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Hemopericardium and Cardiac Tamponade as a Complication of Vena Caval Filters: Systematic Review of the Published Literature and the MAUDE Database

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Introduction

Vena caval filters (VCFs) are used to prevent pulmonary embolism. However, besides the limited evidence of efficacy, filters have been associated with complications such as migration and embolization of the filter or filter components to the heart, with the potential to perforate the cardiac chambers leading to tamponade.[1-6] The goal of this study was to provide a broad perspective about the presence of this complication. Toward that goal, we conducted a systematic review of the published literature as well as the available reports in the Manufacturer and User Facility Device Experience (MAUDE) for hemopericardium and cardiac tamponade following the placement of VCFs.

Methods

We searched PubMed and Embase databases (January 1960 to May 2018) for published reports of hemopericardium or cardiac tamponade as a complication of VCFs (Pubmed search query: ("Pericardial Effusion"[MESH] OR "Cardiac Tamponade"[MESH] OR pericardi*[TIAB] OR tamponad*[TIAB] OR hemoper*[TIAB]) AND (filter* OR "Vena Cava Filters"[MESH]); Embase search query: 'filter*': ti, ab, kw AND ('heart tamponade': ti, ab, kw OR 'pericardial effusion': ti, ab, kw)). We reviewed other published systematic reviews as well as the reference list of relevant reports or studies to ascertain the inclusion of all eligible published reports. We excluded nonhuman studies and duplicate reports.

We separately reviewed the MAUDE database to identify reports on the same topic. MAUDE is a database by the Food and Drug Administration that contains mandatory or voluntary reports (by manufacturers, importers and device user facilities, health-care professionals, or patients) related to suspected device-associated serious injury or death. We separately reported on hemopericardium and cardiac tamponade (a more severe clinical presentation with hemopericardium). Where reports were not explicitly clear about the presence of tamponade, we coded them as hemopericardium to provide a conservative estimate. We determined the rate of coidentification of cases in both the published literature and MAUDE.

Results

Our search of PubMed (n = 170) and Embase (n = 35) retrieved 205 articles, from which we identified 30 relevant publications. Four additional publications were identified

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Table 1. Reports of Hemopericardium or Cardiac Tamponade in the Literature, and the MAUDE Database.

	Total cases	Cases With Tamponade	Fatalities	Events Related to Superior Vena Caval Filters	Associated With a Publication
Published literature	37	25	3	5	37 (from 34 publications)
MAUDE	44	20	2	3	5

Abbreviation: MAUDE, Manufacturer and User Facility Device Experience.

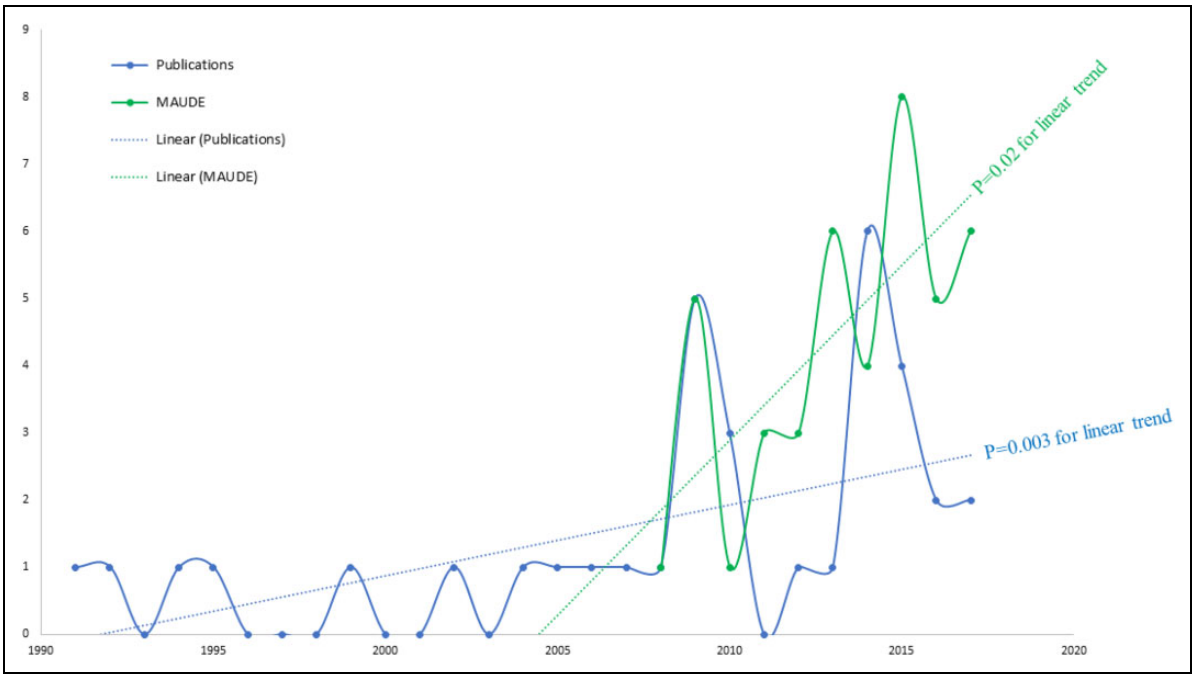

Figure 1. Number of case reports with hemopericardium or cardiac tamponade related to vena caval filters in the published literature (blue) and in the MAUDE database (Green). *P* values are calculated for linear trend in the number of cases over time. MAUDE indicates Manufacturer and User Facility Device Experience.

through the review of prior systematic reviews or the reference list of relevant articles (Rogoff 1992, Dorsa 1992, Ritchie 1995, and Urena 2004). In total, these 34 publications included 37 patients with hemopericardium or tamponade (age range: 22-75 years, hemopericardium/tamponade occurring between the early postprocedural period up to 3 years postplacement). Over time, there was an increase in publication of relevant cases ($P = .003$ for linear trend). Overall, 25 patients had tamponade (3 were fatal) and an additional 12 manifested hemopericardium. Among cases with adequate details, filter strut fracture and migration was the most common cause of hemopericardium/tamponade and the majority required pericardiocentisis or surgical window placement. Five events were related to superior VCFs.

Search of the MAUDE database identified a total of 44 relevant reports (20 with tamponade and an additional 24 reports of hemopericardium) related to VCFs (most requiring pericardiocentesis and/or surgery; Table 1). Overall, there was a significant trend for increased cases in MAUDE over time ($P = .02$ for linear trend; Figure 1). Three of the cases in MAUDE were related to superior VCFs. Only 5 of these 44 were based on or overlapped with published care reports. Most of the reports events in MAUDE were related to the past 10 years and were related to retrievable filters.

Discussion

Our study identified several reports, both from the published literature, and the MAUDE database, related to hemopericardium and cardiac tamponade as a complication of VCFs. Such complications may be potentially related to sizing problems (eg, megacava), suboptimal techniques or deployment problems (especially for early events), or embolization of the entire filter, or filter fracture under biomechanical stress,[7] and subsequent embolization to the heart. Ancillary imaging, including echocardiography and gated computed tomography, may help identify embolized filter fragments. Better operator education, procedural skill and experience, and accurate caval measurement supplemented by intravascular ultrasound when necessary may reduce the operator-related risks of VCF complications. Also, although our findings are hampered by small size and lack of a true denominator, it is prudent to be

cautious about the use of VCFs in the superior vena cava, especially given the absence of any efficacy trials for use of VCFs in that position. Device-related factors such as the design and the material used are also important, but we could not study them due to the small number of reports.

Importantly, we identified evidence for underreporting both in the published literature and in the MAUDE database, with only 5 (6.2%) of all reports overlapping in both data sources. Systematic identification of safety events are challenging, with concern for missing relevant cases due to lack of reporting to regulatory bodies or the published literature or suboptimal indexing.[3,8] It is for this reason that even prior systematic reviews had missed several relevant cases.[3,9]

This study had some limitations. The MAUDE database is based on voluntary reporting of complications. Therefore, it underestimates the number of complications.[10] In this study, we complemented our assessment of MAUDE with that of published reports of hemopericardium. Second, we would have preferred to provide more details related to the complications in each patient and to be able to generate inferences related to comparative event rates over time and among devices. However, in most cases, additional details were not available. Further, in the absence of a denominator, such rates cannot be estimated.

In conclusion, hemopericardium/cardiac tamponade is an underrecognized but important complication in patients with VCFs. Clinicians (both proceduralists and nonproceduralists) should consider this complication in the differential diagnosis of patients with prior VCFs presenting with chest discomfort or hemodynamic compromise. We identified evidence of underreporting both in the published literature and in the reports in MAUDE database. Better systems are required for medical device surveillance. In the interim, the ongoing Predicting the Safety and Effectiveness of Inferior Vena Cava Filters study may provide additional information related to safety of VCFs.

Authors' Note

Drs Bikdeli and Krumholz report that they have been experts (on behalf of the plaintiff) for litigation related to a specific type of IVC filters. The current study is the idea of the investigators and has not been prepared at the request of a third party. The content is the responsibility of the authors and does not necessarily represent the views of the NIH.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article. Dr Krumholz was a recipient of a research grant, through Yale, from Medtronic and the U.S. Food and Drug Administration to develop methods for postmarket surveillance of medical devices; is a recipient of a research agreement with Medtronic and Johnson & Johnson (Janssen), through Yale, to develop methods of clinical trial data sharing; works under contract with the Centers for Medicare & Medicaid Services to develop and maintain performance measures that are publicly reported; chairs a Cardiac Scientific Advisory Board for UnitedHealth; is a participant/participant representative of the IBM Watson Health Life Sciences Board; is a member of the Advisory Board for Element Science and the Physician Advisory Board for Aetna; and is the founder of Hugo, a personal health information platform.

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