# Prophylactic Inferior Vena Cava Filter Placement Does Not Result in a Survival Benefit for Trauma Patients

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**Objective:** Trauma patients are at high risk for life-threatening venous thromboembolic (VTE) events. We examined the relationship between prophylactic inferior vena cava (IVC) filter use, mortality, and VTE.

**Summary Background Data:** The prevalence of prophylactic placement of IVC filters has increased among trauma patients. However, there exists little data on the overall efficacy of prophylactic IVC filters with regard to outcomes.

**Methods:** Trauma quality collaborative data from 2010 to 2014 were analyzed. Patients were excluded with no signs of life, Injury Severity Score <9, hospitalization <3 days, or who received IVC filter after occurrence of VTE event. Risk-adjusted rates of IVC filter placement were calculated and hospitals placed into quartiles of IVC filter use. Mortality rates by quartile were compared. We also determined the association of deep venous thrombosis (DVT) with the presence of an IVC filter, accounting for type and timing of initiation of pharmacological VTE prophylaxis.

**Results:** A prophylactic IVC filter was placed in 803 (2%) of 39,456 patients. Hospitals exhibited significant variability (0.6% to 9.6%) in adjusted rates of IVC filter utilization. Rates of IVC placement within quartiles were 0.7%, 1.3%, 2.1%, and 4.6%, respectively. IVC filter use quartiles showed no variation in mortality. Adjusting for pharmacological VTE prophylaxis and patient factors, prophylactic IVC filter placement was associated with an increased incidence of DVT (OR = 1.83; 95% CI, 1.15–2.93, *P*-value = 0.01).

**Conclusions:** High rates of prophylactic IVC filter placement have no effect on reducing trauma patient mortality and are associated with an increase in DVT events.

**Keywords:** inferior vena cava filter, quality improvement, trauma outcomes, venous thromboembolism

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## BACKGROUND

The first inferior vena cava (IVC) filter was developed by a surgeon: Lazar J. Greenfield, MD, and a petroleum engineer: Garman O. Kimmel. The device was originally conceived as a secondary component of a catheter-based approach to the management of acute massive pulmonary embolism (PE).[1] Hence, the initial purpose for placement of an IVC filter was to decrease the incidence of recurrent PE and reduce associated mortality. Accepted indications for IVC filter placement are characteristically therapeutic, including proximal deep vein thrombosis (DVT) or PE and contraindication to anticoagulation, failure of anticoagulation, massive PE, or severe cardiopulmonary disease with DVT.[2]

Indications for prophylactic placement of an IVC filter are controversial. Also, the definition of what constitutes a ''contraindication'' to anticoagulation or pharmacological prophylaxis to prevent venous thromboembolism (VTE) is variable in the medical literature and among clinicians. Examples of suspected high-risk patients in whom IVC filters have been placed prophylactically in the absence of a VTE event include: bariatric surgery patients, spine surgery patients, and head injured patients.[3–5] Utilizing the Nationwide Inpatient Sample, the incidence of prophylactic IVC filter placement is increasing at a significantly higher rate than placement after a VTE event (157% versus 42%, adjusted rate increase from 1998 to 2005).[6]

Despite development of temporary retrievable IVC filters, these devices often become permanent in trauma patients and are not removed once the VTE risk has subsided.[7] IVC filters are not without complications, including device migration, filter penetration, filter fracture, IVC perforation, IVC thrombosis, and PE even with presence of the device.[2,8] The incidence of PE has increased more than 2-fold from 1994–2001 to 2007–2009 for trauma patients based upon data entered into the National Trauma Data Bank (NTDB).[9] However, during the same time period, the rate of PE-associated mortality has decreased suggesting changes in data capture, disease recognition, and treatment.

Data from a state-wide quality improvement collaborative for bariatric surgery demonstrated that preoperative placement of an IVC filter before performance of gastric bypass surgery was not associated with a reduction in the rate of PE (0.84% versus 0.46%; odds ratio 2.0; 95% confidence interval (CI) 0.6–6.5).[10] Gastric bypass patients with a prophylactic IVC filter had higher rates of serious complications and trended towards an increased rate of death. In the NTDB, 0.86% of all trauma patients underwent placement of an IVC filter and 86% of these 3883 patients received an IVC filter as prophylaxis in absence of a prior VTE event.[11] A meta-analysis of 8-controlled studies examining effectiveness of no IVC filter versus prophylactic IVC filter in trauma patients yielded no significant difference in incidence of DVT or mortality based upon relative risk calculations.[12] The number of patients needed to treat with prophylactic IVC filter placement to prevent 1 additional PE was estimated to range between 109 and 962 patients.

The Michigan Trauma Quality Improvement Program (MTQIP) is a state-wide collaborative quality initiative (CQI)

sponsored by Blue Cross Blue Shield of Michigan and Blue Care Network, focused on trauma.[13] Reduction in VTE events is a global process measure quality improvement initiative for MTQIP. Additional trauma registry data on pharmacological VTE prophylaxis agent, timing of initiation, timing of VTE event, and IVC filter placement is collected to support this performance improvement effort. Utilizing this data, we examined the relationship between prophylactic IVC filter placement and mortality in a higher risk cohort of trauma patients. We also investigated the potential association of prophylactic IVC filter placement with development of a subsequent VTE event.

## METHODS

### Program

MTQIP comprised 26 American College of Surgeons Committee on Trauma verified level I and II trauma centers in Michigan (see Table, Supplemental Digital Content 1, MTQIP participating trauma centers). Data were collected using the existing trauma registry at participating hospitals. MTQIP utilizes a data definitions dictionary, which is published online and updated annually.[14] Trauma registrars and data abstractors from participating centers all underwent training in MTQIP and National Trauma Data Standard data definitions. Each MTQIP center undergoes an annual data validation audit. Written feedback reports detailing audit performance and areas for improvement are provided.

### Data

Data for these analyses were abstracted from the MTQIP database, and the study cohort consisted of patients admitted to participating trauma centers between January 1, 2010, and June 30, 2014. The inclusion and exclusion criteria were selected to allow creation of a similar group of patients for analysis and eliminate bias caused through use of varying entry criteria for patients within each center's trauma registry. We sought to exclude minimally injured patients from the analysis by requiring an injury severity score (ISS) of $\geq$9. Also excluded were patients who were rapidly discharged and unlikely to undergo IVC filter placement. Inclusion criteria to form the analysis patient cohort are listed:

- Age $\geq$16 years.
- At least 1 valid trauma International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code in the range of 800–959.9, excluding late effects (905–909.9), superficial injuries (910–924.9), and foreign bodies (930–930.9).
- Primary mechanism of injury classified as either blunt or penetrating:
  - Blunt is defined as an injury where the primary E-code is mapped to the following categories: fall, machinery, motor vehicle traffic, pedestrian, cyclist, and struck by against.
  - Penetrating is defined as an injury where the primary E-code is mapped to the following categories: cut/pierce and firearm.
- Calculated injury severity score (ISS) $\geq$9.
- Emergency department (ED) discharge disposition and hospital discharge disposition must be known.
- Hospital length of stay $\geq$3 days.

Patients with no signs of life at initial evaluation (ED systolic blood pressure = 0, pulse = 0, Glasgow Coma Scale Score = 3) were excluded.[15] All ISS values were derived from registrar abstracted and recorded abbreviated injury scale (AIS) 2005 codes. Patients who received placement of an IVC filter were identified by searching the procedure data for the ICD-9 procedure code 38.7. MTQIP data collected after January 1, 2012 includes information on date, time, and type of first dose of pharmacological VTE prophylaxis for each patient.

### Analysis

The primary outcome of interest was risk- and reliability-adjusted placement of an IVC filter during hospitalization. We fit a mixed-effects logistic regression model to calculate expected probabilities of IVC filter insertion, using an empirical Bayes technique.[16] Risk adjustment covariates at the patient level were selected using a 2-step process: first selecting from a full set of baseline characteristics and injury severity variables those potentially associated with the outcome ($P < 0.2$, univariate), then using forward selection on this subset of variables to construct the final model. In some instances, specific incidents had missing values for potentially important covariates (GCS motor score, systolic blood pressure, and pulse rate). To minimize bias, these values were imputed using multiple imputations.

Patient covariates were entered into a mixed-effects logistic regression model, with patients grouped at the hospital level. Expected risk- and reliability-adjusted probabilities of IVC filter placement were obtained from the model. Final adjusted rates of IVC filter usage for each hospital were calculated by multiplying the rate ratio of observed to expected events by the overall collaborative rate. Hospitals were then placed into quartiles based on adjusted rates of IVC filter usage. A multivariable logistic regression model for mortality was constructed using the same variable selection method described above. Expected probabilities of death were calculated for each patient and adjusted rates of mortality for each quartile were calculated by multiplying the rate ratio of observed to expected events by the overall collaborative rate.

To examine VTE events, a subset of data collected from January 1, 2012 to June 30, 2014 was used. Type of chemical VTE prophylaxis agent was defined as none, unfractionated heparin, low molecular weight heparin, or other. The time to first dose of pharmacologic VTE prophylaxis was calculated based on time elapsed since patient arrival into the emergency department. Patients were divided into 2 groups: (1) patients who received VTE prophylaxis $\leq$48 hours after arrival; (2) patients who either received VTE prophylaxis >48 hours after arrival or who did not receive any VTE prophylaxis. A multivariable logistic regression model for DVT was constructed to account for differences in baseline characteristics and injury severity, based on significant covariates using forward selection. Missing values for GCS motor score, systolic blood pressure, and pulse rate were handled using indicator variables. DVT was entered into the model as the dependent variable and odds ratio for a DVT event in the presence or absence of a prophylactic IVC filter determined.

This study was submitted to the University of Michigan Medical School Institutional Review Board and given a determination of "not regulated" status as a quality assurance and quality improvement clinical activity.

### Statistical Methods

Statistical analyses were performed using Stata 12.0 (StataCorp LP, College Station, TX). Graphs were produced using GraphPad Prism 5.0 software (GraphPad Software, La Jolla, CA). Results are presented as values ±95% CI, mean, or mean ± standard deviation. Statistical significance was defined as a $P$-value <0.05.

## RESULTS

### Patient Selection

We identified 39,456 trauma patients with an ISS of 9 or greater who were admitted to the hospital for at least 3 days (Fig. 1).

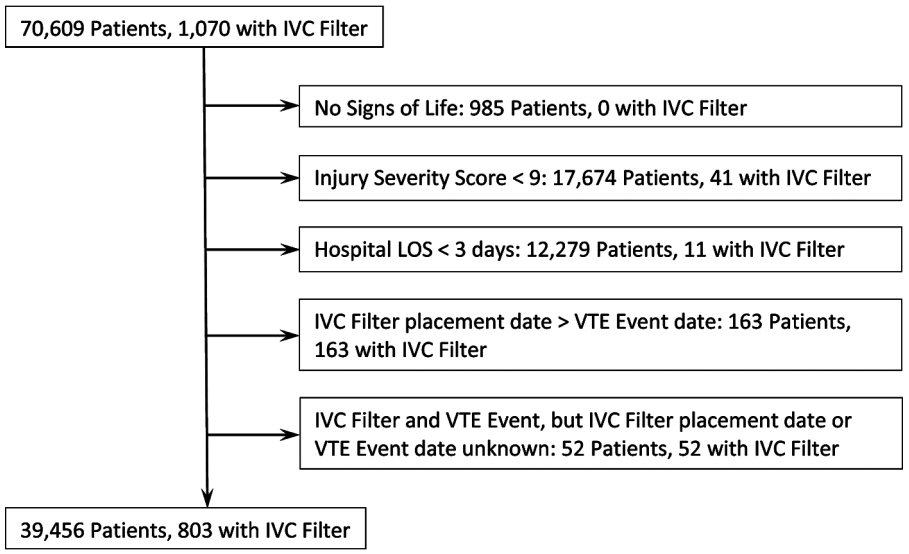


**FIGURE 1.** Patient eligibility flowchart.

There were 4 potential categories of patient with presence of an IVC filter, based on date of IVC filter placement and/or date of identification of a VTE event: 1) IVC filter placement date before VTE event date, 2) IVC filter placement date after VTE event date, 3) IVC filter placed, but no VTE event, and 4) IVC filter placement, but IVC filter placement and/or VTE event date unknown. Only patients who did not receive an IVC filter and patients who received an IVC filter as prophylaxis were included in the study. Thus, patients in categories 2 and 4 were excluded. Within this final cohort, 2.0% (n = 803) of patients underwent prophylactic placement of an IVC filter.

## Adjusted IVC Filter Use

Patients who received a prophylactic IVC filter were younger, male, and had evidence of more substantial traumatic injury (Table 1). Nonrisk adjusted outcomes showed that the IVC filter cohort had higher rates of mortality, DVT, PE, and VTE (Table 2). To account for patient level differences between the No IVC filter and IVC filter cohort, a multivariable logistic regression model was constructed for the dependent variable of IVC filter use. Covariates entered into the final model are detailed in Table 3 and the model had a c-index of 0.81. Risk and reliability-adjusted rates of IVC filter usage were calculated for each participant trauma center and ranged from 0.6% to 9.6% (Fig. 2). Seven trauma centers were low outliers and 11 centers were high outliers for placement of a prophylactic IVC filter when compared with the mean rate across all trauma centers. Prophylactic IVC filter use was increased within American College of Surgeons Committee on Trauma verified level II trauma centers as compared with level I trauma centers (odds ratio = 2.69; 95% CI, 2.29–3.16, *P*-value <0.001). There were 286 prophylactic IVC filters placed in 19,489 patients at level I trauma centers and 517 prophylactic IVC filters placed in 19,967 patients at level II trauma centers.

## Adjusted Mortality

The trauma centers were divided into quartiles based on rates of IVC filter usage. Rates of IVC filter usage in the 4 quartiles progressed in a stepwise fashion from a low of 0.7% to a high of 4.6% (Table 4). A multivariable logistic regression model was constructed for the outcome mortality. Observed and predicted mortalities obtained from the logit equation were collapsed on IVC filter usage quartile as the independent variable (see Table, Supplemental Digital Content 2, mortality prediction model). The c-index for the model was 0.87. Between the 4 separate quartiles of IVC filter usage there was no difference in risk-adjusted mortality with all 4 quartiles exhibiting an adjusted mortality rate of 3.6% (Fig. 3).

## Adjusted Rates of DVT and PE in Patients With Prophylactic IVC Filter Use

Among the 59 patients who received a prophylactic IVC filter and then had occurrence of a VTE event, 54 patients had a subsequent DVT, 9 patients experienced a PE, and 4 patients were diagnosed with both a DVT and PE. The average time elapsed after IVC filter placement to a VTE event was 10.7 ± 11.1 days with a range of 1–69 days.

In a subset analysis, data regarding date, time, and type of anticoagulant used as first dose of VTE pharmacologic prophylaxis were included. A total of 24,134 patients were available for study and 409 underwent prophylactic IVC filter placement. Forty eight percent of trauma patients received their first dose of VTE pharmacologic prophylaxis within 48 hours of hospital admission. Agents used for VTE pharmacologic prophylaxis included unfractionated heparin (28.5%), low molecular weight heparin (35.5%), other oral agents (3.1%), and none (32.9%). Adjusting for pharmacologic VTE prophylaxis and patient factors, prophylactic IVC filter placement was associated with an increased incidence of DVT (odds ratio = 1.83; 95% CI, 1.15–2.93, *P*-value = 0.01) (see Table, Supplemental Digital Content 1, DVT prediction model). The c-index of the model was 0.82. The nonadjusted rate of a DVT event after IVC filter placement was 5.9% (n = 24 patients) compared with 1.1% (n = 265 patients) for patients who did not receive an IVC filter.

# DISCUSSION

Prophylactic IVC filter use, particularly for trauma patients, has increased markedly over the last decade.[6] A recent meta-analysis suggests minimal patient benefit for prophylactic IVC filter placement with no reduction in mortality despite evidence of lower incidence of PE and fatal PE in the setting of traumatic injury.[12] Herein, using data from a large multicenter CQI, we found that placement of an IVC filter prophylactically provided no mortality benefit in trauma patients. We also discovered significant variation in adjusted placement rates of prophylactic IVC filters at the hospital

**TABLE 1.** Patient Characteristics

| Characteristic | No IVC Filter | IVC Filter | *P* |
|---|---|---|---|
| Patients, N | 38,653 | 803 | — |
| Age, mean | 62.9 ± 22.8 | 53.1 ± 20.4 | <0.001 |
| Age, % | | | |
| 16–25, years | 9.0 | 11.8 | <0.001 |
| 26–45 | 15.3 | 25.9 | |
| 46–65 | 24.1 | 32.9 | |
| 66–75 | 12.5 | 12.7 | |
| >75 | 39.1 | 16.7 | |
| Male sex, % | 52.3 | 63.0 | <0.001 |
| White race/ethnicity, % | 77.6 | 77.0 | 0.7 |
| Blunt mechanism, % | 93.0 | 94.9 | 0.03 |
| ED pulse, % | | | |
| 51–120, bpm | 92.0 | 83.2 | <0.001 |
| >120 | 5.1 | 13.4 | |
| 1–50 | 0.9 | 1.5 | |
| Missing | 2.0 | 1.9 | |
| ED systolic blood Pressure, % | | | |
| >90, mmHg | 94.8 | 84.9 | <0.001 |
| 61–90 | 2.6 | 11.7 | |
| ≤60 | 0.5 | 1.4 | |
| Missing | 2.1 | 2.0 | |
| ED GCS motor score, % | | | |
| 6 | 82.9 | 64.3 | <0.001 |
| 5–2 | 5.5 | 16.3 | |
| 1 | 3.8 | 14.3 | |
| Missing | 7.8 | 5.1 | |
| Injury severity score, % | | | |
| 5–15 | 72.1 | 28.1 | <0.001 |
| 16–24 | 17.9 | 27.8 | |
| 25–35 | 8.3 | 30.6 | |
| >35 | 1.7 | 13.5 | |
| AIS head/neck >2, % | 25.6 | 49.6 | <0.001 |
| AIS face >2, % | 0.5 | 2.1 | <0.001 |
| AIS chest >2, % | 20.7 | 40.3 | <0.001 |
| AIS abdomen >2,% | 7.1 | 14.6 | <0.001 |
| AIS extremity >2, % | 49.3 | 44.6 | 0.009 |
| AIS external >2, % | 1.7 | 0.4 | 0.009 |
| Intubated, % | 41.7 | 76.5 | <0.001 |
| Transfer, % | 19.6 | 19.9 | 0.8 |
| Congestive heart failure, % | 5.8 | 2.4 | <0.001 |
| Esophageal varices, % | 0.08 | 0.2 | 0.08 |
| Hypertension, % | 44.1 | 34.9 | <0.001 |
| Statin medication, % | 14.5 | 12.3 | 0.08 |

AIS indicates Abbreviated Injury Scale; ED, emergency department; GCS, Glasgow Coma Scale.

level and an increased risk of DVT following device insertion in these patients.

Virchow triad of a hypercoagulable state, stasis, and endothelial damage outline the 3 classic factors that predispose to thrombosis in a patient. Expanding on the triad, trauma patients are often at high risk for VTE events due to multiple factors, including injury severity, body region injured, immobilization, potential need for multiple surgical interventions, and presence of systemic inflammation and/or infection.[9,11] The 2012 American College of Chest Physicians (ACCP) guidelines recommend that an IVC filter not be placed in a patient without a current VTE.[17] This suggestion is based on absence of high-quality evidence that prophylactic placement of a permanent or temporary IVC filter alters clinical outcomes compared with pharmacological prophylaxis. Hence, the preferred method of VTE prophylaxis in trauma patients is pharmacologic with or without the addition of mechanical prophylaxis depending upon risk profile and pattern of injury.[17]

**TABLE 2.** Patient Outcomes

| Outcome | No IVC Filter | IVC Filter | *P* |
|---|---|---|---|
| Patients, N | 38,653 | 803 | – |
| Mortality, % (N) | 3.5 (1,369) | 5.2 (42) | 0.01 |
| DVT, % (N) | 1.2 (483) | 6.7 (54) | <0.001 |
| Pulmonary embolism, % (N) | 0.5 (187) | 1.1 (9) | 0.01 |
| VTE, % (N) | 1.6 (632) | 7.3 (59) | <0.001 |

DVT indicates deep vein thrombosis; VTE, venous thromboembolism.

A challenge that arises in trauma patients concerns clinical criteria for which patients are not a candidate for early pharmacologic VTE prophylaxis due to bleeding risk, timing of when the bleeding risk has subsided, and what, if anything, should be done to counterbalance the risk of a fatal PE in a patient who cannot receive VTE prophylaxis. The Eastern Association for the Surgery of Trauma practice management guidelines for the prevention of VTE in trauma patients assesses the risk of a fatal PE in a very high-risk trauma patient differently in relation to usage of prophylactic IVC filter placement than the American College of Chest Physicians guidelines. A level 3 recommendation based on studies using retrospective data, expert opinion, or case reports is made and states that insertion of a prophylactic IVC filter should be considered

**TABLE 3.** IVC Use Prediction Model

| Variable | Odds Ratio (95% CI) | *P* |
|---|---|---|
| Age | | |
| 16–25, years | 1.0 | — |
| 26–45 | 1.3 (1.03–1.75) | 0.03 |
| 46–65 | 1.3 (0.99–1.68) | 0.06 |
| 66–75 | 1.3 (0.94–1.82) | 0.1 |
| >75 | 0.7 (0.51–1.00) | 0.05 |
| Non-White race/ethnicity | 0.8 (0.67–0.98) | 0.03 |
| Injury severity score | | |
| 5–15 | 1.0 | — |
| 16–24 | 2.9 (2.30–3.67) | <0.001 |
| 25–35 | 5.0 (3.83–6.46) | <0.001 |
| >35 | 6.4 (4.42–9.21) | <0.001 |
| AIS head/neck >2 | 1.5 (1.23–1.91) | <0.001 |
| AIS chest >2 | 1.3 (1.06–1.57) | 0.01 |
| AIS extremity >2 | 1.9 (1.58–2.26) | <0.001 |
| AIS external >2 | 0.2 (0.09–0.63) | 0.004 |
| ED GCS motor | | |
| 6 | 1.0 | — |
| 5–2 | 1.4 (1.12–1.77) | 0.003 |
| 1 | 1.0 (0.75–1.26) | 0.8 |
| Blunt mechanism | 4.6 (2.15–9.64) | <0.001 |
| Fall | 0.7 (0.61–0.90) | 0.002 |
| Firearm | 2.2 (1.07–4.83) | 0.03 |
| ED systolic blood pressure, mmHg | | |
| >90 | 1.0 | — |
| 61–90 | 2.4 (1.86–3.10) | <0.001 |
| ≤60 | 1.6 (0.84–3.12) | 0.2 |
| ED heart rate, bpm | | |
| 51–120 | 1.0 | — |
| >120 | 1.3 (1.02–1.63) | 0.03 |
| 1–50 | 1.3 (0.68–2.40) | 0.4 |
| Intubated | 2.6 (2.19–3.18) | <0.001 |
| Gastric or esophageal varices | 3.4 (0.77–14.9) | 0.1 |
| Hypertension | 1.2 (0.97–1.41) | 0.1 |
| Statin medication | 1.3 (0.99–1.61) | 0.06 |
| Transfer | 0.8 (0.64–0.94) | 0.009 |

AIS indicates Abbreviated Injury Scale; ED, emergency department; GCS, Glasgow Coma Scale.

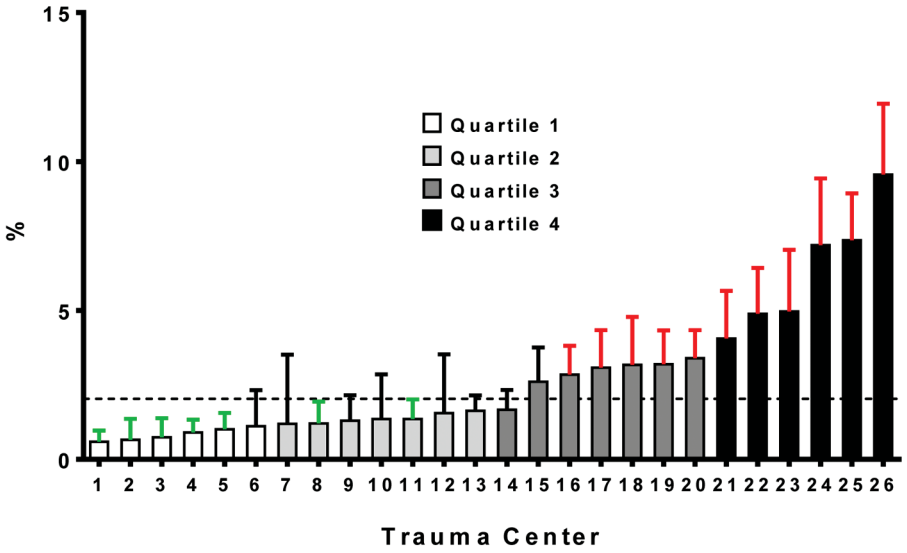


**FIGURE 2.** Risk- and reliability-adjusted rate of IVC filter usage. Green indicates a 95% CI below the average rate for the collaborative (2.0%, dashed line), low outlier status. Red indicates a 95% CI above the average rate for the collaborative, high outlier status. Changes in bar shading represent assignment to quartiles of adjusted IVC filter use.

**TABLE 4.** IVC Filter Usage Quartiles

| | Quartile | | | | |
|---|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th | *P* |
| Trauma centers, N | 6 | 7 | 7 | 6 | — |
| Patients, N | 10,238 | 8898 | 12,717 | 7603 | — |
| IVC filter rate, % (N) | 0.7 (70) | 1.3 (112) | 2.1 (268) | 4.6 (353) | <0.001 |
| Crude mortality, % | 3.94 (403) | 3.64 (324) | 3.24 (412) | 3.58 (272) | 0.045 |

IVC indicates inferior vena cava.

in very high-risk trauma patients: (1) who cannot receive pharmacologic prophylaxis because of increased bleeding risk and (2) have an injury pattern rendering them immobilized for a prolonged period of time.[18] Injury patterns consistent with very high risk include severe closed head injury, spinal cord injury with paraplegia or quadriplegia, complex pelvic fractures with associated long bone fractures, and multiple long bone fractures. Likewise, the Society of Interventional Radiology also endorses consideration of prophylactic IVC filter placement in trauma patients at high risk for VTE where primary pharmacologic prophylaxis is not feasible.[19]

The risk of a PE after traumatic injury is highest during the first week of hospitalization and 37% to 50% of PE's are diagnosed early (≤4–7 days after injury).[20,21] Therefore, it is imperative to begin pharmacologic prophylaxis in trauma patients within 24–48 hours after hospital admission and as soon as bleeding risk contraindication has subsided. Trauma surgeons and

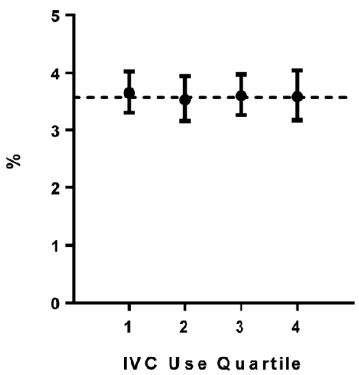


**FIGURE 3.** Risk-adjusted mortality by quartiles of IVC filter usage. The 95% CI for all 4 quartiles spans the mean value of 3.6% indicating no variation in mortality rate with quartile of IVC filter use.

| | Quartile | | | |
|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th |
| Adjusted Mortality, % | 3.64 | 3.53 | 3.60 | 3.59 |
| 95% Confidence Interval | 3.30-4.02 | 3.16-3.94 | 3.26-3.96 | 3.17-4.04 |

subspecialty providers vary widely in their willingness of when to allow initiation of pharmacologic prophylaxis. There has been a trend in traumatic brain injury patients for neurosurgeons and trauma surgeons to agree upon and advocate earlier administration of VTE prophylaxis in the setting of intracranial hemorrhage.[22,23] Providers are now initiating pharmacologic prophylaxis with either unfractionated heparin or low molecular weight heparin 24–48 hours after confirmatory head computed tomography scanning determining stability of intracranial hemorrhage.[24,25]

Significant variation in placement rates of IVC filters is occurring at the level of different trauma centers.[25] There is also considerable variation between hospitals in placement of IVC filters after an acute VTE event.[26] Several developments have likely contributed to this variation. First, the use of ''temporary'' IVC filter devices that are retrievable offer the ability to insert an IVC filter and then remove the device once the VTE risk profile has declined and/or pharmacologic prophylaxis is no longer contraindicated. Removal of temporary IVC filters has turned out to be an overly optimistic expectation and 80% to 90% of these devices end up becoming permanent in current practice.[7,27,28] Second, the technique of insertion has been modified and IVC filters are now able to be placed with ease at the bedside in the intensive care unit with the assistance of ultrasound guidance.[29] Lastly, the diagnosis of VTE has increased substantially owing to bedside extremity duplex scanning and advances in computed tomography scanning that have completely replaced catheter-directed pulmonary angiogram studies.[9] Highlighting these variances is the fact that when a group of 18 trauma surgeons, who have published on thromboembolic disease, were surveyed, profound differences in DVT surveillance for asymptomatic patients, pharmacologic prophylaxis, treatment of diagnosed VTE disease, and placement of IVC filters were found.[30]

In our current study, we found that the risk-adjusted rate of DVT was increased in patients after insertion of a prophylactic IVC filter. This may be related to not using anticoagulant prophylaxis, or less likely, insertion site-associated DVT. In a large randomized controlled trial of IVC filter efficacy, the early reduction in PE was offset by an increase in the rate of recurrence of DVT in the IVC filter group (20.8%) compared with the no filter group (11.6%) at 2 years.[31] Results of 8-year follow-up demonstrated PE to be reduced for patients with an IVC filter, but DVT rates were increased, and there was no effect on mortality.[32] Although highly effective, IVC filters may fail to prevent PE. In our study, 9 patients were diagnosed with a PE after undergoing prophylactic placement of an IVC filter. Although there may have been a few clinically asymptomatic VTE events that were unrecognized at the time of filter insertion, it is likely that some of these PE's occurred later after the IVC filter was in place. PE occurrence in the presence of a IVC filter is a known phenomenon and our rate of 0.1% is comparable to previously published rates of 0.2–0.26%.[7,33]

Our study has several limitations. For 52 (6.4%) patients who received an IVC filter we were unable to determine if the indication was prophylactic or therapeutic, due to missing time and date data. We excluded these patients from the analysis presented, however, in a separate analysis when these patients were included it did not change the primary finding of the study, which was that IVC filter use quartiles showed no variation in mortality. No attempt was made to ascertain the manufacturer or type of IVC filters placed (permanent versus temporary). This could have influenced our results as temporary IVC filters are associated with higher rates of device failure, complications, and VTE/PE when compared with permanent devices.[34] However, our findings when coupled with the substantial increase in placement of temporary IVC filters give practitioners reason to reassess which patients and which type of device they should consider placing in the very high-risk trauma patient. Lastly, surveillance bias for diagnosing VTE may exist across centers, and the true incidence is probably underestimated.[35,36] However, this bias is likely evenly spread across centers and our real world CQI registry including academic and nonacademic hospitals mitigates this factor.

## CONCLUSIONS

This study determined that rates of prophylactic IVC filter insertion vary considerably within a state-wide trauma quality collaborative. Placement of an IVC filter does not reduce the risk of mortality for trauma patients at the hospital level. Prophylactic placement of an IVC filter is associated with an increased risk of subsequent DVT occurrence.

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## DISCUSSANTS

### M. Knudson (San Francisco, CA):

I have nothing to disclose.

I would first like to take the opportunity to acknowledge the many contributions that Dr Hemmila has made at the ACS committee on trauma in the area of Trauma Quality Improvement Program (TQIP). Congratulations, Mark, on your leadership in developing the Michigan Trauma Quality Improvement Program (MTQIP), incorporating 26 ACS-verified trauma centers in Michigan.

A few years ago at this meeting, we presented an analysis of the committee on Trauma's National Trauma Data Bank (NTDB) suggesting that the increased use of a prophylactic vena cava filter was paralleled by the increasing rates of pulmonary emboli. Today, Dr Hemmila and his coauthors have taken this one step further, suggesting that prophylactic vena cava filters have no effect on mortality after injury. Their data also demonstrates that in Michigan, as in other parts of the country, the use of a prophylactic filter varies widely among practitioners, with some centers inserting them in as many as 10% of their trauma patients.

This enthusiastic use of prophylactic filters, a phenomenon that I refer to as ''filter fever'' is not unique to trauma. In fact, if you are a nontrauma patient admitted to a hospital in California, your chance of getting a filter increases with being admitted to a small hospital in a rural area and 1 that is private but not Kaiser.

Mark, I have 2 questions for you.

The first question pertains to mortality. Your data demonstrates that the patients who receive an IVC filter are a much more injured cohort. They arrive at the emergency department with more indicators of shock than those who do not go on to receive an inferior vena cava (IVC) filter. Based on their admission characteristics, it is not surprising that this group of patients has a higher mortality.

Although you have shown that the risk-adjusted mortality is not significantly different across your 4 quartiles of trauma centers, you have not told us what these patients die from. Are these patients dying from their overall injury burden? In particular, what is the pulmonary embolism (PE)-attributable mortality in each quartile?

My second question relates to surveillance bias. You suggested that the reported rate of deep venous thrombosis (DVT) is higher in patients who receive a prophylactic filter and that the presence of the filter is somehow to blame. I would submit an alternative explanation, that the trauma surgeons in Michigan have correctly identified patients at high risk for venous thromboembolic (VTE) and that in addition to placement of a filter, they are liberal with scanning for VTE events. Can you provide us with any data on the use of surveillance DVT scanning among your trauma centers?

The purpose of NSQIP, TQIP, and now MTQIP, is to identify best practices and reduce variability in performance, ultimately leading to reduced costs and improved quality of care. I look forward to hearing how you are going to use this study to change the practices in the MTQIP trauma centers.

### Response From M.R. Hemmila:

To answer your first question, what did they die from? It is actually pretty difficult to find out unless you have a very high autopsy rate. It would be nice to know how many of these patients are dying from an actual (PE) versus some other source. We do have some data within the database about what their complications are and when they occur. We also have information on whether support was withdrawn electively by the family and providers or if the patient suffered an acute unexpected cardiac arrest. There may be a little bit of information that we can tease out, but I am not sure we are going to get the exact answer that you are looking for.

In terms of the surveillance bias, I think that is very much true. The more you look for these, the more you will find. One of the things I observed from this data is that this is a system problem; it is not a problem that is easily solvable by a prospective randomized trial. You have to look at all the factors involved, what is the culture in the hospital in terms of whether the subspecialists, such as neurosurgery or orthopedic surgery, will allow use of VTE prophylaxis, and what are your resources available? In a sense, what you are doing is monitoring your whole system and trying to optimize your mortality with regard to everything that you are doing, not just prophylactic avoidance of a VTE event. I would not want anybody to walk away from here thinking that somehow you do not place a filter but ignore Virchow triad.

### L. Greenfield (Tucson, AZ):

I agree with your conclusion that there are entirely too many prophylactic filters being placed. However, before we let the pendulum swing too far in the other direction, I think we should recognize that patients continue to die of PE, and we should ask

whether or not there is anything or any way to identify the truly high-risk patients who cannot be helped at our present level of management of anticoagulation.

I have some specific questions.

In the filter patients who develop DVT, you discounted the role of insertion site thrombosis, but the insertion procedure through a major vein with subsequent compression to prevent bleeding obligates some nidus of thrombus. Which data support that conclusion?

Further, for those patients who had PE in the presence of a filter, what was its status? One possibility is that it had done its job only to have thrombus progress above that level. Also, when a filter suddenly occludes from a large thrombus, it is equivalent to clamping the vena cava. The patient will collapse, and if not volume resuscitated, death attributed to PE can occur. What autopsy confirmation do you have of actual causes of death? For those patients with extensive lower body trauma, how many had only upper body lines with the potential for subclavian vein thrombosis?

Finally, filters differ in configuration and behavior, with most cone-shaped devices able to trap thrombi without further propagation of clot. This is not the case with those that trap thrombi against the cava wall, a situation well documented to promote cava thrombosis.

Although you may not have patient-specific data, do you know which filter configurations were favored by your participating hospitals? For patients who develop DVT, there is life-long risk of recurrence, making it equally important to know what happens to them after a filter is removed. With the current emphasis on cost-effective care, I hope that you can continue to use this impressive network to refine these important studies.

I should mention that I have no conflict other than a name on a very old product.

### Response From M.R. Hemmila:

Identifying the high-risk patient, I think actually Dr Knudson has done quite a bit of work in that realm, as have you yourself. I think we can pick out who these patients are. Then what it comes down to is do we feel in our institution that they are candidates for pharmacologic prophylaxis? If not, I think they potentially do need a filter.

The next question to ask is, what kind of filter? The permanent filter has a good track record. The temporary filters were developed with the interest of getting them out, but 80% to 90% have become permanent.

Insertion site is certainly a very important cause of potential DVT. We do not have exact information on that, but it is mentioned as a cause in some of the other studies, and is mentioned in the prefix study.

Filter PEs, we actually had a fairly low rate of PE through the filter at 1%. The literature mentions about 0.2%. I think there is also a school of thought that believes that PEs can potentially be due to inflammation and may not always occur as embolism of clot from an extremity.

We do not have any specific information on subclavian vein thrombus, but we do have upper extremity data.

Which filter, I think this is certainly a potential next project. Dr Henke, when he and I sat down and talked about doing something like this, this was one of his major interests. That would require some qualitative analysis across the state, but we can probably look into it.

### C. Hauser (Boston, MA):

First, I do not think you have shown stratification by hospital is as valid as stratification by injury. Most of us who actually care for a lot of severely injured patients have limited our use of filters over the last few years. But we have limited them to selected patients who are going to be immobile for a prolonged period, like patients who have bilateral nonweight-bearing lower extremity fractures, major pelvic fractures, or vertebral injuries. A high percentage of these patients have DVT and have many-fold higher rates of PE with chemoprophylaxis than with a filter (Decousus in *The New England Journal of Medicine* 1998). To what extent does your data identify those high-risk patients with prolonged immobility?

Secondly, I noticed that a lot of patients in your filter group simply did not receive chemoprophylaxis. IVC filters prevent PE, not DVT. So the presence of a prophylactic IVC filter in no way takes away our responsibility to provide DVT prophylaxis in appropriate patients. This approach will bias the results against IVC filters; especially where DVT and PE are combined into an artificial ''VTE'' endpoint. Does your data identify patients who were never started on chemoprophylaxis or taken off prophylaxis despite their immobility because they had an IVCF? These patients will be at extraordinarily high risk for lower extremity DVT precisely because they are taken off of chemoprophylaxis when the filter was placed.

### Response From M.R. Hemmila:

In regard to relative immobility and changing, how we define the use of quartiles that would require some interesting changes in the analysis? We did do an analysis for DVT after filter placement, where we used propensity score matching, and the results were the same. We do not know when the patients came off of prophylaxis and simply are recording the first dose and what type.

In terms of the patients who received no prophylaxis, that is a very interesting question. It is something that we monitor very closely in the collaborative because there are patients who can get up and walk and have a lower risk and probably do not need pharmacologic prophylaxis, and it is completely appropriate to do none. We give participants feedback on the mortality in their none group, the VTE rates in their none group, and then we give them feedback on those results in the ones that got prophylaxis treatment. We are covering all of the possibilities. If somebody had a high occurrence of VTE and death in their none group, then they should probably rethink whether they are correctly stratifying their patients.

### L.N. Diebel (Detroit, MI):

I have a very simple question that Dr Hauser partially asked already. We are one of the trauma centers from Michigan and almost invariably when we put in a prophylactic filter, which you use 99% of the time—Greenfield filters—we stop the heparin. I think that is an important thing to look at. Some people claim that there is endothelial injury from the filter, but that would cause thrombus of the cava and not a DVT, so I think before you blame the filter on this, you need to look at chemoprophylaxis after prophylactic filters.

### Response From M.R. Hemmila:

I would agree with that. I totally admit that we do not know what filters are being placed. I think that that is probably a good step if we were to pursue further action to figure out which filters are being placed in which patients at what hospitals.

### A.X. Holterman (Peoria, IL):

I have nothing to disclose.

With regard to your paradoxical finding that the filter is associated with a high incidence of DVT, Dr Knudson had mentioned the potential for surveillance bias. I would like to suggest another potential source of bias, that of index event bias. By the nature of your selection at the outset of patients who received the filter prophylactically, you also select patients who are at risk for DVT. Many of these patients may have some other unmeasured risk factors, which you

would not be able to control for, in spite of your attempt at regression analysis, perhaps explaining why you have the paradoxical higher incidence in patients receiving the filter.

### Response From M.R. Hemmila:

I see what you are saying. We tried to account for that in 2 ways. One was by doing the risk adjustment that does take into account the fact that some people are more injured and at higher risk for DVT.

The other is that we did a secondary analysis with propensity scores that takes into account who would have gotten a filter versus who did not and adjusts for virtually everything that is present. The difference between the filter group and nonfilter group held up.