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Stratifying the Risk of Venous Thromboembolism in Otolaryngology

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Abstract

Objective—The consequences of perioperative venous thromboembolism (VTE) are devastating; identifying patients at risk is an essential step in reducing morbidity and mortality. The utility of perioperative VTE risk assessment in otolaryngology is unknown. This study was designed to risk-stratify a diverse population of otolaryngology patients for VTE events.

Study Design—Retrospective cohort study.

Setting—Single-institution academic tertiary care medical center.

Subjects and Methods—Adult patients presenting for otolaryngologic surgery requiring hospital admission from 2003 to 2010 who did not receive VTE chemoprophylaxis were included. The Caprini risk assessment was retrospectively scored via a validated method of electronic chart

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Author Contributions

Andrew G. Shuman, initial conception and design of the study, patient care, chart review, analysis and interpretation of data, drafting the article and revising it, and final approval of the version to be published; **Hsou Mei Hu**, contribution to study design; acquisition of data, statistical analysis and interpretation of data, revising the article critically for important intellectual content, and final approval of the version to be published; **Christopher J. Pannucci**, initial conception and design, acquisition of data, analysis and interpretation of data, critically revising the article, and final approval of the version to be published; **Christopher R. Jackson**, substantial contributions to initial conception and design, chart review, analysis and interpretation of data, drafting the article, and final approval of the version to be published; **Carol R. Bradford**, initial conception and design, patient care, acquisition of data, analysis and interpretation of data, revising the article critically for important intellectual content, and final approval of the version to be published; **Vinita Bahl**, initial conception and design, statistical analysis and interpretation of data, drafting the article and revising it, and final approval of the version to be published.

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abstraction. Primary study variables were Caprini risk scores and the incidence of perioperative venous thromboembolic outcomes.

Results—A total of 2016 patients were identified. The overall 30-day rate of VTE was 1.3%. The incidence of VTE in patients with a Caprini risk score of 6 or less was 0.5%. For patients with scores of 7 or 8, the incidence was 2.4%. Patients with a Caprini risk score greater than 8 had an 18.3% incidence of VTE and were significantly more likely to develop a VTE when compared to patients with a Caprini risk score less than 8 ($P < .001$). The mean risk score for patients with VTE (7.4) was significantly higher than the risk score for patients without VTE (4.8) ($P < .001$).

Conclusion—The Caprini risk assessment model effectively risk-stratifies otolaryngology patients for 30-day VTE events and allows otolaryngologists to identify patient subgroups who have a higher risk of VTE in the absence of chemoprophylaxis.

Keywords

venous thromboembolism; prophylaxis; deep venous thrombosis; pulmonary embolism; risk stratification; patient safety; risk factor; Caprini

Venous thromboembolism (VTE), which includes both deep venous thromboses (DVT) and pulmonary emboli (PE), is an important cause of morbidity and mortality in hospitalized patients. Approximately 250,000 VTE events are diagnosed annually in the United States.¹ Venous thromboembolism is the most common cause of preventable death in US hospitals and the third most common cause of all hospital-related deaths.^{2,3} Patients who survive a VTE event are at risk for developing pulmonary hypertension, recurrent PE, and postthrombotic syndrome.^{4,5} The impressive morbidity and mortality associated with VTE events have prompted groups such as the National Quality Forum, the Center for Medicare & Medicaid Services, the Joint Commission on Accreditation of Health Care Organizations, and the Office of the Surgeon General of the United States to develop initiatives to address this major threat to patient safety.^{6,7}

Venous thromboembolism risk increases with hospitalization for surgery or an acute medical illness, with hospitalized patients having an estimated 150-fold higher VTE risk than community residents.⁸ This increased risk reflects the higher prevalence of VTE risk factors in hospitalized populations.² Moreover, surgical patients admitted to the hospital have nearly a 70-fold increase in VTE risk compared with the general population and a 10-fold increased risk compared with surgical outpatients.⁹ As a result, surgical specialties have studied the incidence of VTE extensively. Earlier studies of hospitalized surgical patients who did not receive thromboprophylaxis provide an estimate of VTE risk.² In general surgery and gynecologic surgery, the incidences of DVT and fatal PE are 15% to 40% and 0.2% to 0.9%, respectively.¹⁰⁻¹² Orthopedic procedures carry a DVT risk of 40% to 60%, with a fatal PE rate of up to 5%.²

The Caprini Risk Assessment Model (RAM) was developed to provide an individualized VTE risk assessment based on patient-specific risk factors.¹³⁻¹⁵ The Caprini RAM assigns a weighted risk score to each of approximately 40 VTE risk factors (eg, prior VTE, oncologic status, age). The risk factors are weighted and summed, and the cumulative score is used to risk-stratify patients into 1 of 4 risk levels. Subsequently, clinicians can approximate the

patient's VTE risk and make informed decisions about thromboprophylaxis. A retrospective risk-scoring method based on the Caprini RAM was validated for 30-day VTE events in a series of 8216 general, urology, and vascular surgery patients and provided evidence in support of individual risk assessment.¹⁶ The Caprini RAM was validated for 60-day VTE events in 1126 plastic and reconstructive surgery patients.¹⁷ Versions of the Caprini RAM have also been tested among medical inpatients and postbariatric body contouring patients.¹⁸⁻²⁰ At our institution, the Caprini RAM has been used to risk-stratify patients and guide perioperative thromboprophylaxis decisions for surgical patients (**Figure 1**).

To date, there are no conclusive or high-quality data exploring the accuracy of perioperative VTE risk assessment in otolaryngology–head and neck surgery. This study was designed to examine if the Caprini RAM could risk-stratify a diverse population of otolaryngology patients for 30-day VTE events.

Methods

Study Design and Participants

The University of Michigan Medical School Institutional Review Board reviewed and approved the study protocol. This study was performed as a retrospective cohort study of all adult patients (≥ 18 years old) who presented to the Department of Otolaryngology–Head and Neck Surgery at the University of Michigan for surgery requiring hospital admission from September 2003 through June 2010. The cohort included patients admitted to either otolaryngology or neurosurgery services, whose primary surgeon was from the otolaryngology service. Patients admitted to other inpatient services or undergoing outpatient surgeries were excluded. All patients with orders for thromboprophylaxis with subcutaneous heparin or low molecular weight heparin were also excluded from the analysis.

Caprini Risk Assessment

A retrospective VTE risk-scoring method has been developed, tested for reliability, and validated in a large population of surgical patients at our institution.¹⁶ We used a similar method in this study and briefly describe its implementation herein. Data for each VTE risk factor included in the Caprini RAM (**Figure 1**) were abstracted from electronic medical databases. These databases included hospital billing records, which included International Classification of Diseases, Ninth Revision, Clinical Modification (*ICD-9-CM*) diagnosis and procedure codes, operating room data, and an institutionally maintained clinical data repository. Risk factors were weighted per the Caprini RAM and summed to determine the total Caprini risk factor score and risk level (low, moderate, high, and highest).

VTE Determination

Diagnostic test results were reviewed to identify DVT or PE events within 30 days of surgery. Deep venous thrombosis required confirmation by venous duplex ultrasound, and a PE event required confirmation by ventilation-perfusion scan or PE-protocol computed tomography (CT) scan. Patients who experienced sudden death were included if a VTE event was confirmed either pre- or postmortem. The Department of Otolaryngology–Head

and Neck Surgery retains prospectively maintained morbidity and mortality data that were cross-referenced to ensure the capture of all documented VTE events.

Statistical Analysis

Venous thromboembolism risk factors were identified and Caprini RAM scores were calculated for each patient in the study population. A descriptive analysis of the percentage of patients with each VTE risk factor was conducted. The difference in the percentage of patients with each risk factor was compared between patients who did and did not develop VTE using χ^2 or Fisher exact tests. A comparison of the Caprini RAM score between the 2 groups was reported, and because the Shapiro-Wilk test indicated that the distribution of Caprini RAM scores departed slightly from normality ($P = .01$), the difference in scores was evaluated using the Wilcoxon rank-sum test.

A distribution of the incidence rate of VTE by total risk factor score and the significance of differences were reported. The significance of differences was tested using a χ^2 test or Fisher exact test.

Results

A total of 2016 patients were included in the study population. Only 1.4% of the population were classified as low risk (total risk factor score of 0 or 1), 10% were moderate risk (total score of 2), 31% were high risk (total score of 3 or 4), and the remaining 57% were highest risk (total score of 5 or more) (**Table 1**).

The overall 30-day rate of VTE was 1.3%. The incidence of VTE in patients with a Caprini risk score of 6 or less was 0.5%. For patients with scores of 7 or 8, the incidence was 2.4%. Patients with a Caprini risk score greater than 8 had an 18.3% incidence of VTE (**Figure 2**).

The mean total risk factor score for patients with VTE ($n = 27$) was 7.4 (median 8). The mean total risk factor score for patients without VTE ($n = 1989$) was 4.8 (median 5). This difference was significantly different ($P < .001$). A comparison of VTE risk factors between these 2 groups showed that a significantly higher proportion of patients who developed a VTE had risk factors such as cancer, chronic obstructive pulmonary disease, recent stroke, central venous catheter, and infections, including sepsis and pneumonia (**Table 2**).

Patients with a Caprini risk score greater than 8 were significantly more likely to develop a VTE when compared with patients with scores of 7 to 8 (2.4% vs 18.3%, $P < .001$), 5 to 6 (0.9% vs 18.3%, $P < .001$), and 3 to 4 (0.2% vs 18.3%, $P < .001$). In addition, patients with Caprini scores of 7 to 8 were significantly more likely to have 30-day VTE events when compared with patients with scores of 3 to 4 (0.2% VS 2.4%, $p = .018$).

Of the 27 patients who developed VTE, 11 patients had a confirmed upper and/or lower extremity DVT without PE, and 16 patients had a confirmed PE. There were 0 perioperative mortalities in this group. Seventeen of the 27 incidents of VTE occurred in patients undergoing microvascular free tissue transfer.

Discussion

Perioperative VTE in Otolaryngology

Few studies have examined the incidence of VTE events in the field of otolaryngology–head and neck surgery. Lee and colleagues²¹ reviewed 9835 otolaryngology operations performed between 1989 and 2004 at a Canadian tertiary care hospital for a postoperative DVT or PE. The authors identified 10 patients (0.10%) with a DVT and 5 patients (0.05%) with a PE. Moreano and colleagues²² reviewed 12,805 otolaryngology operations performed on adults between 1987 and 1994 at the University of Iowa. They identified 34 patients (0.3%) with a DVT, 24 (0.2%) of whom also had a PE. Both the Lee and Moreano studies reported the highest DVT and PE incidence among patients undergoing a head and neck procedure. An increased risk of VTE among patients requiring oncologic head and neck reconstruction was also documented by Chen et al,²³ despite VTE rates less than 1% in this population. Similarly, in oral surgery patients, VTE events were quite rare but were associated with increasing body mass index (BMI) and longer hospital stays.²⁴ In general, these large retrospective analyses, although useful, invariably underestimate VTE incidence due to the dearth of risk stratification, which identifies clinically relevant subgroups with disproportionate levels of risk, thereby increasing the power to detect differences between them.²⁵

The Caprini RAM was recently tested in a large cohort of plastic surgery patients.¹⁷ In this study, the incidence of VTE was markedly similar to the findings in our study, with a significantly higher risk among patients with Caprini scores greater than 8. Data are also consistent with the findings from our institution among the general surgery population.¹⁶ As the studies by Bahl et al¹⁶ and Pannucci et al¹⁷ demonstrated, and we corroborate, a diverse group of surgical patients with Caprini scores greater than 8 are at an approximately 20-fold increased risk of VTE, and those with scores of 7 to 8 are at an approximately 5- to 10-fold risk when compared with low-risk patients across surgical specialties.

Evaluation of individual risk factors in our patient population revealed that cancer, chronic obstructive pulmonary disease, recent stroke, central venous catheter, and infections are all associated with a significantly higher rate of VTE, which is consistent with data in other populations. It is somewhat surprising that the population with VTE did not have a higher percentage of patients with a prior history of VTE, but this may be due to either incomplete documentation or a type II error.

Next Steps

The effectiveness of thromboprophylaxis in lowering the rates of DVT, PE, and fatal PE has been well established through many randomized clinical trials.² A survey indicates that individual practice patterns among otolaryngologists with regard to thromboprophylaxis vary significantly, with the majority of providers not routinely administering prophylaxis.²⁶ Critical to optimizing the risk/benefit ratio of thromboprophylaxis is obtaining an accurate assessment of a patient's VTE risk. Although several approaches to assess VTE risk and guide thromboprophylaxis have been advocated, recent studies support the use of

individualized patient risk assessment to more accurately identify a given patient's VTE risk.²⁷

Our data provide otolaryngologists with a useful tool to risk-stratify their patients for perioperative VTE events. The Caprini RAM allows otolaryngologists to identify patient subgroups who have a low risk (1 in 200; Caprini score less than 7), medium risk (1 in 42; Caprini score 7-8), and high risk (1 in 5.5; Caprini score greater than 8) of 30-day VTE if no chemoprophylaxis is provided. The next crucial question involves how best to apply this information to decrease the incidence of VTE in this population. Clearly, high-risk patients with Caprini scores greater than 8 merit aggressive thromboprophylaxis; the risk/benefit ratio of such treatments in low-risk and medium-risk otolaryngology patients remains unknown. A disproportionate number of VTE events occurred in patients undergoing microvascular free flaps. We plan further studies designed to describe the impact of thromboprophylaxis upon the incidence of perioperative VTE stratified by risk score, as well as specifically within the free flap population.

Strengths and Weaknesses

We used a large group of patients and employed a validated method of VTE risk stratification, adding weight to the data. The remarkable association between increasing risk score and VTE incidence underscores the biologic plausibility and veracity of our outcomes. The data should be quite generalizable to otolaryngologists in practice, as they span a 7-year period of all patients requiring admission for surgery in a large academic department and serve to risk-stratify patients regardless of specific demographic or clinical factors.

The retrospective nature of the study engenders the element of bias and is a weakness. Caprini risk scores may be underestimated because of incomplete documentation of risk factors, which were not always documented in a manner amenable to retrospective chart abstraction; prior studies suggest that this scoring system underestimates risk in approximately 5% of patients.¹⁶ The incidence of VTE may also be underestimated because of patients who were lost to follow-up, including those who may have presented to other institutions with perioperative VTE or those who may have developed a VTE more than 30 days after surgery. Previous work has shown that the risk for perioperative VTE may remain elevated for at least 90 days.⁹ In addition, patients with asymptomatic VTE events would not be identified, and patients who died without confirmation of a VTE were excluded, yielding an underrepresentation of the true 30-day rate of VTE.

We did not account for the role of sequential compression devices (SCDs) in this cohort, despite the fact that the overwhelming majority of patients had SCDs ordered, because we did not measure compliance with their usage or length of time that they remained on. Although SCDs may have a role in decreasing VTE incidence, studies have demonstrated that noncompliance is nearly ubiquitous and could severely confound the data unless it is rigorously measured.²⁸ Moreover, the role of VTE chemoprophylaxis in otolaryngology has yet to be studied systematically, and this question is not addressed in this study.

Conclusion

The Caprini RAM is an effective and facile tool to predict 30-day VTE events in otolaryngology patients. The Caprini RAM allows otolaryngologists to identify patient subgroups who have a low risk (1 in 200; Caprini score <7), medium risk (1 in 42; Caprini score 7-8), and high risk (1 in 5.5; Caprini score >8) of 30-day VTE in the absence of chemoprophylaxis. Additional research is necessary to establish effectiveness and set specialty-specific guidelines for perioperative thromboprophylaxis among otolaryngology patients.

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<p>Each Risk Factor Represents 1 Point</p> <ul style="list-style-type: none"> <input type="checkbox"/> Age 41-60 years <input type="checkbox"/> Swollen legs (current) <input type="checkbox"/> Varicose veins <input type="checkbox"/> Obesity (BMI >25) <input type="checkbox"/> Minor surgery planned <input type="checkbox"/> Sepsis (<1 month) <input type="checkbox"/> Serious lung disease including pneumonia (<1 month) <input type="checkbox"/> Oral contraceptives or hormone replacement therapy <input type="checkbox"/> Pregnancy or postpartum (<1 month) <input type="checkbox"/> History of unexplained stillborn infant, recurrent spontaneous abortion (≥ 3), premature birth with toxemia or growth-restricted infant <input type="checkbox"/> Other risk factors _____ <p style="text-align: right;">Subtotal: _____</p>	<p>Each Risk Factor Represents 2 Points</p> <ul style="list-style-type: none"> <input type="checkbox"/> Age 61-74 years <input type="checkbox"/> Arthroscopic surgery <input type="checkbox"/> Malignancy (present or previous) <input type="checkbox"/> Laparoscopic surgery (>45 minutes) <input type="checkbox"/> Patient confined to bed (>72 hours) <input type="checkbox"/> Immobilizing plaster cast (<1 month) <input type="checkbox"/> Central venous access <input type="checkbox"/> Major surgery (>45 minutes) <p style="text-align: right;">Subtotal: _____</p>
<p>Each Risk Factor Represents 5 Points</p> <ul style="list-style-type: none"> <input type="checkbox"/> Stroke (<1 month) <input type="checkbox"/> Elective major lower extremity arthroplasty <input type="checkbox"/> Hip, pelvis or leg fracture (<1 month) <input type="checkbox"/> Acute spinal cord injury (paralysis) (<1 month) <p style="text-align: right;">Subtotal: _____</p>	<p>Each Risk Factor Represents 3 Points</p> <ul style="list-style-type: none"> <input type="checkbox"/> Age 75 years or older <input type="checkbox"/> History of DVT/PE <input type="checkbox"/> Positive Factor V Leiden <input type="checkbox"/> Elevated serum homocysteine <input type="checkbox"/> Heparin-induced thrombocytopenia (HIT) <input type="checkbox"/> Elevated anticardiolipin antibodies <input type="checkbox"/> Other congenital or acquired thrombophilia <p>If yes: Type _____</p> <p>* most frequently missed risk factor</p> <p style="text-align: right;">Subtotal: _____</p>
<p>TOTAL RISK FACTOR SCORE: </p>	

Figure 1.
Caprini venous thromboembolism (VTE) risk assessment.

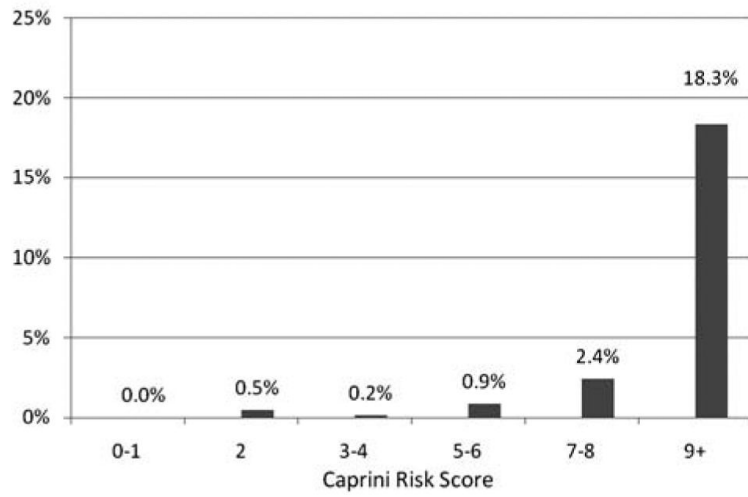


Figure 2. Incidence of 30 day venous thromboembolism (VTE) by estimated Caprini risk score in otolaryngology.

Table 1

Incidence of VTE in Otolaryngology by Caprini Risk Score

Caprini RAM	0-1	2	3-4	5-6	7-8	9+	Total
VTE, No. (%)	0	1 (0.5)	1 (0.2)	7 (0.9)	7 (2.4)	11 (18.3)	27 (1.3)
No VTE, No. (%)	29 (100)	202 (99.5)	623 (99.8)	804 (99.1)	282 (97.6)	49 (81.7)	1989 (98.7)
% VTE (95% CI)	NA	0-2.7	0-0.9	0.4-1.8	1.0-4.9	9.5-30.4	0.1-0.7

Abbreviations: CI, confidence interval; NA, not applicable; RAM, Risk Assessment Model; VTE, venous thromboembolism.

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Table 2

Incidence of VTE Based on Caprini VTE Risk Factors (n = 2016)

	No VTE (n = 1989), No. (%)	+ VTE (n = 27), No. (%)	P Value ^a
Age 41-60 y (1 point)	778 (39)	10 (37)	.826
Age 61-74 y (2 points)	535 (27)	10 (37)	.239
Age >75 y (3 points)	273 (14)	5 (19)	.473
Acute myocardial infarction (1 point)	6 (0.3)	1 (3.7)	.090
Congestive heart failure (1 point)	33 (1.7)	1 (3.7)	.370
Varicose veins (1 point)	0	0	NA
BMI >25 (1 point)	420 (21)	7 (26)	.544
Inflammatory bowel disease (1 point)	11 (0.6)	0	1.000
Sepsis (1 point)	9 (0.5)	2 (7.4)	.009
COPD (1 point)	103 (5.2)	6 (22)	.003
Pneumonia (1 point)	19 (1.0)	2 (7.4)	.031
Oral contraceptives or HRT (1 point)	1 (0.1)	0	1.000
Pregnancy or postpartum (1 point)	1 (0.1)	0	1.000
Prior pregnancy complication (1 point)	0	0	NA
Minor surgery (<45 min) (1 point)	181 (9.1)	3 (11)	.732
Major surgery (>45 min) (2 points)	1807 (91)	24 (89)	.732
Central venous access (2 points)	57 (2.9)	10 (37)	<.001
Cancer (2 points)	1071 (54)	21 (78)	.013
History of VTE (3 points)	36 (1.8)	1 (3.7)	.396
Positive factor V Leiden (3 points)	9 (0.5)	0	1.000
Other coagulopathy (3 points)	1 (0.1)	0	1.000
HIT (3 points)	2 (0.1)	0	1.000
Stroke (5 points)	15 (0.8)	4 (15)	<.001
Acute spinal cord injury (5 points)	0	0	NA

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; HIT, heparin-induced thrombocytopenia; HRT, hormone replacement therapy; NA, not available; VTE, venous thromboembolism. Bold values are statistically significant.

^a A χ^2 test was used to test the differences in proportion of patients with a risk factor between patients with and without VTE. For risk factors with less than 5 patients, the *P* value was based on the Fisher exact test.