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EDITORIAL COMMENT

Inferior Vena Cava Filter Placement With Catheter-Directed Lysis

How Did We Get to This Point?*

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Interruption of the inferior vena cava (IVC) is a widely practiced strategy used to prevent pulmonary embolism (PE). Although a strong biological rationale for the use of filtration devices that partially obstruct the IVC exists, there is extremely limited evidence to support their clinical use. Particularly in the United States, IVC filters are inserted for both prophylactic and therapeutic indications. Prophylactic indications, such as insertion before bariatric surgery or immediately after polytrauma, proliferated after the introduction of devices that can be both inserted and removed percutaneously. Similarly, insertion in patients who have PE or acute deep vein thrombosis (DVT) who are perceived to be at high risk of PE increased steadily through the first decade of this century.

Insertion of a vena cava filter is associated with both short- and long-term complications. In the short term, the procedure requires large-bore, intravenous cannulation and use of imaging technology with its associated radiation exposure. Long-term complications include thrombosis at or below the level of the filter, placement or migration above the renal veins with the potential for their thrombotic occlusion and renal failure, perforation of vascular structures with associated risk of hemorrhage, failure of components of the filter with local consequences, or centripetal migration, which can lead to complications such as pericardial tamponade (1–5). Additionally, many experts would consider the placement of an IVC filter an indication for long-term anticoagulation, which has its own associated cost and risk. Further, rates of retrieval of removable filters have been reported at <20%, with many of the filters remaining in situ for unclear reasons (3).

Adverse events such as these are tolerated for interventions with proven benefit. Unfortunately, the devices used for IVC interruption have not been subject to the same degree of rigorous study as drugs, which can often be directly substituted for an IVC filter. There have only been 2 sizeable randomized controlled trials of IVC filter use. Both enrolled patients with acute DVT and equally randomized subjects to an IVC filter (in one case a permanent filter and in the other a retrievable filter) versus no filter. All patients received parenteral anticoagulants, and nearly all were transitioned to oral anticoagulant agents for at least 3 months. The first study (6) included 400 patients and found at day 12 follow-up a reduction in symptomatic or asymptomatic PE among patients who received an IVC filter. At 2-year follow-up, the filter-receiving group had a higher rate of recurrent DVT, but there was no difference in the risk of death. The authors concluded that the initial benefit of IVC filters was counterbalanced by an excess of recurrent thrombosis. A follow-up analysis performed 8 years later (7) confirmed a lower rate of PE but a higher rate of recurrent DVT in the filter-receiving group and no impact on survival. The second study (8) enrolled 399 patients and concluded that filters did not reduce the risk of symptomatic recurrent PE at 3 months.

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Aside from these 2 studies, data supporting the use of IVC filters are limited. A small randomized controlled trial in polytrauma patients was underpowered for clinical events (9). Although large numbers of cohort studies and case series have been published, these are subject to significant bias and lack appropriate control groups to make firm conclusions. Moreover, these analyses have not uniformly supported the use of filters, with one large analysis demonstrating an increased risk of DVT without a survival advantage in trauma patients who underwent prophylactic IVC filter insertion (10).

Similarly, catheter-directed thrombolysis (CDT) has been increasingly used despite limited clinical evidence of long-term benefits. The largest clinical trial performed to date randomized 692 patients with proximal DVT to receive anticoagulation alone or with pharmacomechanical thrombolysis (11). There were more major bleeding events in the patients who underwent thrombolysis and no reduction in the risk of recurrent venous thrombosis over 24 months of follow-up. Moderate-to-severe post-thrombotic symptoms were reduced with thrombolysis, but there was no difference in quality-of-life measures at 2 years. The authors concluded that the addition of pharmacomechanical thrombolysis to anticoagulation did not result in a reduction in post-thrombotic syndrome but did increase the risk of major bleeding. In a remarkable confluence of 2 controversial interventions, IVC filter placement and CDT have come together in patients who have proximal leg DVT and who are undergoing pharmacological or pharmacomechanical thrombolysis. IVC filters are frequently placed in such patients due to concerns regarding the risk of clot-fragment embolization during the procedure.

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On this background in this issue of *JACC: Cardiovascular Interventions*, Akhtar et al. (12) have produced a report examining data on the trends and outcomes of adjunct IVC filter placement among patients undergoing CDT. The authors are to be congratulated on this study, which provides a sobering counterpoint to the high frequency of IVC filter use. The authors queried the National Inpatient Sample Database to identify patients who underwent CDT with or without prophylactic IVC filter placement between 2005 and 2013. Propensity matching was used to derive cohorts for analysis. A total of 7,119 patients were identified, of whom 2,421 received a filter. The authors found no difference in mortality, or procedure-related or intracranial hemorrhage. Patients with a filter had higher rates of hematoma and hospital charges, and a marginally significant increase in length of hospital stay. The authors also articulated the rapid increase in the use of CDT and CDT with filter placement in the first decade of this century. The authors identified important limitations to their analysis, including its observational nature and lack, therefore, of randomization. However, this study used robust methodology, and its conclusions are supported by 2 well-performed sensitivity analyses.

What is the reader to take away from this paper? Firstly, this paper provides moderate-quality evidence supporting the lack of utility of IVC filter placement in patients with acute DVT who are undergoing CDT. Taken in the context of the 2 randomized controlled trials previously discussed, this paper supports ongoing concerns around the use of IVC filters in patient who can undergo pharmacological treatment of venous thromboembolism. Secondly, this paper identifies the rapid increase in the use of CDT in patients with acute leg DVT despite a lack of methodologically rigorous evidence to support this intervention. Finally, the remarkable increase in the frequency of use of both CDT and IVC filter placement that has occurred over the last 2 decades lacks reliable supportive evidence of safety or efficacy. This observation strongly supports calls for enhanced regulatory oversight of devices including introduction of an evaluative schema like that required for drugs. Urgent action is needed for both vena cava filters and CDT, particularly in light of their cost, complexity, and potential toxicity.

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REFERENCES

1. Deso SE, Idakoji IA, Kuo WT. Evidence-based evaluation of inferior vena cava filter complications based on filter type. Semin Intervent Radiol 2016;33:93–100.

2. Doshi MH, Narayanan G. Late endovascular removal of Günther-Tulip inferior vena cava filter and stent reconstruction of chronic post-thrombotic iliocaval obstruction after 4753 days of filter dwell time: a case report with review of literature. Radiol Case Rep 2016;11:348–53.

3. Sarosiek S, Crowther M, Sloan JM. Indications, complications, and management of inferior vena cava filters: the experience in 952 patients at an academic hospital with a level I trauma center. JAMA Intern Med 2013;173:513–7.

4. McLoney ED, Krishnasamy VP, Castle JC, Yang X, Guy G. Complications of Celect, Gunther Tulip, and Greenfield inferior vena cava filters on CT follow-up: a single-institution experience. J Vasc Interv Radiol 2013;24:1723–9.

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5. Tam MD, Spain J, Lieber M, Geisinger M, Sands MJ, Wang W. Fracture and distant migration of the Bard Recovery filter: a retrospective review of 363 implantations for potentially life-threatening complications. J Vasc Interv Radiol 2012;23:199–205.e1.

6. Decousus H, Leizorovicz A, Parent F, et al. Prevention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. N Engl J Med 1998;338:409–15.

7. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. Circulation 2005;112:416–22.

8. Mismetti P, Laporte S, Pellerin O, et al. Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism: a randomized clinical trial. JAMA 2015;313:1627–35.

9. Rajasekhar A, Lottenberg L, Lottenberg R, et al. A pilot study on the randomization of inferior vena cava filter placement for venous thromboembolism prophylaxis in high-risk trauma patients. J Trauma 2011;71:323–8; discussion 328–9.

10. Hemmila MR, Osborne NH, Henke PK, et al. Prophylactic inferior vena cava filter placement does not result in a survival benefit for trauma patients. Ann Surg 2015;262:577–85.

11. Vedantham S, Goldhaber SZ, Julian JA, et al. Pharmacomechanical catheter-directed thrombolysis for deep-vein thrombosis. N Engl J Med 2017;377:2240–52.

12. Akhtar OS, Lakhter V, Zack CJ, et al. Contemporary trends and comparative outcomes with adjunctive inferior vena cava filter placement in patients undergoing catheter-directed thrombolysis for deep vein thrombosis in the United States: insights from the National Inpatient Sample. J Am Coll Cardiol Intv 2018;11:1390–7.

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