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REVIEW

WILEY

Navigating inferior vena cava filters in invasive cardiology procedures: A systematic review

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Abstract

Background: Transfemoral venous access (TFV) is the cornerstone of minimally invasive cardiac procedures. Although the presence of inferior vena cava filters (IVCFs) was considered a relative contraindication to TFV procedures, small experiences have suggested safety. We conducted a systematic review of the available literature on cardiac procedural success of TFV with IVCF in-situ.

Methods: Two independent reviewers searched PubMed, EMBASE, SCOPUS, and Google Scholar from inception to October 2020 for studies that reported outcomes in patients with IVCFs undergoing TFV for invasive cardiac procedures. We investigated a primary outcome of acute procedural success and reviewed the pooled data for patient demographics, procedural complications, types of IVCF, IVCF dwell time, and procedural specifics.

Results: Out of the 120 studies initially screened, 8 studies were used in the final analysis with a total of 100 patients who underwent 110 procedures. The most common IVCF was the Greenfield Filter (36%), 60% of patients were males and the mean age was 67.8 years. The overall pooled incidence of acute procedural success was 95.45% (95% confidence interval = 89.54–98.1) with no heterogeneity ($I^2 = 0\%$, $p = 1$) and there were no reported filter-related complications.

Conclusion: This systematic review is the largest study of its kind to demonstrate the safety and feasibility of TFV access in a variety of cardiac procedures in the presence of IVCF.

KEYWORDS

inferior vena cava filter, large bore venous access

1 | INTRODUCTION

Transfemoral venous access (TFV) is integral to invasive cardiovascular procedures. Percutaneous balloon mitral valvuloplasty was one of the earliest structural heart interventions employing trans-venous access to the left heart.[1] Since then, many complex interventions utilizing TFV access have been developed including leadless pacemaker implantation, arrhythmia ablations, septal occluder device placement, transcatheter valve-in-valve replacements, left atrial appendage occlusion, balloon valvuloplasty, and mechanical circulatory support placement.

Abbreviations: DVT, deep vein thrombosis; IVCF, inferior vena cava filter; TFV, transfemoral venous access.

Kuldeep Shah and Sati Patel contributed equally and are co-first authors.

Percutaneous inferior vena cava filters (IVCFs) are generally indicated to prevent venous thromboembolism in those with deep vein thrombosis (DVT) or pulmonary embolism (PE) who have contraindications to anticoagulation.[2,3] Following the introduction of percutaneous IVCFs in the 1970s, the annual implantation rate has markedly increased in the United States with 13% of patients with venous thromboembolism undergoing IVCF placement.[4–8] IVCFs are not without risk and can be complicated by device thrombosis, migration, embolization, perforation, and fracture.[9–13] There are 17 types of filters available but only 53% are considered retrievable.[14] In light of these complications and reports of guidewire entrapment, the presence of IVCF has been considered a relative contraindication for cardiovascular procedures requiring transfemoral approach.[15,16] However, recent studies have demonstrated the safety and feasibility of complex intracardiac procedures using TFV with catheter passage through an IVCF.[17–20] We sought to conduct a systemic review of available cardiovascular literature in patients with IVCF undergoing cardiovascular procedures. We have also proposed a workflow on the management approach in patients with IVCF.

2 | METHODS

2.1 | Search strategy

The reporting of this systematic review was in compliance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines.[21] The initial search strategy was developed by two authors (Kuldeep Shah and Sati Patel). Systematic search, using PubMed, EMBASE, SCOPUS, and Google Scholar from inception to October 25, 2020, for studies that had reported outcomes in patients with IVC filter that underwent TVA for invasive procedures. We used the "AND" function to perform our literature search (ivc filter) AND (femoral venous access), (ivc filter) AND (ablation), (ivc filter) AND (left atrial appendage), (ivc filter) AND (mitral valve), (ivc filter) AND (leadless pacemaker).

2.2 | Study selection and data extraction

The eligibility criteria for our systematic review included: (1) all studies reporting data on TFV access in patients with IVCF and (2) studies that included human subjects and published in the English language. The references of all identified articles were also reviewed for relevant studies meeting the eligibility criteria. Case reports, editorials, or systematic reviews were excluded from our analysis. Due to paucity of data, we decided to include case series with three or more patients. Two investigators (Kuldeep Shah and Sati Patel) independently performed the literature search and screened all titles and full-text versions of all relevant studies that met study inclusion criteria. The data from included studies were extracted using a standardized protocol and a data extraction form. Any discrepancies between the two investigators were resolved with consultation with the senior investigator (Nishaki Mehta). The following data from the eligible studies were extracted: author name, study design, publication year, follow-up duration, number of patients, number of procedures, age, gender, duration of IVC filter, type of IVC filter, type of procedure, number of sheaths, catheters and their sizes, type of anticoagulation, success, and complications. The Newcastle Ottawa Risk bias assessment tool was used to appraise the quality of included studies.

2.3 | Outcomes

The primary efficacy outcome of our study was acute procedural success (defined as ability to cross the IVC filter). In addition, we reviewed the literature for causes of mortality, IVC thrombosis, and procedural complications.

3 | STATISTICAL ANALYSIS

The meta-analysis was performed using the meta package for R version 4.0 and RStudio version 1.2 (R Core Team). For pooled analysis, we used Logit method to establish variance of raw proportions. Subsequently, we used DerSimonian–Laird random effect model to combine the transformed proportions. Finally, we then back transformed the pooled estimates using generalized mixed linear models and plotted the data on the forest plot.[22,23] Heterogeneity of effect size among the included studies was assessed by Higgins I-squared (I^2) statistic.[24] We used the Wan method to estimate mean and standard deviation when median with interquartile range was reported.[25]

4 | RESULTS

4.1 | Search results and study characteristics

A total of 120 citations were identified during the initial search. After a detailed evaluation, 112 records were excluded, and 8 studies were included in the final analysis (Figure 1). This meta-analysis of eight studies incorporated a total of 100 patients who underwent 110 procedures.[17–20,26–28] All studies included were published between 2001 and 2020. The mean follow-up period was 7 months, 60% of patients were males, and the mean age was 67.8 years. The mean duration of IVCF dwell time was 24 months. The type of filter was reported in seven studies with Greenfield filter being the most common type (36%), though filter type was unknown or not reported in 26% patients (Figure 2).[29] The number of sheaths or catheters traversing the IVC filter simultaneously ranged from 1 to 5 sheaths and/or catheters with cumulative French size ranging from 6 to 33 Fr. The detailed baseline characteristics of patients included in our study and the quality of studies are highlighted in Tables 1 and S1.

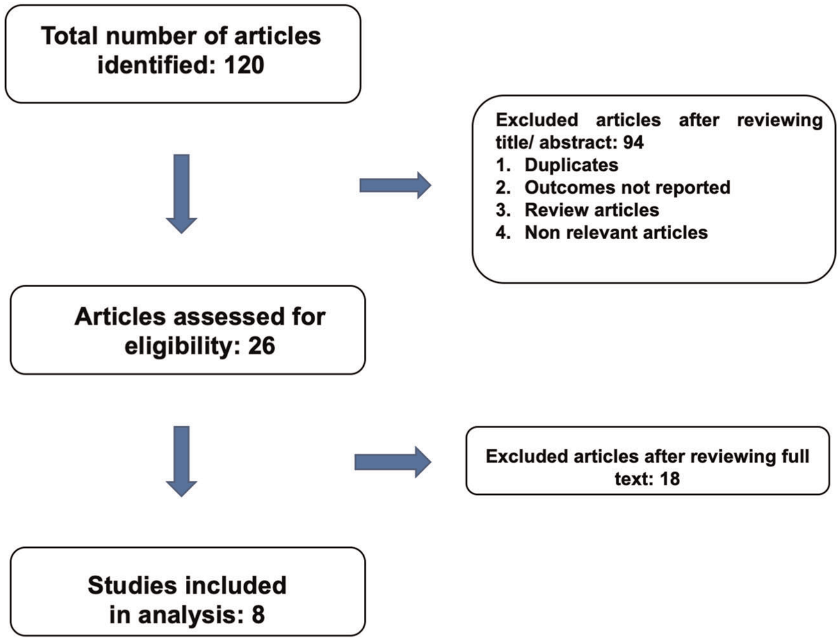

FIGURE 1 PRISMA flow diagram for studies focusing on IVCF in invasive cardiology procedures. IVCF, inferior vena cava filter; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analysis

4.2 | Acute procedural success

The data for acute procedural success, defined as the ability to successfully cross the IVCF was reported in all eight studies. The overall pooled incidence of acute procedural success was 95.45% (95% confidence interval [CI] = 89.54–98.1) with no heterogeneity (I^2 = 0%, p = 1; Figure 3). No study reported IVC filter-related complications including entrapment, filter migration, or damage to the filter integrity. The IVCF was occluded in three patients undergoing ventricular tachycardia (VT) ablations and in one patient undergoing leadless pacemaker implantation.[18,20] In all three patients undergoing VT ablation, TFV access was abandoned and a retrograde arterial approach was used instead.[18] In the patient undergoing leadless pacemaker implantation, various wires and sheaths were used in attempts to cross the occluded IVCF, however, these efforts were unsuccessful and ultimately the procedure was aborted altogether.[20] In one patient undergoing leadless pacemaker implantation, the IVCF was patent, however, there were multilevel stenoses in the venous system requiring balloon angioplasty of the right femoral vein, external iliac vein, and IVCF itself before the 27 Fr introducer sheath could be safely introduced.[20] No studies included reported any instances of filter-related complications including entrapment/entanglement, filter migration, fracture, or embolic events. Of all studies, Houmsse et al.[20] reported three in-hospital mortalities,

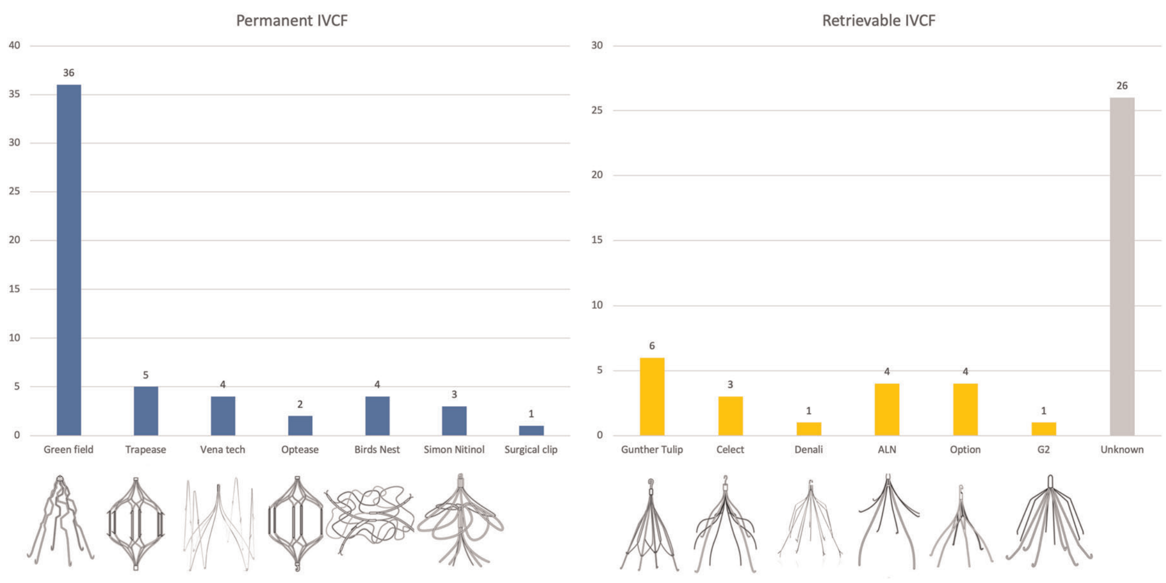

FIGURE 2 Bar graph showing the number and different types of filters studied in the systematic review

TABLE 1 Baseline characteristics of the studies included in the meta-analysis

Study	Awadalla et al.	El Ayech et al.	Houmsse et al.	Kanjwal et al.	Kussmaul et al.	Mendelson et al.	Rhodes et al.	Sinha et al.
Year	2004	2019	2020	2009	2001	2019	2003	2005
Type	Case series	Retrospective	Retrospective	Prospective	Case series	Retrospective	Case series	Prospective
Number of patients	3	5	23	10	10	40	4	5
Number of procedures	3	5	23	10	10	50	4	5
Age	59 ± 14.8	81.4 ± 6.1	73.8 ± 13.3	34-75	69.1 ± 8.4	63.8 ± 10.9	66.26 ± 15.39	75.2 ± 7.33
Males	1(33.3)	2(40)	12(52)	5(50)	7(70)	27(68)	2(50)	4(80)
duration of IVC filter	1 month	7.2 ± 10.5 months	96.7 ± 97.2 months	3 months->1 year	3.9 ± 3.3 years	69.1 ± 19.1 months	1–2 years	15 ± 9 months
Type of IVC filter								
Green field	2		8	9	10	5	2	
Trapease			1	1		3		
Gunther tulip			2			4		
Celect						3		
Vena tech		1	1			2		
Optease						2		
Birds nest			3			1		
Simon nitinol			2			1		
Denali						1		
ALN		4						
option			4					
G2			1					
Surgical clip						1		
Unknown/NR	1		1			17	2	
Type of procedure								
EPS				10				4
SVT ablation				5		3		
Atrial fibrillation ablation				1		21		
Atrial flutter ablation				3		3		3

TABLE 1 (Continued)

Study	Awadalla et al.	El Ayech et al.	Houmsse et al.	Kanjwal et al.	Kussmaul et al.	Mendelson et al.	Rhodes et al.	Sinha et al.
Ventricular Tachycardia ablation						20		
Lead extraction						3		
Temporary pacing								1
Leadless pacemaker			23					
LAAO		5						
RHC					10			
PFO closure	3						4	
sheath and catheter size	25	12.8 ± 1.1	27	29.8 ± 3.94			19.75 ± 6.29	14.4 ± 6.07
Mean number of catheters				3.6 ± 0.52	1	1.68 ± 1.04		2.2 ± 0.84
mean number of sheaths	2	1	1	1 ± 0.67		1.63 ± 0.48	2	
Anticoagulation								
Warfarin			9	10		36		5
NOAC			6			12		
None			8			2		
Complications	0	0	1	0	0	0	0	1
Occluded IVC filter	0	0	1	0	0	3	0	
Follow-up		10.1 ± 3.9 m	8.7 ± 9.5 m	1 m		3 m	18.3 ± 11 m	1 m

Abbreviations: EPS, electrophysiology study; IVC, inferior vena cava; LAAO, left atrial appendage occlusion; NOAC, novel oral anticoagulant; PFO, patent foramen ovale; RHC, right heart catheterization; SVT, supraventricular tachycardia.

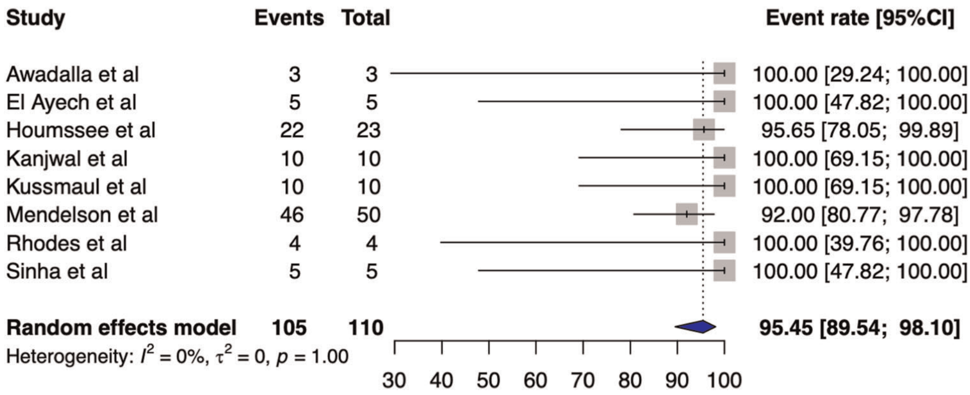

FIGURE 3 Forest plot of incidence of acute safety with IVCFs. IVCF, inferior vena cava filter

which were unrelated to the IVCF/EP procedure (septic shock, endocarditis complication, and withdrawal of care for refractory HF).

5 | DISCUSSION

Through this systematic review, we demonstrate a high procedural success rate (95%) using TFV access through IVCFs. To our knowledge, this is the only systematic review assessing the outcome of cardiac procedures in patients requiring TFV access with pre-existing IVCF. We determined a high procedural success rate (95%). However, patients with pre-existing IVC thrombosis may pose procedural challenge and should be evaluated. IVC thrombosis has been reported to occur in all IVCFs, with a higher incidence in those with retrievable filters, TrapEase (Cordis), and OptEase (Cordis) filters.[30] Angel et al.[10] in their systematic review found an overall 2.8%–8.8% incidence of vena cava thrombosis or stenosis in patients with IVCFs, with a higher incidence in those with Option Filters. We report a 4% incidence of filter thrombosis in this systematic review consistent with prior reports. All cases required the use of alternative access sites or abandoning the procedure. When the TFV approach is not feasible, cardiovascular procedures have been successfully performed using alternative access sites.[31–36] The transhepatic access offers the inferior approach familiar to operators for these procedures. However, the transhepatic approach carries a greater risk of hematoma as it uses a noncompressible access site requiring vascular plug or coil to achieve hemostasis. Additionally, the transhepatic approach may favor anterior catheter angulation, making transseptal puncture more challenging. Transhepatic access should therefore be performed at experienced centers to reduce complications, which may limit widespread applicability.[32,35] Electrophysiology procedures employing a superior approach via the superior vena cava have also been reported.[37–39] However, the superior approach carries a greater risk of operator radiation exposure as positioning is closer to the image intensifier. Further, catheter manipulation and contact can be challenging from a superior approach owing to lack of familiarity and equipment not designed for this route.[38,39] Though alternative procedural access sites can be considered in patients with IVCFs, these carry their own risks and can be challenging to perform.[32,35,38–43]

Several case reports and small case series have reported outcomes of intracardiac procedures with IVCFs in situ. Kussmaul et al.[26] first reported the ability to perform transfemoral right heart catheterizations across IVCFs in 10 patients with Greenfield (Boston Scientific) IVCFs without complication.[26] This success highlighted that the presence of IVCFs does not serve as a strict contraindication to the transfemoral approach. Soon after, many reported the safety and feasibility of transfemoral structural heart interventions across IVCFs including septal occluder device placement, transcatheter percutaneous balloon mitral valvuloplasty, atrial septostomy, and percutaneous mitral clip placement.[27,28,44–46] Similarly, many EP procedures have been successfully performed across a range of IVCFs including percutaneous defibrillator lead extraction, cavotricuspid isthmus ablations, leadless pacemaker implantation, and pulmonary vein isolation.[41,47–54] In each of these interventions, authors advocate using direct fluoroscopic guidance when traversing the IVCF and most used preprocedural CT scans or venograms to ensure filter patency. Several procedural modifications have been suggested to avoid IVCF complications. For example, preprocedural CTs or venograms use of straight tipped or soft J-tipped guidewires,[26,44,51] first traversing the IVCF with the guidewire only to ensure patency,[18] and direct fluoroscopic guidance when traversing the IVCF. Based on the aerial views of the filters, navigating circumferentially versus centrally can offer more room for passage of the sheaths. Utilizing multipurpose sheaths to redirect passage of the wires might permit more leeway (Figure 4). Collectively, these reports have supported the safety to navigate IVCFs during cardiac procedures.

In our review, two high-volume center studies accounted for over 60% of the patients. These studies did not have routine pre-procedure testing or contrast venogram unless there was difficulty crossing the wire. In such instances, contrast injection and serial dilation were utilized. Attempted procedures through an IVCF with either a partially or completely occluding thrombus may result in iatrogenic PE. Since our systematic review has a limited number of studies, we propose the following stepwise approach to all patients

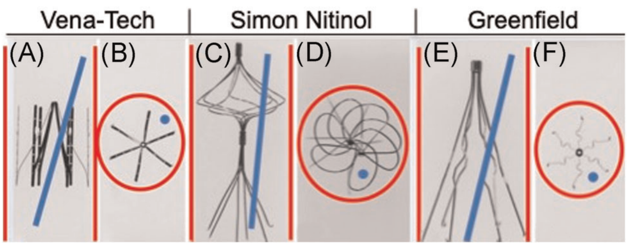

FIGURE 4 Frontal and aerial views of three representative filters (A, B: Vena-Tech LGM filter; C, D: Simon nitinol filter; and E, F: Greenfield filter) in the inferior vena cava (red outlines) and the blue arrows indicate passage of the wire/sheath. As noted in the aerial views, lateral or circumferential area for passage exceeds central area

with IVCFs undergoing intracardiac procedures from a transfemoral approach based on the limited literature review and an informal survey of experienced cardiologists. Pre-procedurally, the type of filter (manufacturer, retrievable vs. non-retrievable) and dwell time should be ascertained as well as the indication to support the ongoing need for the filter. The IVCF should then be crossed first with a guidewire with possible use of multipurpose sheaths under direct fluoroscopic guidance followed by over the wire passage of necessary equipment. In cases in which there is difficulty in crossing the filter with a wire, contrast injection should be performed. In higher-risk patients, especially those at high risk of vena cava thrombosis-such as those with retrievable filters, those not on anticoagulation, and in those with specific filter types that harbor higher rates of thrombosis, a pre-procedure CT venogram or after obtaining TVA, contrast venography may be considered in advance of wire passage

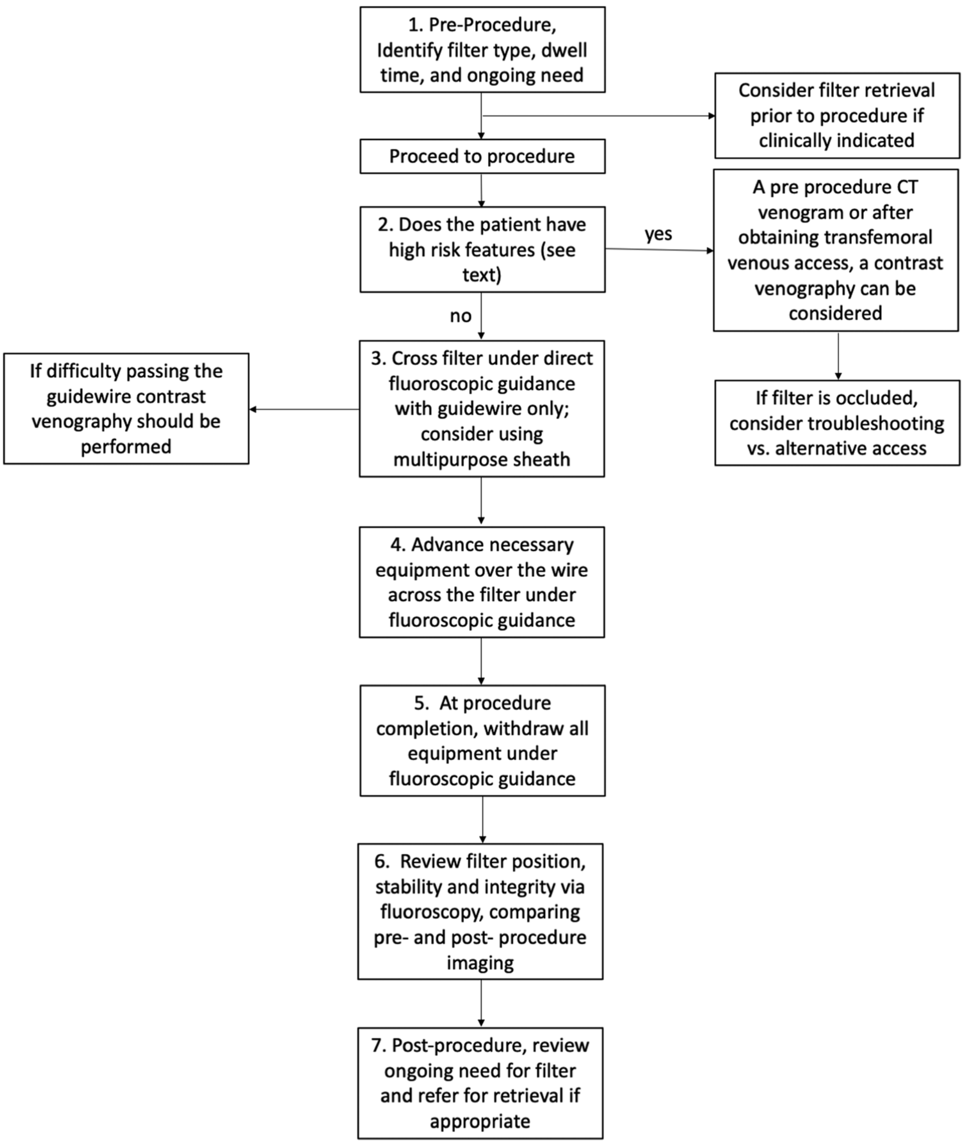

FIGURE 5 Proposed algorithm for managing a patient with IVCF who presents for invasive cardiology procedure requiring transfemoral access. IVCF, inferior vena cava filter

to ensure filter patency. Similarly, all procedural equipment should be withdrawn under fluoroscopic guidance. At procedure completion, IVCF positioning should be reviewed by fluoroscopy to ensure stable filter positioning and integrity. If there is any concern, post-procedure venogram can be performed. Finally, the necessity for ongoing IVCF should be addressed and patients should be referred for retrieval if appropriate (Figure 5).

Due to the limited data on this topic, our systematic review is confined by the small number of available studies. All studies included in our pooled analysis were single-arm, non-randomized studies (three case series, three retrospective, and only two prospective studies), two large studies contribute to 60% of the patients and therefore subject to confounding factors. Additionally, the majority of filters in the studies included were implanted for an average of 7 months (ranging from 1 month to 16 years), thus limiting application to more recently placed filters.

6 | CONCLUSION

TVA is important to the success of a variety of invasive cardiac procedures and IVCFs are not infrequently encountered. This systematic review and the current landscape of literature support the safe and effective passage of equipment through a variety of IVCFs for complex EP and structural heart cases. We have also proposed an algorithmic approach for management based on our collative experiences and systematic review of the literature.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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