	1	
IVCF migration	0	
Vena cava penetration	0	

Documented complications were low, with three cases of in filter thrombus. Two prevented IVCF retrieval, but one was small enough to allow retrieval of the IVCF. These complications were discovered at time of attempted retrieval. The two patients with the failed retrieval were anticoagulated with warfarin, with the patient with the successful retrieval on rivaroxaban. All three patients had malignancy.

There were two documented cases of IVCF tilting preventing removal (incidence of 5%). There were no documented cases of IVCF fracture, embolization, vena cava penetration, or IVCF-related deaths (Table 3).

Discussion

In this single-center study conducted over a three-year period, we identified 45 patients who underwent IVCF insertion. Our hospital has a large oncology unit and does not deal with major trauma. Thus, our cohort is different to some others that have been reported. The majority of patients in whom a filter was inserted had a contraindication to anticoagulation (61%) and/or underlying malignancy (71%). The incidence of VTE and the risk of recurrent VTE is recognized to be higher in cancer patients.[12]

Evidence for the use of IVCFs has predominantly come from observational and retrospective studies. There are a limited number of RCTs published to date.[7–10]

The two largest studies are PREPIC 1 (Prevention du Risque D'Embolie Pulmonaire par Interruption Cave Study Group) and PREPIC 2.[7,8] Both studies failed to demonstrate any additional benefit of insertion of an IVCF on mortality in patients who were already on therapeutic anticoagulation. However, these RCTs lack sufficient

power to provide clear direction on the role of IVCFs in patients with malignancy.

We identified 32 patients with a thromboembolic event and malignancy who received an IVCF over a three-year period. In the PREPIC2 study, there were 33 patients with malignancy who received a filter, and in another study comparing the use of IVCF and fondaparinux against fondaparinux alone in patients with VTE and malignancy, 31 patients received a filter.[8,10]

A recent retrospective study published by Coombs et al. looked at outcomes of cancer patients diagnosed with PE. Out of 1270 patients diagnosed with a PE over a one-year period, 317 received an IVCF; however, the indication for insertion was unclear in 23%.[13]

In this study, patients who received an IVCF had a reduced overall survival (OS) when compared with patients with malignancy and VTE treated with anticoagulation alone. These findings have been replicated elsewhere by Barginear et al., where patients with VTE and malignancy requiring an IVCF had a twofold increase in the risk of death.[14]

These findings likely reflect that IVCFs tend to be used in patients with more advanced disease, 46% of patients receiving an IVCF had stage IV disease against patients who were just treated with anticoagulation with 57% having Stage I or II disease. Patients with more advanced disease have a greater risk of bleeding and VTE recurrence perhaps reflecting the increased use of IVCFs in this cohort.[12,15,16]

Although we did not directly compare outcomes in patients with malignancy and VTE treated with anticoagulation alone, all our deaths came in patients with malignancy and 51% of the use of IVCFs in the entire hospital cohort over a three-year period came in patients with metastatic disease.

The lack of evidence, especially with respect to malignancy and associated VTE, is reflected in the guidelines published by the ACCP, ACR, the SIR, the AHA, the CIRSE, and the BCSH (Table 4),[17–21] in which no mention is made of patients with additional risk factors such as extensive metastatic disease. On the other hand, the American Society of Clinical Oncology (ASCO) and European Society for Medical Oncology (ESMO)[22,23] guidelines suggest "considering" an IVCF in patients with recurrent PE in the setting of malignancy despite adequate anticoagulation or with a contraindication to anticoagulation.[23]

The ASCO guidelines, published more recently, recommend IVCF insertion only in patients with VTE and a contraindication to anticoagulation. They advise that IVCF insertion may be considered as an adjunct in those with progression of thrombosis who have been optimally managed with LMWH or alternatively increasing the dose of LMWH by 20–25%, if tolerated.[22,24]

Recent studies have shown that IVCFs may be particularly useful in this scenario. In a cohort study to establish the effectiveness of IVCFs in patients with recurrent symptomatic VTE on anticoagulation. There was a statistically significant survival benefit in patients with a recurrent PE on

Table 4. Summary of recommendations of international societies.*

Guidelines	ACCP	SIR/ACR	AHA	CIRSE	BCSH
1. Acute DVT/PE with contraindication to anticoagulation	✓	✓	✓	✓	✓
2. Failure of anticoagulationa.	NM	✓	NM	NM	NM
a. Recurrent/progressive DVT despite anticoagulation					
b. Recurrent PE despite anticoagulation	NM	✓	✓	✓	✓†
c. Inability to achieve/maintain adequate anticoagulation	NM	✓	NM	✓	NM
3. Massive PE with residual DVT	NM	✓	✓	✓	NM
4. Free floating ileofemoral or inferior vena cava thrombus	NM	NM	NM	✓	NR
5. Severe cardiopulmonary disease and DVT (e.g. pulmonary hypertension, cor pulmonale)	NM	✓	NM	✓	NM
6. Prophylactic use, in patients without documented DVT/PE at high risk of developing DVT/PE and/or complications from anticoagulation	NR	✓	NM	✓	NM

*American College of Chest Physicians (ACCP), American Heart Association (AHA), British Committee for Standards in Haematology, Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and American College of Radiology/Society of International Radiology (ACR/SIR).
†Only after increasing INR or switching to LMWH.
R, recommended; NR, not recommended; NM, not mentioned.

anticoagulation treated with an IVCF.[25] This may be of particular relevance in oncology, where the there is an increased risk of PE recurrence despite anticoagulation.

Two patients had a recurrent VTE while anticoagulated with rivaroxaban. While its use is not licensed in patients with cancer-associated thrombosis, the use of DOACs in this situation is often a pragmatic one for oncology patients who require ongoing anticoagulation and are struggling with the significant burden of daily injections. Recent phase III data with Endoxaban, has shown its non-inferiority to Dalteparin in preventing VTE and risk of major bleeding.[26] This gives some reassurance to the use of DOACs in this situation.

A combination of increased use, lack of international consensus, and low retrieval rates has resulted in a number of questions being raised regarding the safety profile of IVCFs. In 2010, after reviewing 921 adverse events over a five-year period, the US Food and Drug Administration (FDA) issued a safety statement recommending "that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVCFs consider removing the filter as soon as protection from pulmonary embolism is no longer needed."[27]

Potential IVCF complications include DVT, IVC thrombosis, access site thrombosis, filter migration, cava penetration, filter fracture, and even filter-related deaths.[28] There is a distinct correlation between indwelling time of the filter and subsequent complication rates.[29] In Western Australia, there is an Operational Directive from the Department of Health associated with the use of retrievable IVCFs. The directive outlines the need for patient follow-up as well as collection of all data on IVCF insertion and retrieval rates which is sent to the Office of the Chief Medical Officer by the first of March each year.[30] That said, complication rates in our cohort, which included a majority of patients with malignancy, were very low and not severe.

We compared the indications recorded for use of an IVCF in our cohort with the available guidelines. The guidelines published by the radiological societies (SIR/ACR and the CIRSE) tended to have more liberal indications for insertion. Overall adherence with the SIR/ACR guidelines was 86% and there was 91% adherence with the more dated CIRSE guidelines. When using the more conservative and most recently updated ACCP guidelines, which have been the latest guidelines to be updated, in only 51% of cases insertion was consistent with the guidelines (Fig. 2).

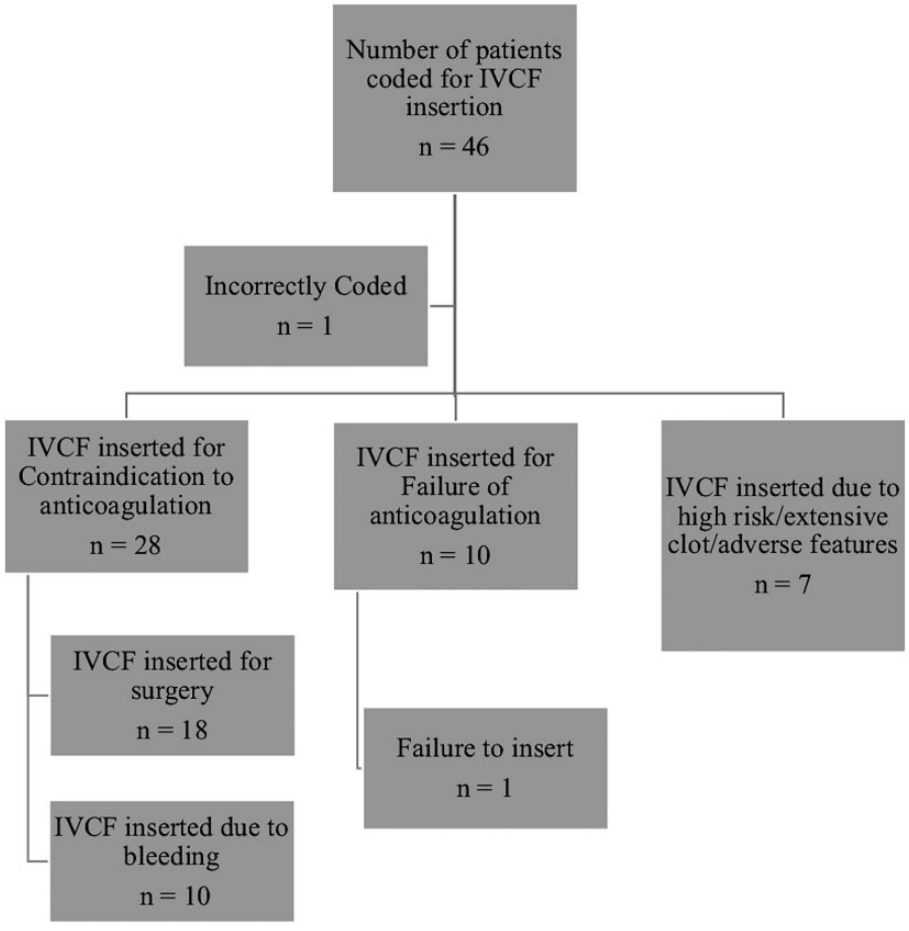

Fig. 1. Patient flow chart.

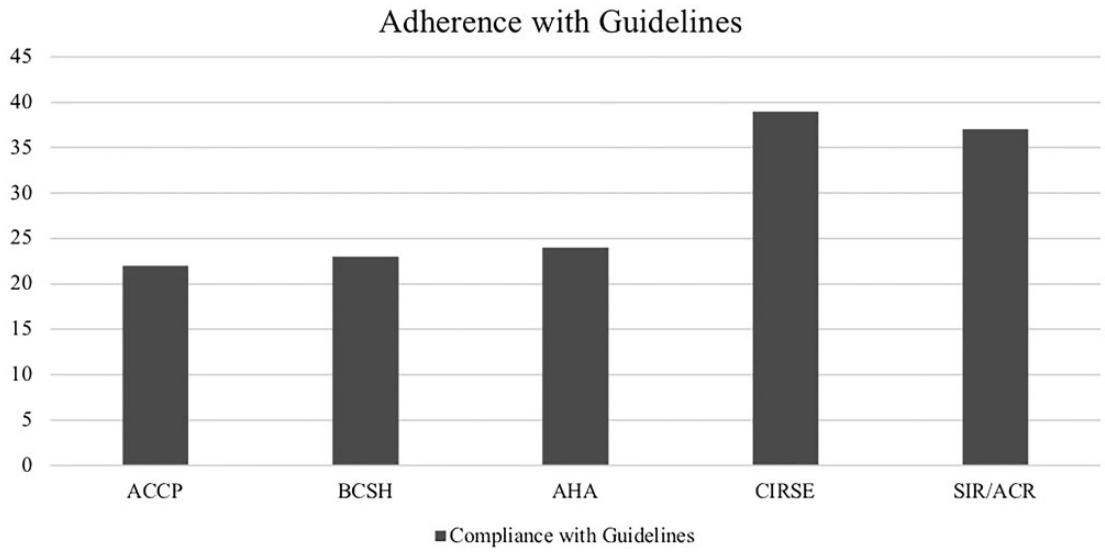

Fig. 2. Overall IVCF insertion adherence rates to published guidelines. American College of Chest Physicians (ACCP), American Heart Association (AHA), British Committee for Standards in Haematology, Cardiovascular and Interventional Radiology Society of Europe (CIRSE), and American College of Radiology/Society of International Radiology (ACR/SIR).

Four patients did not appear to have an indication for IVCF insertion by any of the published guidelines. This group primarily consisted of patients with an extensive VTE burden, no contraindication to anticoagulation, and without adverse features (such as right heart strain or hypotension). These patients had other significant risk factors such as extensive metastatic disease on myelosuppressive chemotherapy. This not only heightens their risk for a further thromboembolic event but also elevates their risk of developing an acute contraindication to anticoagulation from either bleeding or thrombocytopenia. Conversely, 15 patients had IVCF insertion that was consistent with indications recommended by all five available guidelines. These patients all had a diagnosis of VTE and a contraindication to therapeutic anticoagulation (because of a planned surgery or a bleed).

In our series, the attempted retrieval rate was 30% with a successful overall retrieval rate of 23%. This is in line with published data. In a systematic review of 37 studies with 6384 patients, the retrieval rates of retrievable IVCFs were in the range of 12–45%.[31]

We identified trends associated with decreased retrieval attempt and success. These included the presence of malignancy, long indwelling time, and insertion for failure of anticoagulation.

In our cohort, patients without malignancy had an IVCF retrieval rate of 69%, whereas patients with malignancy had a retrieval rate of 12.5%, which reflects the poor overall prognosis of patients with metastatic disease.

Retrieval success rates are proven to be high especially when conducted in a timely fashion. A large prospective study carried out by the British Society of Interventional Radiology (BSIR) found that retrieval was statistically more successful when performed within nine weeks (62 days) of insertion.[32] These findings were reinforced in a study carried out by Geisbusch, where an interval of > 90 days from insertion to attempted retrieval was associated with increased rates of retrieval failure.[33] These findings were consistent with our data, with the successful retrievals having a median time to retrieval of 68 days versus the median time to attempted retrieval in failed attempts of 158 days.

IVCF complication rates were low overall with no serious adverse events or filter-related mortality in either cohort. There was one documented case of IVCF failure with a patient suffering a recurrent PE. We had no documented cases of vena cava perforation.

Often, several physicians are involved in the care of patients who subsequently undergo IVCF insertion, with a collaborative effort to arrive at the decision to insert an IVCF. This has the potential to complicate the responsibility of follow-up and decisions around attempted retrieval of an IVCF. In our study, we identified 16 patients who remain alive with an IVCF in situ, in whom we could find no documentation of planned retrieval.

Conclusion

In our center, 44 IVCFs were inserted over a three-year period. The most common indication (28/44) was in the setting of VTE and a contraindication to anticoagulation. This indication is unanimously supported by the available guidelines. However, in the other 16 patients, IVCF insertion is not supported by all the guidelines, which provide conflicting recommendations.

Available guidelines do not comment on the use of IVCFs in the setting of malignancy, the most common

group where IVCFs were used in our hospital. Such patients are at heightened risk of VTE due to their pro-coagulant state and often have reasons to require interruption to their anticoagulation.

A lack of clarity and uniformity across available guidelines reflects the paucity of high-quality clinical trial evidence, especially in oncology patients. In our view, it is appropriate for guidelines to address the indications and complications of IVCF insertion in patients with malignancy.

Conflict of interest

The author(s) declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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