

Meta-Analysis of the Usefulness of Inferior Vena Cava Filters in Massive and Submassive Pulmonary Embolism



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To conduct a systematic review and meta-analysis evaluating the safety and effectiveness of inferior vena cava filter (IVCF) placement in the setting of massive and submassive pulmonary embolism (PE), Pubmed and Cochrane Library were queried to identify all clinical studies evaluating IVCF placement in patients with massive and submassive PE from database establishment to December 2019. The rate of recurrent PE, PE-related mortality, adverse events, IVCF type, additional treatment intervention, DVT status, and follow-up length were retrieved. Recurrent PE, mortality, and complication rates were pooled. Meta-analysis was performed to compare mortality rates between groups with and without IVCF placement. Subgroup analysis was performed based on whether catheter-directed therapy was used for PE intervention. Fifteen observational studies with a total of 232 patients who received IVCF for submassive or massive PE were included. The pooled overall recurrent symptomatic PE and mortality rates were 1.4% and 5.5%, respectively. A lower mortality rate among patients with IVCF was observed than those without (6.8% vs 26.3%; odds ratio [OR] 0.275 [95% confidence interval] 0.090 to 0.839), $I^2 = 30.6%$, $p = 0.023$). Patients who received concurrent catheter-directed therapy demonstrated a lower recurrent PE (0% vs 2.8%) and mortality rate (3.4% vs 7.8%) than those who did not. The cumulative IVCF-related complication rate was 0.63%. In conclusion, based on a limited amount of low-quality evidence, IVCF placement is associated with low recurrent PE and PE-related mortality rates among patients with massive and submassive PE, suggestive of a potential clinical benefit in this scenario. Prospectively designed studies are warranted to confirm these findings. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;128:54–59)

In the United States, pulmonary embolism (PE) occurs in 302 per 100,000 patients and accounts for over 100,000 deaths annually.¹ Among those with acute massive and submassive PE, the in-hospital mortality rate can reach 30%.² Massive PE is associated with signs of hemodynamic instability (defined as a systolic arterial pressure <90 mm Hg or a decrease in systolic pressure of at least 40 mm Hg for >15 minutes), whereas submassive PE is defined by right-sided cardiac dysfunction without hypotension.³ In both groups, the cardiopulmonary reserve is significantly compromised and subsequent emboli to the pulmonary circulation may be fatal. Inferior vena cava filters (IVCF) are mechanical devices designed to prevent transit of lower extremity deep venous emboli to the lungs and thus may provide a mortality benefit for patients with either massive or submassive PE.⁴ For this reason, societal guidelines from the American College of Chest Physicians, Society of Interventional Radiology, and American College of Radiology allow

consideration for IVCF placement in this clinical setting.⁴ Despite these recommendations, population-based studies have reported that only 2.7% of hemodynamically unstable PE patients receive IVCF placement.⁵ Stein et al reported a survival advantage offered by IVC filters among patients with hemodynamically unstable PE.⁶ Although such studies may have immortal time bias, they are also limited by a lack of patient-level data with no specific information regarding other concurrent therapeutic interventions (i.e., medical, catheter, or surgical based treatments) provided. Therefore, the purpose of the present study was to conduct a systematic review and meta-analysis aiming to describe the efficacy of IVCF in patients with massive and submassive PE.

Methods

PubMed and Cochrane Library were queried to identify peer-reviewed articles regarding IVCF insertions in patients presenting with massive or submassive PE. All databases were queried from their establishment up until December 2019. The following keywords were used: “inferior vena cava filter,” “pulmonary embolism,” “massive,” and “submassive.” There was no language restriction.

The following inclusion criteria were adopted: (1) patients presented with massive or submassive PE; (2) an IVCF was placed with or without medical anticoagulation, thrombolysis, or catheter-directed therapy (CDT); and (3)

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outcomes were reported: recurrent PE, mortality, and/or adverse event. A study was excluded if the following criteria were met: (1) non-human studies; (2) case report and study with a sample size fewer than 5; (3) letter, editorial, commentary, or review; (4) duplicated or patient samples used by more than 1 study; and (5) population-level study.

Endnote X8 (Clarivate Analytics, Philadelphia, Pennsylvania) was used to identify and delete duplicates. Titles, abstracts, and key words were screened, followed by the review of full texts of the remaining studies. The screening process was depicted in Figure 1.

The following baseline characteristics were extracted: author, year of publication, country, study design, sample size, PE clinical classification (i.e., massive or submassive), filter subtype, other therapeutic interventions used, recurrent PE rate, mortality rate, and adverse events. Additional therapeutic interventions were recorded as medical anticoagulation, systemic thrombolytic agent, and/or catheter directed therapies. Studies focusing on surgical embolectomy were excluded. Evaluation approaches for recurrent PE were noted. For mortality, only PE-related deaths were examined, primarily including cardiogenic shock and respiratory distress. Mortality from unrelated baseline co-morbidities such as cancer or trauma were excluded. Complications associated with IVCF placement were recorded, including procedure-related complications and long-term complications such as filter migration, perforation, and fracture. Presence of DVT at the time of filter placement was also noted. Two researchers extracted the data from the original studies.

Any disagreement was discussed and arbitrated by a third author.

Quantitative analysis was performed with Stata 15.1 (STATA Corp., College Station, Texas). Meta-analysis was conducted with the *-metan* function. A fixed-effect model was implemented if heterogeneity $I^2 < 50$. A random-effect model was used if $I^2 > 50$. Outcomes were pooled if reported by original articles. Incidences were calculated by dividing the cumulative number of events by the total number of patients from each study. Subgroup analysis was performed based on whether concurrent CDT was implemented. For the assessment of publication bias, funnel plot and Egger test were performed.

Results

Fifteen retrospective studies with a total of 218 patients were included in the present meta-analysis (Table 1).^{7–22} Twelve studies included patients with only massive PE, whereas 3 studies included both massive and submassive PE. Presence of DVT was not reported in every study. Among those reported studies, 25% to 100% of the cases of all massive and submassive PE cases had existing DVT at the time of IVCF placement. Both permanent and retrievable IVCFs were used, including Greenfield, Bard G2 series, TrapEase/OptEase, Gunther Tulip, and B Braun (VenaTech). All IVCF were placed under fluoroscopy in an angiographic suite. In addition to IVCF insertion, other

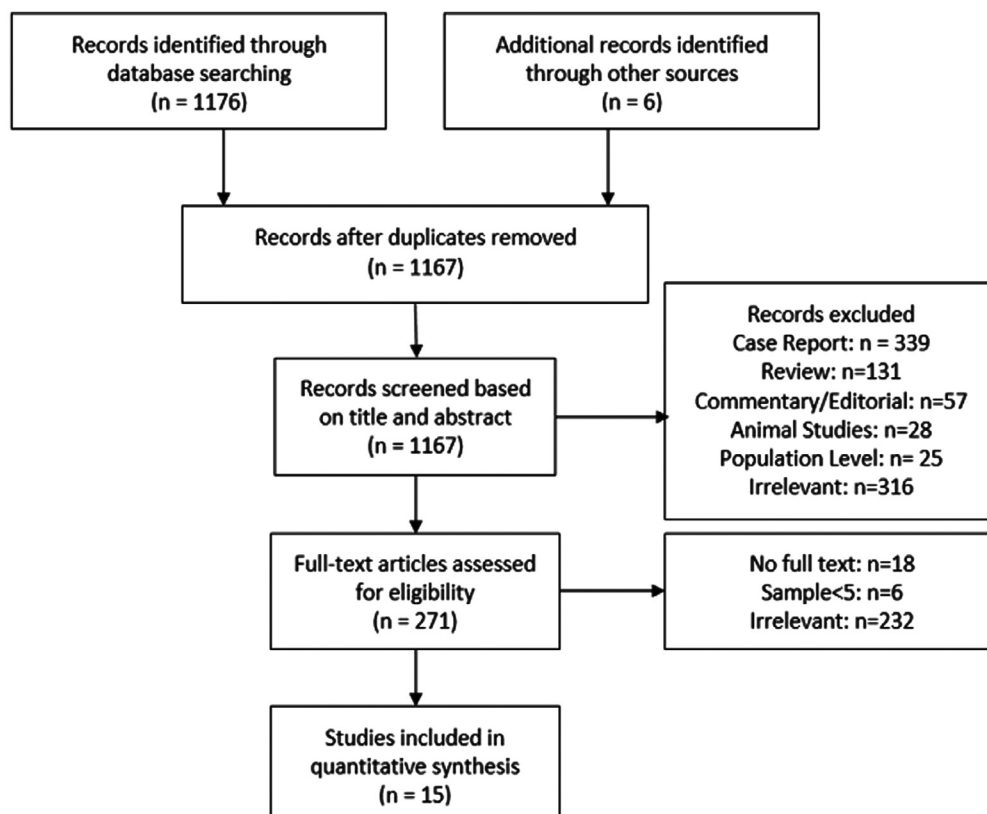


Figure 1. PRISMA flow-diagram demonstrating the screening process.

Table 1
Baseline characteristics of the included studies

Study/Year	Region	Sample size	Etiology	DVT	Additional treatment	IVCF type	Follow-up (mean/median)
Deshpande 2002	USA	6	All Massive	5 (83.3%)	Heparin (4/6), catheter-directed thrombolysis (1/6)	NA	In-hospital
Schneider 2002	USA	13	All Massive	NA	tPA (2/13), heparin (8/13)	NA	In-hospital
Zeni 2003	USA	12	All Massive	NA	Heparin*, reteplase*, AngioJet (12/12)	NA	18.7 months
Bandyopadhyay 2006 Submassive 10	USA	16 14 (87.5%)	Massive 6; Greenfield (8/16), Bard (8/16)	6mo			
Kucher 2006	USA	11	All Massive	NA	NA	NA	3 months
Yoshida 2006	Japan	18	All Massive	NA	Heparin (18/18), Mechanical Thrombectomy (8/10)	NA	In-hospital
Arriagada 2007	Chile	31	All Massive	NA	Anti-coagulation*	NA	41.5 months
Chauhan 2007	USA	11	All Massive	NA	Heparin (11/11), r-TPA*, AngioJet (5/11)	TrapEase (11/11)	6 months
Margheri 2008	Italy	11	Both	11 (100%)	Heparin (8/11), AngioJet (11/11)	NA	61 months
Ziegler 2008	USA	5	All Massive	NA	Anti-coagulation*, thrombolytic*	OptEase (5/5)	66% completed 6-month follow-up
Vijayvergiya 2009	India	5	All Massive	2 (40%)	Heparin (5/5)	Green Field*, TrapEase*	3.5 years
Zhou 2009	China	27	All Massive	26 DVT (96.3%)	Low-molecular weight heparin (27/27), urokinase (27/27), mechanical Thrombectomy	Bard*, TrapEase*	1-5 years (range)
Nassiri 2012	USA	10	Both	NA	Anti-coagulation (10/10), AngioJet (10/10)	NA	In-hospital
Chow 2015	China	12	All Massive	3 (25%)	Anti-coagulation*	Greenfield*, Gunther* Tulip*, OptEase*	36 months
Zhang 2016	China	30	All Massive	30 (100%)	Urokinase (30/30), mechanical Thrombectomy (14/30)	Braun	3-6 months (range)
Total		232					

* Treatment applies to at least a portion of patients, but the exact number was unspecified.

DVT = deep venous thrombosis at the time of inferior vena cava filter (IVCF) placement. NA = data were not available.

performed interventions included medical anticoagulation with heparin, systemic thrombolysis with tissue plasminogen activator, and CDT such as rheolytic thrombectomy, catheter-directed thrombolysis, and percutaneous mechanical thrombectomy. Although 4 studies only followed patients through the index event hospital admission, the remainder had a mean/median follow-up from 3 to 42 months.

Ten studies measured the rate of symptomatic recurrent PE among 149 patients who received IVCF for massive or submassive PE (Table 2). Only 2 of 149 patients developed recurrent PE (1.4%). Both patients received IVCFs without undergoing CDT. No recurrent PE was observed in the CDT subgroup. The monitoring methods of all studies mainly relied on clinical observation.^{8-11,14,16,17,19,20} Additional radiographical modalities such as CT,⁹⁻¹¹ echocardiogram,^{9,11,16} and V/Q scans^{11,16} were not used in every patient.

Five studies reported PE-related mortality rates of both patients who received IVCFs and those who did not (Table 3). In the IVCF group, a total of 4 of 58 (6.8%) patients deceased during the follow-up period from PE. In comparison, a total of 42 of 160 (26.3%) deceased during

Table 2

Symptomatic recurrent pulmonary embolism (PE) after inferior vena cava filter (IVCF) placement. Among 149 patients, a total of two symptomatic PE was observed during the follow-up period (1.4%). None of the patients who received concurrent catheter directed therapy (CDT) encountered PE recurrence, whereas two patients who only received IVCF without catheter directed therapy developed recurrent PE (2.8%). PE monitoring methods were mostly based on clinical observation. Radiographical modalities were utilized in selected patients with high clinical suspicion

STUDY	OVERALL	NON-CDT	CDT
DESHPANDE 2002	0/6	0/5	0/1
BANDYOPADHYAY 2006	0/16	0/16	NA
KUCHER 2006	0/11	NS	NS
YOSHIDA 2006	1/18 (5.6%)	1/10 (10%)	0/8
CHAUHAN 2007	1/11 (9.1%)	1/6 (16.7)	0/5
VIJAYVERGIYA 2009	0/5	0/5	NA
ZHOU 2009	0/27	NA	0/27
NASSIRI 2012	0/10	NA	0/10
CHOW2015	0/12	0/12	NA
ZHANG 2016	0/30	0/16	0/14
TOTAL	2/146 (1.4%)	2/70 (2.8%)	0/65

NA = not available; NS = not specified.

Table 3

PE-related mortality rates of patients who received inferior vena cava filter placement and those who did not. Five studies reported the mortality rates of both IVC group and non-IVC group. Among patients who did not receive an IVC filter, a total of 4 of 58 (6.8%) deceased during follow, whereas 42 of 160 (26.3%) deceased in the IVC filter group

Study	Number of death with IVCF	Total patients with IVCF	Number of death without IVCF	Total patients without IVCF
SCHNEIDER 2002	1 (7.7%)	13	1 (2.4%)	41
ZENI 2003	1 (8.3%)	12	1 (20.0%)	5
KUCHER 2006	0	11	35 (36.1%)	97
CHAUHAN 2007	2 (18.2%)	11	0	3
MARGHERI 2008	0	11	5 (35.7%)	14
TOTAL	5 (6.8%)	58	42 (26.3%)	160

follow-up from PE in the non-IVCF group (Figure 2; odds ratio [OR] 0.275 [95% confidence interval 0.090 to 0.839], $p = 0.023$). Funnel plot (Figure 2) and Egger test were insignificant for publication bias ($p = 0.402$).

Twelve studies measured PE-related mortality rates after IVCF placement (Table 4). In total, 11 patients died from PE during follow-up (5.5%). Only 3 patients died when CDT was implemented in addition to IVCF placement (3.4%). In comparison, 9 patients died among patients who received IVCF only without CDT (7.2%). Kucher et al did not specify whether CDT was implemented; 1 of 11 patients died during follow-up.²²

A total of 11 studies reported procedure-related complications.^{8–11,13,14,16–20} Out of 161 patients, only 1 complication occurred: a guide wire tangled in the right ventricle during the procedure caused cardiac tamponade and underwent subsequent sternotomy.¹⁰ The patient was ultimately discharged 3 weeks postsurgery.

Discussion

The present meta-analysis attempted to assess the potential mortality benefit of IVCF for patients with massive or submassive PE. Among a total of 218 patients who met inclusion criteria, the mortality in patients receiving IVCFs was significantly lower at 6.8% compared with 26.3% for patients without filters (Table 3). Although the cohort of

Table 4

Pulmonary embolism (PE)-related mortality after inferior vena cava filter placement. Among 201 patients, a total of 11 PE-related deaths were observed during the follow-up period (5.5%). Eight of 102 and 3 of 88 patients died in the groups without and with catheter directed therapy (7.6% and 3.4%), respectively

Study	Overall	Non-CDT	CDT
DESHPANDE 2002	0/6	0/5	0/1
SCHNEIDER 2002	1/13 (7.7%)	1/13 (7.7%)	NA
ZENI 2003	1/12 (8.3%)	NA	1/12 (8.3%)
BANDYOPADHYAY 2006	0/16	0/16	NA
YOSHIDA 2006	3/18 (16.7%)	3/10 (30.0%)	0/8 (0%)
KUCHER 2006	1/11	NS	NS
ARRIAGADA 2007	3/31 (9.7%)	3/31 (9.7%)	NA
CHAUHAN 2007	2/11 (18.2%)	1/6 (16.7%)	1/5 (20.0%)
MARGHERI 2008	0/11	NA	0/11
VIJAYVERGIYA 2009	0/5	0/5	NA
ZHOU 2009	1/27 (3.7%)	NA	1/27 (3.7%)
NASSIRI 2012	0/10	NA	0/10
ZHANG 2016	0/30	0/16	0/14
TOTAL	11/201 (5.5%)	8/102 (7.8%)	3/88 (3.4%)

CDT = catheter-directed therapy; NA = not available; NS = not specified.

218 (IVCF vs non-IVCF = 58 vs 160) meeting inclusion criteria for this study is seemingly low, the number is roughly similar to the 200 patient sample size in each arm of the

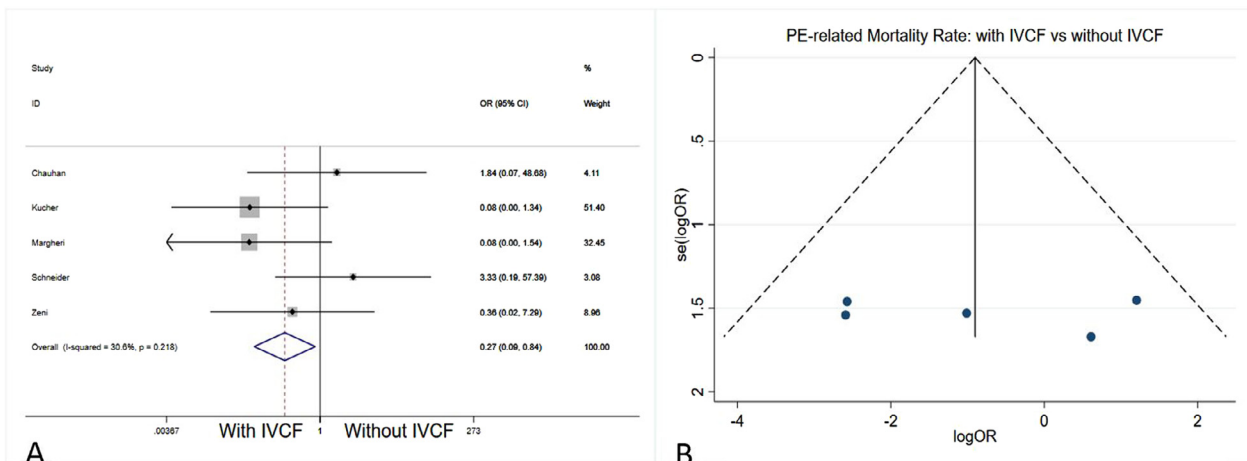


Figure 2. Pulmonary embolism (PE)-related mortality rates of patients who received inferior vena cava filter placement (IVCF) and those who did not. (A) Odds ratio (OR) between 2 groups was plotted on Forest plot. OR 0.275 [95% CI 0.090 to 0.839], $p = 0.023$; $I^2 = 30.6\%$ a fixed-effect model was used. (B) Funnel plot was not suggestive of publication bias. CI = confidence interval.

Prevention du Risque d'Embolie Pulmonaire par Interruption Cave 1 and 2 trials.^{23,24} The results of the present meta-analysis are consistent with the study based on the Nationwide Inpatient Sample, in which unstable PE patients who received IVCF showed lower case fatality rates in every age group.⁶ In another international multicenter study, Kucher et al calculated the univariate hazard ratio for predictors of mortality, which demonstrated that IVCF was associated with a reduction of 90-day mortality among patients with massive PE.¹² In a separate multicenter survey of 832 PE patients in Japan, Tanabe et al compared the 30-day mortality rates between patients who received IVCF and those who did not. The statistical significance of the survival benefit offered by IVCF increased as the severity of the PE progressed: submassive (4.1% vs 2.3%, $p=0.43$), massive (36.6% vs 21.1%, $p=0.20$), and collapse (75.8% vs 20.0%, $p=0.0009$).²⁵ This finding suggests a potential survival benefit in patients with a poor baseline cardiopulmonary reserve, likely due to an increased risk of mortality after a pulmonary embolus.

In practice, a number of patients develop PE due to comorbidities like major trauma or cancer, rendering it difficult to distinguish between PE-related and general mortality.²⁶ It is necessary to distinguish between PE-related mortality versus other general causes of death. In the present meta-analysis, 11 of 201 patients died from PE-related causes (i.e., cardiogenic shock) with a pooled rate of 5.5% (Table 4). Whereas most deaths were attributed to cardiogenic shock from the initial PE, 2 of 11 deaths were attributed to recurrent PE (18.2%), which mostly relied on clinical examination with radiological studies in selected patients. The observed recurrent PE rate was lower than previously reported.²⁷ One explanation is the shorter follow-up periods in the present meta-analysis, as many included studies only followed patients <1 year (Table 1). Regarding additional factors influencing mortality and recurrent PE rates such as the use of a systemic thrombolytic agent and the presence of DVT, information was inconsistently reported by authors of the original studies (Table 1), so subgroup analyses based on these variables were impossible to perform. Nevertheless, one phenomenon encountered during IVCF observational studies is "immortal time bias": because a multidisciplinary approach is required for selecting IVCF candidates, extremely critical-ill patients may not survive long enough to undergo filter placement.²⁸ Thus, the negative control group potentially included patients who died before IVCF could be inserted, attributing to the lower mortality rate observed in the IVCF group. In a previously published literature focusing on IVCF placement in patients who underwent pulmonary embolectomy, immortal time bias was minimized by performing a time-dependent analysis.²⁹ Future comparative studies focusing on IVCF placement in massive and submassive PE would ideally be designed to minimize the "immortal time bias."

Subgroup analysis in the present review also suggested lower mortality and PE-recurrent rates among patients who received combined CDT and IVCF placements (Tables 2 and 4). Percutaneous CDT of the present meta-analysis included 3 types: pure mechanical thrombectomy,^{17,19,20} rheolytic therapy,^{9,13,14,18} and local injection of thrombolytic

agents.¹¹ It is feasible to perform CDT during the placement of IVCF in the angiosuite, in order to reduce the clot burden of the existing PE.

Based on the present meta-analysis, IVCF insertion is considered as a safe procedure. Other than one patient (0.63%) who developed cardiac tamponade from guide-wire-related right ventricular perforation,¹⁷ no IVCF-related complication such as filter migration, thrombosis, fracture, and vena cava perforation was observed. This finding is however limited by the overall shorter follow-up duration among studies and lack of routine radiographical imaging.

In addition to the previously mentioned limitations, the results of the present meta-analysis deserve careful interpretation. First, it is now recognized that IVCFs should be retrieved once protection from PE is no longer indicated, to reduce the complications mentioned above. However, only Zhang et al documented this outcome in the original article: 28 of 30 filters were eventually removed.¹⁹ The long-term safety profile of IVCF may be under-reported and only retrievable filters should be utilized for this indication. Second, the mortality and PE-recurrent rates are likely to change over time. Future studies should report these outcomes in discrete follow-up time intervals, which may be helpful in determining variable predictors. Third, PE severity is a spectrum with different prognoses. On the one hand, PE severity stratification based on the Pulmonary Embolism Severity Index was not implemented to characterize outcome variations. In contrast, in the present study, subgroup analysis of massive versus submassive PE was not possible, due to the small sample size of the latter. Further, the baseline characteristics among included patients were rather heterogenous in nature. For example, clinical outcomes were not reported separately according to DVT status. Whether the benefits varied between patient with and without concurrent DVT remained unanswered. Perhaps most importantly, this study is based on a limited amount of literature to support IVCF placement for submassive and massive PE. Notably, all of the included original studies were of Level III or IV evidence. Establishing multi-center prospective registries to track such patients would increase study power and allow study designs with improved quality of evidence.

In conclusion, a limited amount of low-level retrospective evidence suggests that IVCF is safe and effective in preventing recurrent PE in the setting of massive and submassive PE.

Author Contributions

OA: Conceptualization, Methodology, Data Curation, Formal analysis, Investigation, Writing, Project administration, Supervision.

QY: Methodology, Formal analysis, Data Curation, Investigation, Software, Visualization, Writing.

JP, RN, and BF: Writing, Review, Editing.

TVH: Formal analysis, Writing, Review, Editing.

Disclosures

OA reports speaking fees from Canon Medical, Cook Medical, Argon Medical, Cardiva Medical.

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