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Evaluation of Changing Vena Cava Filter Use and Inpatient Hospital Mortality from 2016-2019: A Single-Institution Quality Improvement Project

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Abstract

Objective: To evaluate the changing trends of vena cava filter (VCF) insertion and determine whether changes in VCF use affected inpatient mortality.

Patients and Methods: A quality improvement project at Mayo Clinic, Rochester, Minnesota, tracks the type and reason for VCF insertions from January 1, 2016, through December 31, 2019, to facilitate appropriate retrieval. The rate of VCF insertions was compared with inpatient mortality rates, normalized for patient volumes using the number of hospital inpatient discharges.

Results: A total of 698 VCFs were placed in 695 patients: 2016 (n=243), 2017 (n=156), 2018 (n=156), and 2019 (n=120). The rate of VCF insertions (per 1000 inpatient discharges) was 4.02 in 2016, 2.91 in 2017, 2.54 in 2018, and 1.93 in 2019. Mean ± SD age at placement was 62±16.4 years and 59.2% (413/698) were men. Most VCFs were retrievable (85.1%; 594/698) and were placed for treatment (78.4%; 547/698) indications (acute venous thromboembolism within 3 months). The rate of VCF insertions was compared with the inpatient mortality rate (per 100 inpatient discharges) and remained stable (1.83 in 2016, 1.79 in 2017, 1.83 in 2018, and 1.76 in 2019) despite the significant decline in VCF use.

Conclusion: Data from this quality improvement study demonstrate a reduction of more than 50% in the use of VCFs from 2016 through 2019 at a large academic hospital. These changes are difficult to attribute to any single change in clinical use and there was no appreciable increase in the inpatient hospital mortality rate associated with this decrease in VCF filter use.

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Venous thromboembolism (VTE), composed of both deep vein thrombosis (DVT) and pulmonary embolism (PE), has a significant lifetime incidence of 5% and is associated with significant morbidity and mortality.[1] Although anticoagulation is the mainstay of treatment for VTE, treatment of patients with VTE with a contraindication for anticoagulation therapy or with anticoagulation failure is difficult to manage. Vena cava filters (VCFs) are regarded by many as the treatment of choice for VTE in patients with a contraindication to anticoagulation therapy[2] but have also been used for different prophylactic indications, including in the setting of trauma or perioperatively for high-risk surgical procedures. As VCF technology improved at the end of the last century, so did the rates of VCF insertion, with a broadening list of potential indications, including perceived added protection in conjunction with anticoagulation in the treatment of VTE. Rates of filter insertion continued to increase into the early part of the 2000s.[3,4]

Several studies and updated professional society guidelines have called into question the efficacy of VCFs as an adjuvant for anticoagulation therapy in patients with VTE and

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many of its previously acceptable prophylactic indications.[5-9] As a result of this new literature on long-term outcomes and US Food and Drug Administration safety alerts in 2010 and 2014, there has been a subsequent decrease in the rate of VCF placement nationwide.[10,11] A similar decline in VCF use has been observed at our institution since 2016, without specific institutional guidelines, policies, or restrictions on VCF insertion that would account for the decreased use. We sought to determine the clinical practice changes that lead to decreased use and evaluate whether this reduction was appropriate and safe or whether VCFs might now be underusd due to fears of adverse events in a way that could lead to increased mortality.

PATIENTS AND METHODS

A quality improvement project at Mayo Clinic in Rochester, Minnesota, tracks all VCF placements (inpatient and outpatient) to facilitate clinical follow-up and retrieval of VCFs when appropriate. The age, sex, dates of insertion, brand of filter, and clinical circumstances for filter insertions are recorded. All types of VCF insertions were included in this project from January 1, 2016, through December 31, 2019. Treatment indications were defined as acute DVT or PE within 3 months of the VCF placement, whereas a prophylactic indication would indicate a VCF placement in the absence of any prior VTE or a previous VTE event occurring more than 3 months before placement. The presence or absence

TABLE. Baseline Characteristics of Patients With Vena Cava Filters Placed From 2016 to 2019

Characteristics	Total	2016	2017	2018	2019	*P*
All filters	698	243	179	156	120	
Retrievable, no. (%)	594 (85.1)	200 (82.3)	150 (83.8)	135 (86.5)	109 (90.8)	.16
Permanent, no. (%)	104 (14.9)	43 (17.7)	29 (16.2)	21 (13.5)	11 (9.2)	
Age (y), mean ± SD		61.2±17.1	63.0±15.2	59.7±17.2	65.0±15.0	.17[a]
Male sex		143 (58.8)	106 (59.2)	93 (59.6)	71 (59.2)	>.99
Prophylactic, no. (%)	151 (21.6)	57 (23.5)	39 (21.8)	37 (23.7)	18 (15.0)	.26
Bariatric surgery	1 (0.7)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	.41
Surgery, other	46 (30.5)	14 (24.6)	18 (46.2)	10 (27.0)	4 (22.2)	.10
Trauma	96 (63.6)	40 (70.2)	18 (46.2)	24 (64.9)	14 (77.8)	.05
Medical illness	3 (2.0)	1 (1.8)	1 (2.6)	1 (2.7)	0 (0.0)	.91
Malignancy	10 (6.6)	3 (5.3)	2 (5.1)	5 (13.5)	0 (0.0)	.22
Other	8 (5.3)	2 (3.5)	5 (12.8)	1 (2.7)	0 (0.0)	.10
Treatment, no. (%)	547 (78.4)	186 (76.5)	140 (78.2)	119 (76.3)	102 (85.0)	.26
Bleeding	483 (88.3)	182 (97.9)	129 (92.1)	77 (64.7)	95 (93.1)	<.001
Anticoagulation failure	21 (3.8)	7 (3.8)	5 (3.6)	6 (5.0)	3 (2.9)	.87
Thrombolysis	4 (0.7)	2 (1.1)	1 (0.7)	1 (0.8)	0 (0.0)	.78
Free-floating thrombus	2 (0.37)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.0)	.39
Massive pulmonary embolism	15 (2.7)	5 (2.7)	2 (1.4)	6 (5.0)	2 (2.0)	.32
Anticoagulation interruption	156 (28.5)	48 (25.8)	41 (29.3)	33 (27.7)	34 (33.3)	.59
Other	37 (6.8)	25 (13.4)	2 (1.4)	2 (1.7)	8 (7.8)	<.001
Ischemic stroke	17 (3.1)	3 (1.6)	4 (2.86)	4 (3.4)	6 (5.9)	.26
Postoperative	34 (6.2)	4 (2.2)	20 (14.3)	8 (6.7)	2 (2.0)	<.001
Thrombocytopenia	23 (4.2)	6 (3.2)	8 (5.7)	5 (4.2)	4 (3.9)	.74
Proximal deep vein thrombosis	319 (58.3)	119 (64.0)	75 (53.6)	65 (54.6)	60 (58.8)	.22
Pulmonary embolism	302 (55.2)	106 (57.0)	79 (56.4)	71 (59.7)	46 (45.1)	.14
Isolated distal deep vein thrombosis	60 (11.0)	16 (8.6)	15 (10.7)	13 (10.9)	16 (15.7)	.33

[a]Indicates statistical testing using Student *t* test; other *P* values calculated using χ^2.

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and location of VTEs were confirmed by imaging studies by a trained nurse.

Age and sex were compared for patients with VCFs inserted in each of the years evaluated. The type of filter (retrievable or permanent) and placement indication (treatment vs prophylactic) were tabulated within by year. Continuous variables were reported as mean ± SD and were compared between groups using Student *t* test. Categorical variables were reported as number and percentage and compared between groups using χ^2 test for independence. VCF insertion rates were calculated on a monthly, quarterly, and annual basis and compared with the number of hospital inpatient deaths. Inpatient hospital deaths and the number of hospital discharges were obtained from standardized hospital quality metrics. The number of hospital discharges was used to account for any differences in patient volumes. Data on rates of VCF insertions were compared with inpatient mortality rates using Pearson correlation coefficient. Savings estimates were calculated for the reduction in VCF insertion and retrievals based on cost from our facilities' charge for non-Medicare rates, including facility fees.

RESULTS

From January 1, 2016, through December 31, 2019, a total of 698 VCFs were placed in 695 patients: 2016 (n=243), 2017 (n= 156), 2018 (n=156), and 2019 (n=120). Mean ± SD age was 62±16.4 years and 59.2% (413/698) were men. Most VCFs placed were retrievable (85.1%; 594/698) and were placed for treatment (78.4%; 547/698) indications (acute VTE within 3 months). The most commonly inserted VCF type was the Option Elite (Argon Medical Devices; 67.3%; 470/698), followed by the VenaTech (B. Braun Interventional Systems Inc; 14.6%; 102/698) and Gunther Tulip (Cook; 11.9%; 83/698).

Among treatment indications for VCFs, 319 of 547 (58.3%) patients had proximal DVTs, 302 (55.2%) patients had PEs, and 60 (11.0%) had isolated distal (calf) DVTs. Active bleeding was the most common contraindication to anticoagulation therapy and the reason for placement overall (n=483; 88.3%) in each year studied, followed by anticoagulation therapy interruption for procedures (n=156; 28.5%). Other treatment indications included anticoagulation failure (n=21; 3.8%), protection during thrombolysis (n=4; 0.7%), free-floating thrombus (n=2; 0.37%), massive pulmonary embolism (n=15; 2.7%), ischemic stroke (n=17; 3.1%), high-risk postoperative state (n=34; 6.2%), thrombocytopenia (n=23; 4.2%), and other (n=37; 6.8%). Among prophylactic VCF placements, trauma was the most common indication overall (n=96; 63.6%) and in each year studied. Other prophylactic indications included bariatric surgery (n=1; 0.7%), other surgeries (n=46; 30.5%), medical illness (n=3; 2.0%), malignancy (n=10; 6.6%), and other (n=8; 5.3%).

Analyzing by year of placement (Table), no significant difference was observed in the use of retrievable vs permanent filters (P=.16) or prophylactic vs treatment indications (P=.26). No difference was observed in age (P=.17) or sex (P>.99) and year of placement. Comparing 2019 with 2016, there were significantly fewer permanent (9.2% vs 17.7%; P=.03) and prophylactic VCFs placed (15.0% vs 23.5%; P=.06).

The rate of VCF insertions (per 1000 inpatient discharges) was 4.02 in 2016, 2.91 in 2017, 2.54 in 2018, and 1.93 in 2019 (Figure 1). There was a strong linear correlation (R^2=0.96) in VCF decline at a rate of 39.2 fewer VCFs per year. The rate of VCF insertions was compared with the inpatient mortality rate (per 100 inpatient discharges) and

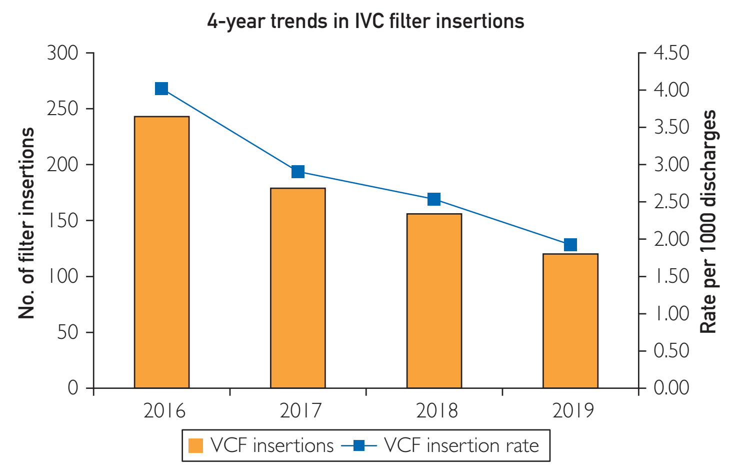

FIGURE 1. Four-year trends in vena cava filter (VCF) insertions. IVC, inferior vena cava.

was 1.83 in 2016, 1.79 in 2017, 1.83 in 2018, and 1.76 in 2019.

The downward trend in VCF insertions from 2016 through 2019 was not associated with an upward trend in the inpatient mortality rate (Figure 2). There was a weak correlation between annual (R^2=0.40) VCF rates and inpatient mortality rates that might indicate that higher VCF rates were associated with higher inpatient mortality.

No correlation was observed between the monthly (R^2=0.0001) or quarterly (R^2=0.091) rates of VCF insertions and inpatient mortality (Figure 3).

The number of prophylactic filters for trauma decreased in every year observed, from 40 in 2016 to 14 in 2019 (*P*=.05), although among prophylactic indications, the relative frequency of placements for trauma within this category has increased from 70.2% (40/57) in 2016 to 77.8% (14/18) in 2019 (*P*=.05). However, when comparing VCF insertion in patients with trauma with overall inpatient trauma admissions/discharges during the study period, there was a decreased rate of VCF insertion (per 100 trauma discharges) from 2.46 in 2016 to 1.15 in 2017, with subsequent fluctuations of the rate at 1.63 in 2018 and 0.95 in 2019 (Figure 4).

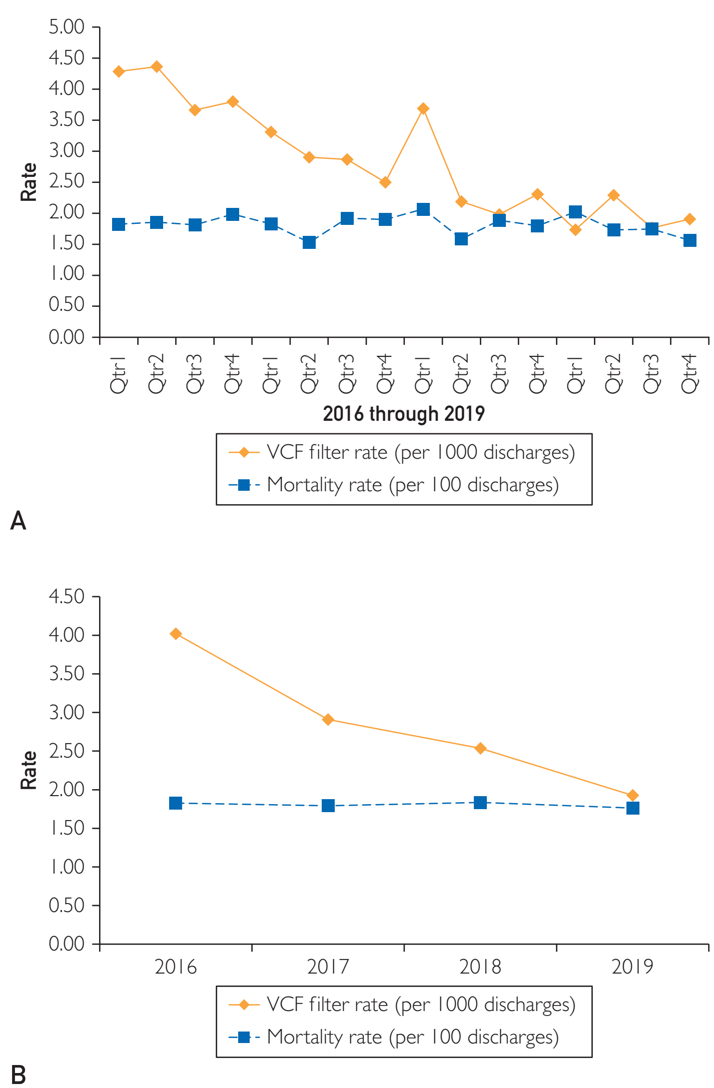

FIGURE 2. Comparison of (A) quarterly and (B) annual vena cava filter insertions and mortality rates. Qtr, quarter.

DISCUSSION

The present data demonstrate a linear reduction in VCF placement rates from 2016 through 2019 at a large referral center that was independent of specific institutional policies governing filter placement and is similar to previously described national trends.[11] Rather than a reduction in VCFs for specific uses that are perhaps no longer well supported, we observed a decline in use across many indications, both treatment and prophylactic placements. The decline in filter use was not associated with any appreciable difference in inpatient mortality, suggesting that the decreased use of VCFs has been safe and appropriate.

Previous data on the trends on VCF placement nationwide show a peak of placement in 2010[10] with a subsequent yearly decline until 2015.[10,11] Another study also addressing trends between 2009 and 2015 show a decline in VCF filter placement not only in Medicare patients but also in the privately insured.[12] This same study also investigated regional and state-specific differences in insertion rates, demonstrating insertion rates continuing to trend downward for both our state and the surrounding region (West North Central). The more than 50% reduction in filter placement observed at our institution during the study period would be much larger than the nationally observed downward trends from 2010 to 2014, which showed no more than a 25% decrease in filter placement in hospitalized patients during that period. There are not more recent publications describing the national trend since 2015.

Most prophylactic filters at our institution were placed for the indication of trauma, and although the number of patients receiving prophylactic filters for trauma saw an absolute decrease in number during the study period, trauma became the overwhelming majority indication for prophylactic filter placement during the study period in comparison to other prophylactic indications. This is likely due to the widely accepted more contemporary guidelines and recommendations from nontrauma societies such as the American College of Chest Physicians recommending against the use of VCFs for primary PE prophylaxis in patients without known DVT.[13]

The guidelines from professional trauma societies are less clear and less universally accepted. A 2002 practice management guideline from the Eastern Association for the Surgery of Trauma recommends considering prophylactic VCF placement in high-risk patients with trauma who cannot adequately undergo systemic anticoagulation. In this study, the initial decrease in the rate of VCF insertion in patients with trauma was most pronounced between 2016 and 2017, for unclear reasons. After 2017, the rate of insertions did not decline linearly, possibly reflecting continually evolving clinical practice changes or imprecision due to small absolute numbers included in this subgroup analysis. Newer studies in the trauma population, including meta-analyses, question the use of VCFs in high-risk patients with trauma, citing the adverse events that can be associated with both insertion and retrieval, as well low retrieval rates, as significant reasons to avoid prophylactic filters in this population.[14,15] A similar controversy and debate in the literature exist regarding the use of prophylactic VCFs for high-risk patients undergoing bariatric surgery,[16-18] although this practice was rare at our institution.

The results from this study identify several areas on which to focus further efforts for VCF reductions. The use of VCFs in patients with isolated distal (calf) DVTs is not an endorsed indication for a VCF by any major medical society; however, many guidelines do not differentiate between proximal and distal DVTs when clinically they are associated with significantly different risks for PEs.[19,20] Furthermore, anticoagulation is not always indicated or necessary for distal DVTs; therefore, the rationale for insertion of VCFs should be questioned. From a purely mechanical

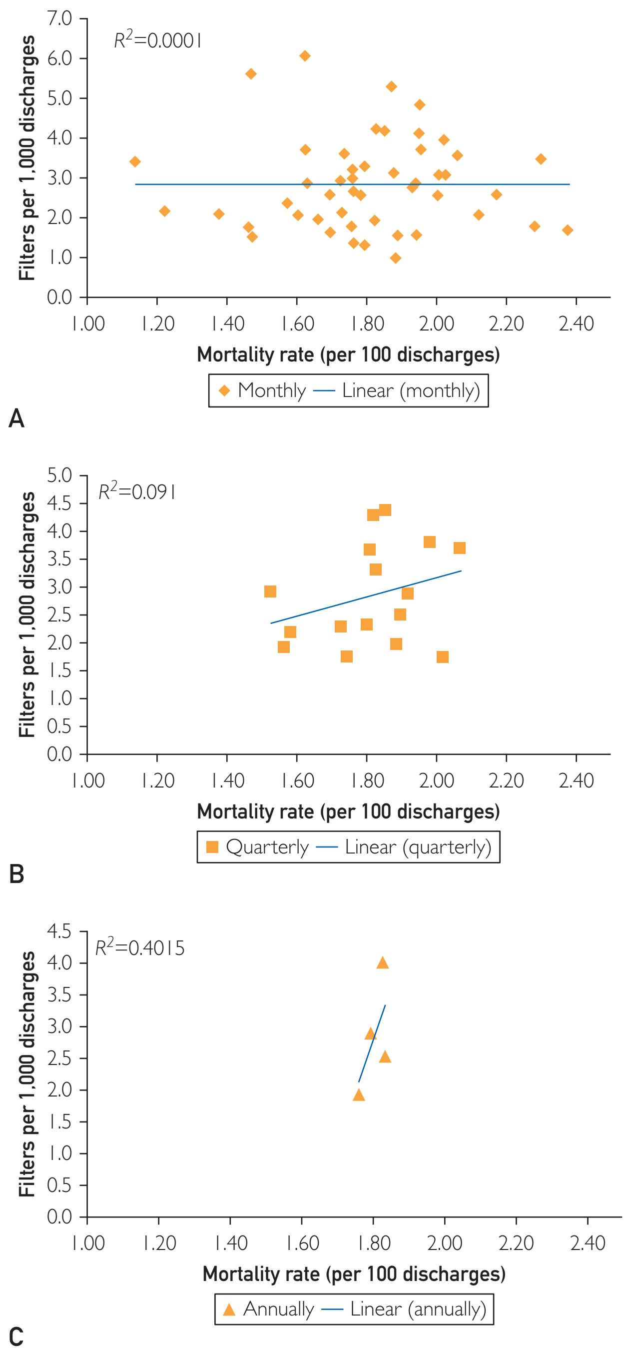

FIGURE 3. Correlation between vena cava filter insertions and (A) monthly, (B) quarterly, and (C) annual hospital mortality rates (2016-2019).

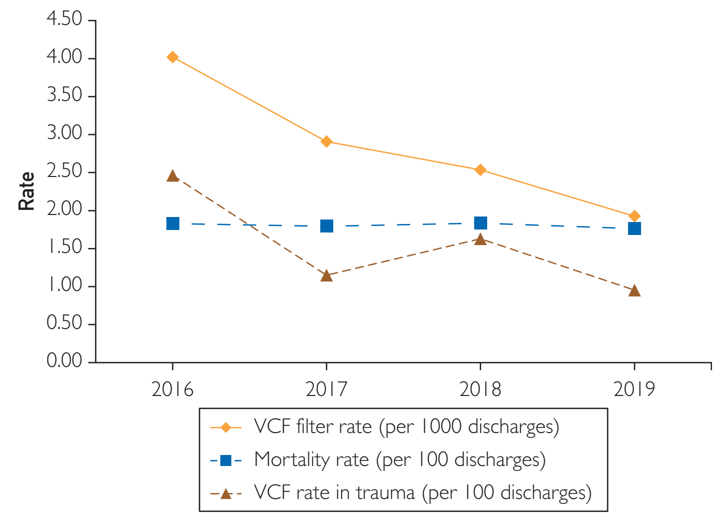

FIGURE 4. Comparison of inferior vena cava filter (VCF) insertions, mortality rates, and trauma admissions/discharges (2016-2019).

standpoint, it is unclear whether VCFs could even catch small emboli that might occur from distal DVTs.

The other area for focus from a quality improvement standpoint is on the prophylactic insertion of VCFs for nonbariatric surgeries, which, outside of trauma, was the main use of prophylactic filters. Most patients in this category had a history of VTE and were receiving long-term anticoagulation therapy that needed to be interrupted for surgery and was not included within the treatment designation because they did not have the VTE event within the preceding 3 months. Although inferior vena cava filters would not typically be recommended for a short-term anticoagulation interruption in a patient with a prior VTE, many patients had a history of recurrent events and events occurring shortly after previous procedures and were undergoing complex staged procedures and high-risk surgeries that precluded timely reinitiation of anticoagulation therapy postoperatively. Because this is an area without guidelines or high-quality research, this should be an area of increased scrutiny and further examination.

Based on the reduction in VCF insertions alone observed during the past 4 years (n=218), the estimated reduced health care cost at our institution was 2.2 million dollars. Assuming that 70% of inserted VCFs are retrieved (a conservative estimate based on our retrieval data), a combined 3.5 million dollars have been saved in total health care expenditures including the cost of VCF retrieval.

The present data are limited by the observational nature and lack of a control group. A strength of the data collected in this quality improvement initiative was that they allowed for a detailed examination of the insertion indications within our practice. Furthermore, information on type and location of VTE events was collected and allowed for a more complete understanding of VCF use. Inpatient mortality rates were readily available for the period during which the study took place but may not be the best measure for assessing outcomes related to both treatment and prophylactic VCF placement. However, rather than demonstrating a definitive absence of harm in the reduction of filters, we view these data in the setting of numerous other studies being unable to demonstrate a mortality advantage to VCF insertions as reassuring. Prospective follow-up on patients who received filters including all-cause mortality and VTE-related mortality over specific intervals including both short- and longer-term follow-up would likely be more revealing than comparison to hospital-wide inpatient mortality rates.

Prospective follow-up and a control population would allow assessment of secondary VTE outcomes and bleeding events and also add insight into the effect of VCF reduction on ambulatory mortality rates, which was not tracked by the present quality improvement project. Similarly, these data would likely benefit from a comparison in a case-control type study design, although finding an appropriate control group that might have previously received a VCF for comparison is not possible, as has been done in the trauma population.[21] Last, because this quality improvement initiative was done at a large tertiary-care academic medical center, and as previously stated, the rate in reduction at our institution was much larger than the previously reported trends over a similar time; our data may not be representative of the national trends during the same period.

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CONCLUSION

While observing the rates of VCF insertions in this quality improvement project, we found a dramatic reduction in the use of VCFs from 2016 through 2019 at a large academic hospital. The insertion rate has decreased greater than 50% since 2016 among multiple potential indications with no appreciable increase in the inpatient hospital mortality rate. These data suggests that the reduction in VCF use has been safe and appropriate and secondarily is likely associated with health care savings related to avoiding VCF placement and retrieval procedures. The reduction in the number of prophylactic VCFs mirrored the reduction in VCFs placed for treatment indications and there was a similar reduction in both retrievable and permanent filter types. Additional data are needed to understand these changing trends and continue to refine our institutional VCF practices.

Abbreviations and Acronyms: **DVT,** deep venous thrombosis; **IVC,** inferior vena cava; **PE,** pulmonary embolism; **Qtr,** quarter; **VCF,** vena cava filter; **VTE,** venous thromboembolism

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