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Development of a Predictive Model for 6 Month Survival in Patients with Venous Thromboembolism and Solid Malignancy Requiring IVC Filter Placement

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Abstract

Purpose—Our purpose was to develop a predictive model for short-term survival (i.e. less than 6 months) following inferior vena cava filter placement in patients with venous thromboembolism (VTE) and solid malignancy.

Materials and Methods—Clinical and laboratory parameters were retrospectively reviewed for patients with solid malignancy who received a filter between January 2009 and December 2011 at a tertiary care cancer center. Multivariate Cox proportional hazards modeling was used to assess variables associated with 6 month survival following filter placement in patients with VTE and solid malignancy. Significant variables were used to generate a predictive model.

Results—397 patients with solid malignancy received a filter during the study period. Three variables were associated with 6 month survival: (1) serum albumin (hazard ratio [HR] 0.496, $P < 0.0001$), (2) recent or planned surgery (< 30 days) (HR 0.409, $P < 0.0001$), (3) TNM staging

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Compliance with Ethical Standards: Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Approval for this retrospective review study was obtained from our institutional review board. The requirement for informed consent was waived by the institutional review board.

(stage 1 or 2 versus stage 4, HR 0.177, $P=0.0001$; stage 3 versus stage 4, HR 0.367, $P=0.0002$). These variables were used to develop a predictive model to estimate 6 month survival with an area under the receiver operating characteristic curve of 0.815, sensitivity of 0.782, and specificity of 0.715.

Conclusions—Six month survival in patients with VTE and solid malignancy requiring filter placement can be predicted from 3 patient variables. Our predictive model could be used to help physicians decide whether a permanent or retrievable filter may be more appropriate as well as to assess the risks and benefits for filter retrieval within the context of survival longevity in patients with cancer.

Keywords

IVC filter; malignancy; survival

Introduction

Inferior vena cava (IVC) filters provide patients with protection against pulmonary embolism (PE). A previous randomized study among patients with proximal deep venous thrombosis (DVT) showed that placement of a permanent filter in addition to anticoagulation significantly reduced the short- and long-term risk of recurrent PE compared with anticoagulation alone [1, 2]. A subsequent randomized study, however, showed that placement of a retrievable filter in addition to anticoagulation did not reduce the risk of recurrent PE [3]. Despite the lack of data showing that retrievable filters are at least as effective as permanent filters in preventing recurrent PE, retrievable filters are used with increasing frequency [4] as Removal of filters can mitigate filter-associated complications, such as IVC thrombosis, device fracture, device migration, caval penetration, increased risk of recurrent venous thromboembolism (VTE), and post-thrombotic syndrome [5, 1, 6-9]. Nonetheless, for patients who are unlikely to undergo filter retrieval (e.g. patients with limited life expectancy and a plan to transition to hospice care), there may be a role for permanent filters.

When retrievable filters are implanted, the United States Food and Drug Administration encourages implanting physicians and clinicians responsible for the care of these patients to consider removing them as soon as protection from PE is no longer needed. A patient should be referred for retrieval when the risk/benefit profile favors removal and the procedure is feasible given the patient's health [10]. In order to appropriately assess the risk/benefit profile, clinicians must consider variables such as risk of recurrent VTE, risk of hemorrhage from anticoagulation, risk of filter complication, and expected patient survival. Expected patient survival in patients with malignancy can be difficult to predict [11-13]. Also, diagnosis of VTE in a cancer patient is a significant predictor of < 1 year survival regardless of cancer type and stage, potentially reflecting the presence of a biologically more aggressive cancer [14-16].

Improved methods to predict survival in patients with solid malignancy and VTE may help implanting physicians decide whether a permanent or retrievable filter may be more appropriate for a particular clinical scenario. It may be possible that a subset of oncology

patients are best served by permanent devices for prevention of recurrent PE. Furthermore, for oncology patients the decision to remove a retrievable-type filter should be made within the context of overall survival (OS). Experts from the Society of Interventional Radiology (SIR) Consensus Conference in 2006 recommended that patients expected to survive less than 6 months are unlikely to derive any discernible benefit from filter retrieval [17]. Therefore, our purpose was to develop a predictive model for short-term survival (i.e. less than 6 months) following inferior vena cava filter placement in patients with VTE and solid malignancy.

Materials and Methods

Approval for this retrospective review study was obtained from our institutional review board, and the study was compliant with the Health Insurance Portability and Accountability Act. The requirement for informed consent was waived by the institutional review board.

Data collection

A retrospective review of all patients receiving filters at a single tertiary care cancer center was performed on all patients with active solid malignancy aged 18 years from January 2009 to December 2011 (n=426 patients). Study variables included (a) age, (b) sex, (c) body mass index (BMI, kg/m²), (d) serum albumin (g/dL), (e) serum platelets (K/ μ L), (f) patient located in the intensive care unit during time of IVC filter placement, (g) IVC filter location (i.e. infrarenal versus suprarenal), (h) IVC filter indication (i.e. contraindication to anticoagulation, failure of anticoagulation, heparin-associated thrombocytopenia-thrombosis syndrome, or poor candidate for anticoagulation) using guidelines published by the SIR [17, 18], (i) presence of VTE (PE, DVT, both, none), (j) tumor stage using the tumor-node-metastasis (TNM) cancer staging system [19], and (k) cancer treatment history (no therapy, 1st line therapy, beyond 1st line therapy). Of note, contraindications to anticoagulation were further stratified according to recent (<1 month) or planned surgery at the time of IVC filter placement, recent gastrointestinal bleed or intracranial bleed, significant hematoma, hemoptysis, hematuria, thrombocytopenia (<50,000/mm³), central nervous system (CNS) neoplasm, CNS infarct, and trauma.

Patient disposition was observed as alive, deceased, or lost to follow-up. Patients who were lost to follow-up 6 months before filter placement were censored. Follow-up data was collected until December 2015. Whenever feasible, the date of death as determined by in-hospital notes, telephone notes, or annual mailings to the patient's address sent by the hospital as well as cause of death were recorded.

The database contains data on 426 patients with solid malignancy staged using the TNM cancer staging system. Of these 426 patients with solid malignancy, 29 patients were excluded because at least one study variable was unavailable (n=24 patients excluded because of missing albumin data; n=5 excluded because they were lost to follow-up within 6 months following filter placement). Thus, our study population consisted of 397 patients. The classification of patients according to type of solid malignancy is presented in Table 1.

Derivation of prediction model

The starting time for all survival analyses was the date of the filter placement. Patients lost to follow-up were censored on the date of last known communication; that is, the patient was alive on that date, but that was the extent of follow-up. Patient survival was censored at 6 months. Cox proportional-hazards regression was used to determine the significant predictors of survival ($P < 0.05$) using stepwise selection. A model to predict 6 month survival following filter placement was created from these candidate variables. Of note, TNM staging was categorized into three groups: stage 1 and stage 2 ($n=40$ patients), stage 3 ($n=60$ patients), and stage 4 ($n=297$ patients). Stage 4 was used as the referent level for the disease stage. We used logistic regression to predict the probability of death within 6 months following filter placement. Patients who were lost to follow-up within 6 months following filter placement were excluded from analysis ($n=5$ patients).

Based on the logistic regression model, we developed a Venous ThromboEmbolic and Cancer (VTEC_{6mo}) score function to predict 6 month survival following filter placement for patients with solid malignancy. The point estimate of 6 month survival was calculated using the product-limit method. The 95% confidence intervals presented for the product-limit method are computed using the normal theory approximation and back-transforming the confidence limits for log of minus the log of the survivor function. This method is typically called the log cumulative hazard transformation or the complementary log-log transformation.

Continuous data group differences were compared with a t-test or one-way ANOVA, as appropriate, and categorical data were compared with a Fisher's exact test. All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA). Statistical significance was defined as $P < 0.05$.

Results

Patient characteristics

The study population consisted of 397 patients. Median survival for the derivation cohort was 5.2 months (range, 0.07 – 60.8 months) following filter placement for patients with active solid malignancy. There were 211 deaths within 6 months of filter placement (Figure 1). General characteristics of the study cohort are shown in Table 2.

Derivation of prediction model

A multivariate Cox proportional hazards model was used to determine the significant predictors of survival: (1) serum albumin (hazard ratio [HR] 0.496, 95% confidence interval [CI] 0.418 - 0.588, $P < 0.0001$), (2) filter placement indication of recent surgery or planned surgery (< 30 days) (HR 0.409, 95% CI 0.285 - 0.585, $P < 0.0001$), (3) extent of disease assessed by TNM staging criteria (TNM stage 1 or TNM stage 2 versus TNM stage 4, HR 0.177, 95% CI 0.072 - 0.433, $P = 0.0001$; TNM stage 3 versus TNM stage 4, HR 0.367, 95% CI 0.216 - 0.625, $P = 0.0002$). A model to predict survival following filter placement in patients with Venous ThromboEmbolic and Cancer at 6 months (VTEC_{6mo}) was then built using stepwise selection using the factors significant at the 0.05 level. VTEC_{6mo} scores for

individual patients were calculated by applying knowledge of their prognostic values into the following equation:

$$\text{VTEC} = 8 - 0.7009 * X_1 - 0.8949 * X_2 - 1.7316 * X_3 - 1.0023 * X_4$$

The four variables in the model (X_{1-4}) are coded as follows:

$$\begin{aligned} X_1 &= \{\text{albumin level (continuous variable, g/dL)} \\ X_2 &= \begin{cases} 1, & \text{if surgery within 30 days prior to IVC filter placement or planned after filter implant} \\ 0, & \text{if no surgery within 30 days prior to IVC filter placement or planned after filter implant} \end{cases} \\ X_3 &= \begin{cases} 1, & \text{if TNM stage 1 or stage 2} \\ 0, & \text{otherwise} \end{cases} \\ X_4 &= \begin{cases} 1, & \text{if TNM stage 3} \\ 0, & \text{otherwise} \end{cases} \end{aligned}$$

Note: If both X_3 and X_4 are zero, the patient is TNM stage 4, which was used as the reference level during analysis.

A logistic regression model was fitted to the study cohort ($n=397$ patients) such that the developed $\text{VTEC}_{6\text{mo}}$ score function was used as the predictor/independent variable (significant factors from multivariate analysis) and 6 month status was used as the response/dependent variable (i.e., deceased or alive). Death was the event of interest (i.e., the model was developed to predict death). Table 3 provides 6 month survival estimates and associated 95% confidence intervals for selected values of the $\text{VTEC}_{6\text{mo}}$ score function.

To assess the fit of this logistic regression model, the area under the receiver operating characteristic curve (AUC). The receiver operating characteristic (ROC) curve was used to describe the discrimination abilities and to explore the trade-offs between sensitivity and specificity of the model (Figure 2). The area under the ROC curve is frequently viewed as a robust indicator of performance for classification models. The logistic regression model yielded an AUC of 0.815. The Hosmer-Lemeshow test is a statistical test for goodness of fit for logistic regression models that assesses whether or not the observed event rates match expected event rates in subgroups of the model population. This analysis yielded $P = 0.6644$.

Sensitivity and specificity are optimized (the point closest to perfect differentiation) when the threshold for the $\text{VTEC}_{6\text{mo}}$ score function is 3.78; the values of the score function greater than 3.78 indicate death within 6 months following filter placement in patients with solid malignancy. This threshold yields a sensitivity of 0.782 (true positive $n=165$ patients, false negative $n=46$ patients), specificity 0.715 (true negative $n=133$ patients, false positive $n=53$ patients), positive predictive value of 0.757 (true positive $n=165$ patients, false positive $n=53$ patients), negative predictive value of 0.743 (true negative $n=133$ patients, false negative $n=46$ patients), accuracy of 0.751 (true positive $n=133$ patients, true negative $n=165$ patients, total number of patients 397 patients).

Discussion

Six month survival can be predicted for patients with VTE and solid malignancy requiring filter placement. Knowledge of the patient's serum albumin, recent surgery or planned surgery (<30 days), and extent of disease can be used to estimate patient survival at 6 months by utilizing a VTEC_{6mo} score function.

The VTEC_{6mo} score function is valuable for 3 reasons. First, because the VTEC_{6mo} score helps to quantify patient survival, the benefit of filter retrieval can be better defined for a particular cancer patient helping physicians to tailor the clinical decision of filter retrieval. In the same way that liver surgeons would consider a patient's Child-Pugh class prior to performing surgery, limited life-expectancy should be taken into consideration when discussing IVC filter retrieval. There are risks with every procedure. The VTEC_{6mo} score may help physicians to counsel patients about the risks of filter retrieval (e.g. device fracture, caval injury, and procedural over-sedation) against the benefits (e.g. mitigating device migration, recurrent VTE, and post-thrombotic syndrome) within the context of expected patient survival. Second, results from a randomized study among patients with proximal DVT indicated that permanent filters in addition to anticoagulation were more effective at preventing PE than anticoagulation alone [1, 2]; while a subsequent randomized study failed to show this same benefit with retrievable filters [3]. Based on these study findings, patients with poor OS may benefit more from a permanent filter, which is potentially more efficacious at preventing PE. Third, two recent studies found significantly higher complication rates with retrievable filters when compared with permanent filters [20, 21]. It should be noted, however, that these studies were limited by retrospective design, length of follow-up, and heterogeneity of filter types. Certain oncology patients may be best served by permanent devices for more efficacious prevention of recurrent PE, avoidance of additional procedures, improved resource utilization, and mitigation of complications from the device and retrieval procedure.

Many components of our study are consistent with prior work. Our findings suggest a strong association of VTE with gastrointestinal, lung, gynecologic, and genitourinary cancers [22-24]. The most common indication for IVC filter placement in our population was VTE with a contraindication to anticoagulation. This coincides with the known paradox that cancer patients are at increased risk for both DVT and bleeding complications [25].

Factors associated with improved 6 month survival include early stage of disease (i.e. TNM cancer staging), normal albumin, and recent/upcoming surgery. The utility of TNM staging for predicting survival in patients with solid malignancies is well-known [19]. It is interesting to note that cancer treatment history (i.e. no therapy, 1st line therapy, beyond 1st line therapy) was not a statistically significant predictor of 6 month survival. In our patient cohort, cancer treatment history paralleled cancer staging. Patients who were TNM stage 1 and stage 2 were more likely to have received no therapy or 1st line therapy compared with patients who were TNM stage 4. Based on our Cox proportion hazards model, disease stage was a better predictor of 6 month survival than treatment history, and, thus, disease stage was included in the VTEC_{6mo} score. Albumin is a general marker for overall nutritional health and has been cited in other models as a predictor of survival [26, 27]. Surgery

represents a known risk factor to patient survival. Thus, surgeons are appropriately discriminatory when selecting patients to take to surgery. The VTEC_{6mo} score combines these risk factors into a quantifiable score capable of predicting 6 month survival in patients with solid malignancy.

Our study population was heterogeneous. The Hosmer-Lemeshow test of our model yielded a p-value of 0.6644, which is adequate and underscores the difficulty in predicting survival in such a heterogeneous population of cancer patients. Nonetheless, the VTEC_{6mo} score is meant to help quantify an imprecise variable, OS. OS is only one of many variables implanting physicians should evaluate prior to placing a retrievable or permanent filter and when assessing the appropriateness of filter retrieval.

The strengths of our model are the large sample size and large number of events (i.e. death within 6 months, n=211 events). The next step would be to validate our model in a prospective fashion. A weakness in our model is that it does not include an assessment of patient performance status (e.g. Eastern Cooperative Oncology Group Performance Scale), which is known to correlate with survival for various malignancies [28]. This is because performance status was rarely available during retrospective review of our electronic medical record for our patient cohort at the time of filter implantation. It may very well be an excellent discriminator of short-term survival and incorporation of this risk factor in future iterations of this model may improve its accuracy. Finally, indications for filter placement can be subjective (e.g. recent surgery may not preclude anticoagulation for all patients at different institutions). This inherent subjectivity may limit generalizability of the VTEC_{6mo} score, which could be further evaluated during the validation phase.

In conclusion, this study demonstrates that 3 patient variables (serum albumin, recent or planned surgery, and disease stage) can be used to predict 6 month survival in patients with solid malignancy following filter placement. While retrievable filters can be associated with significant morbidity, the decision to retrieve a filter is based on multiple factors, including patient survival. Our risk model could be used by implanting physicians to decide whether a permanent or retrievable filter may be more appropriate as well as to assess the risks and benefits for filter retrieval in patients with cancer.

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Figure 1. Overall survival for 6 months following filter placement in patients with venous thromboembolism and solid malignancy (n=397 patients).

Figure 2. Receiver operating characteristic curve of the Venous ThromboEmbolic and Cancer (VTEC_{6mo}) prediction model to estimate 6 month survival following filter placement for patients with solid malignancy.

Table 1

Classification of patients included in study stratified by cancer type.

Tumor type	Number of patients (n=397 patients, percentage in parentheses)
Lung cancer (NSCLC)	59 (14.9%)
Colorectal carcinoma	38 (9.6%)
Esophageal adenocarcinoma	31 (7.8%)
Ovarian cancer	30 (7.6%)
Pancreatic adenocarcinoma	27 (6.8%)
Melanoma	26 (6.5%)
Breast cancer	26 (6.5%)
Sarcoma	22 (5.5%)
Cervical cancer	20 (5.0%)
Bladder cancer	16 (4.0%) TCC n=15 SCC n=1
RCC	14 (3.5%)
Prostate cancer	14 (3.5%)
Gastric cancer	14 (3.5%)
Endometrial cancer	12 (3.0%)
Head and neck SCC	11 (2.8%) Tongue n=6 Supraglottis n=1 Glottis n=2 Tonsil n=1 Paranasal sinus n=1
Thyroid cancer	7 (1.8%)
Uterine cancer	4 (1.0%)
Vaginal, vulvar, penile SCC	4 (1.0%)
Neuroendocrine cancer	4 (1.0%)
Thymic cancer	3 (0.8%)
Cutaneous SCC	3 (0.8%)

Tumor type	Number of patients (n=397 patients, percentage in parentheses)
Cholangiocarcinoma	2 (0.5%)
Small bowel carcinoma	2 (0.5%)
HCC	2 (0.5%)
Small cell lung cancer	1 (0.3%)
GIST	1 (0.3%)
Mesothelioma	1 (0.3%)
Germ cell tumor	1 (0.3%)
Appendiceal carcinoma	1 (0.3%)
ACC	1 (0.3%)

NSCLC: non-small cell lung carcinoma

RCC: renal cell carcinoma

SCC: squamous cell carcinoma

TCC: transitional cell carcinoma

ACC: adrenocortical carcinoma

HCC: hepatocellular carcinoma

GIST: gastrointestinal stromal tumor

Sarcoma: includes liposarcoma, malignant fibrous histiocytoma, spindle cell sarcoma, Ewing's sarcoma, chondrosarcoma, leiomyosarcoma, small round cell sarcoma, angiosarcoma

Table 2

Characteristics of patients in the study cohort.

Study Variable	Value (n=397 patients)
Age (median, range)	61.5 (range 22.3 - 93.1)
Sex, male (%)	197 (49.6%)
BMI (kg/m ² , range)	26.9 (range 13.2 - 77.3)
Permanent IVC filter (%)	224 (56.4%)
Suprarenal location (%)	12 (3.0%)
Indication (%)	
1. Contraindication to anticoagulation:	
a. Anticoagulation complication (i.e. recent GIB/intracranial bleed, significant hematoma, hemoptysis, hematuria)	104 (26.2%)
b. CNS infarct, neoplasm, trauma, surgery	46 (11.6%)
c. Severe thrombocytopenia (<50,000/mm ³)	19 (4.8%)
d. Recent (<1 month) or planned surgery	142 (35.8%)
2. Failure of anticoagulation (i.e. recurrent/worsening PE despite adequate therapy and inability to achieve/maintain adequate anticoagulation)	45 (11.3%)
3. Heparin-associated thrombocytopenia-thrombosis syndrome	40 (10.1%)
4. Poor candidate for anticoagulation (i.e. history of falls/ataxia, poor compliance, neoplasm with potential bleeding risk, free floating thrombus in IVC)	1 (0.3%)
5. No VTE, though high risk patient	
PE (%)	131 (33.0%)
DVT (%)	149 (37.5%)
Both PE and DVT (%)	83 (20.9%)
None (%)	34 (8.6%)
Cancer treatment:	
No therapy (%)	48 (12.1%)
1 st line therapy (%)	117 (29.5%)
Beyond 1 st line therapy (%)	232 (58.4%)
Patients located in ICU at time of IVC filter placement (%)	60 (15.1%)
Lowest albumin level within 30 days prior to IVC filter placement (g/dL), median (range)	3.1 (range 1.2 - 4.9)
Lowest platelet level within 30 days prior to IVC filter placement (K/ μ L), median (range)	152 (4 - 946)
Stage of disease (TNM staging system)	
Stage 1 (%)	17 (4.3%)
Stage 2 (%)	23 (5.8%)
Stage 3 (%)	60 (15.1%)
Stage 4 (%)	297 (74.8%)

Study Variable	Value (n=397 patients)
Survival (months), median (range)	5.2 (range 0.07 - 60.8)

BMI: body mass index (kg/m^2)

IVC: inferior vena cava

GIB: gastrointestinal bleed

CNS: central nervous system

VTE: venous thromboembolism

PE: pulmonary embolism

DVT: deep venous thrombosis

ICU: intensive care unit

TNM: tumor node metastasis staging system [17]

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Table 3

Six month survival estimates and associated 95% confidence intervals for selected values of the Venous ThromboEmbolic and Cancer (VTEC_{6mo}) prediction model.

Score	Survival (%)		
	Estimate	Lower confidence level	Upper confidence level
6.0	0.1	0.0	1.0
5.5	1.8	0.5	4.8
5.0	8.8	5.1	13.8
4.5	22.9	18.0	28.2
4.0	40.9	35.5	46.2
3.5	58.2	51.9	63.8
3.0	72.0	65.4	77.5
2.5	81.9	75.7	86.7
2.0	88.6	83.2	92.4
1.5	92.9	88.6	95.7
1.0	95.6	92.3	97.6
0.5	97.3	94.8	98.6