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The Majority of Venous Thromboembolism Events Should Occur in Lower Risk Aesthetic Surgery Patients: A Simulation Study

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Introduction: Evidence-based venous thromboembolism (VTE) prevention among aesthetic patients is lacking. This study seeks to (1) quantify 2005 Caprini scores in primary breast augmentation patients, (2) determine the proportion of patients with potentially modifiable VTE risk factors, and (3) project, using Monte Carlo simulation, the expected distribution of Caprini scores among aesthetic surgery patients who develop VTE.

Methods: The observational study (part 1) screened consecutive primary breast augmentation patients for VTE risk using the 2005 Caprini score. Aggregate scores were compiled, and the proportion of patients with potentially modifiable risk factors were identified. Part 2 used Monte Carlo simulation to generate risk score distributions for VTE events predicted to occur among randomly sampled patient cohorts with baseline Caprini risk profiles derived from the part 1 data.

Results: One hundred patients had mean age of 35.7 years and mean body mass index of 23.8 kg/m^2. Median 2005 Caprini score was 3 (range, 2–8), with the majority (96%) having scores of ≤6. Twenty-eight percent of patients had at least one potentially modifiable risk factor or risk factor potentially benefiting from further investigation. Monte Carlo simulations demonstrated that for a population with 96% Caprini ≤6 (and 4% Caprini ≥7), 80% of VTE events would be expected to occur in patients with Caprini scores ≤6.

Conclusions: The majority of breast augmentation patients in this study (96%) have 2005 Caprini scores ≤6. Twenty-eight percent of patients have potentially modifiable risk factors. The majority of patients with VTE after aesthetic surgery are expected to have lower Caprini risk scores. *(Plast Reconstr Surg Glob Open 2022;10:e4573; doi: 10.1097/GOX.0000000000004573; Published online 11 October 2022.)*

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INTRODUCTION

Venous thromboembolism (VTE) is a top-tier patient safety issue in aesthetic surgery capable of producing both short-term mortality and long-term morbidity. Breast augmentation is one of the five most commonly performed aesthetic surgery procedures,[1] and VTE is uncommon after breast augmentation. Existing data support that VTE after breast augmentation occurs in only 0.01%–0.02% of patients, increasing to 0.1% when combined with other procedures, and that VTE risk in the overall aesthetic surgery population is 0.09%.[2,3]

Individualized VTE risk stratification can identify high-risk individuals nested within low-risk populations. This has been shown among plastic surgery inpatients, who have an 18-fold variation in baseline VTE risk.[4] Thus, the

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value of patient-centric VTE risk calculation is clear: it allows surgeons to identify the "needle in the haystack," or the high-risk outlier masked by a plethora of low-risk individuals. These patients, when identified, may benefit from risk modification or additional medical workup. Existing recommendations from the American Society of Plastic Surgeons and the American Association of Plastic Surgeons support the use of the 2005 Caprini score[5] to quantify individual VTE risk.[6] However, due to a paucity of data, controversy still exists regarding optimal VTE prevention strategies for the outpatient and lower risk cosmetic surgery populations.[7]

Survey data from aesthetic surgeons show that more than 90% utilize a patient-centric VTE risk stratification tool. The Caprini score is the most common tool used, reported by 74% of respondents. Despite its widespread use, surgeons expressed broad concern with its "poor application to aesthetic surgery patients," likely due to the lack of formal validation data in this population.[8] Previous work by Keyes et al[9] has shown that 89.5% of abdominoplasty patients with VTE had Caprini scores ≤6. In that study, the majority of VTE events occurred in lower risk patients, leading some to question the utility of Caprini risk stratification in aesthetic surgery. Similar questions have been raised for the inpatient plastic surgery population.[10] The Keyes study provided retrospective Caprini scores for 200 patients with VTE events, but provided no information about the Caprini risk levels of the overall population from which these VTE events were derived. As the baseline population characteristics were unknown, the utility of these results in evaluating individualized VTE risk stratification was limited. Understanding the distribution of baseline Caprini score risk profiles among aesthetic surgery patients would provide much needed clarity to such studies.

At present, the baseline VTE risk level among the breast and body aesthetic population remains unknown. Part 1 of this study seeks to (1) establish a baseline VTE risk profile among patients being evaluated for elective breast augmentation, calculated using the 2005 Caprini score and (2) determine the proportion of such patients who have modifiable risk factors for VTE. Part 2 of this study then uses these observations to better explain existing data demonstrating that the majority of aesthetic surgery patients with VTE have low Caprini risk scores, modeled using straightforward Monte Carlo simulation to generate risk score distributions for predicted VTE events among those aesthetic surgery patients.

METHODS

This project was undertaken following the principles outlined in the Declaration of Helsinki. The first author (C.J.P.) has previously published an algorithmic and data-driven approach to VTE risk reduction[11] and utilizes this paradigm in his day-to-day practice. This paradigm incorporates preoperative VTE risk stratification using the 2005 Caprini score to quantify baseline VTE risk and identify opportunities for VTE risk reduction through risk factor modification.

Takeaways

Question: What VTE risk factors exist among breast augmentation patients? Why do most VTE events occur in lower risk (Caprini ≤6) aesthetics patients?

Findings: Most (96%) breast augmentation patients were at lower risk (Caprini ≤6) for VTE. Many (28%) had modifiable VTE risk factors. Monte Carlo simulation demonstrated that most VTE will occur among lower risk (Caprini ≤6) patients, because rare events in a very common population (96% are Caprini ≤6) are more likely to occur than frequent events in a rare population.

Meaning: Many breast augmentation patients have potentially modifiable VTE risk factors, and most (96%) are at lower risk for VTE (Caprini ≤6).

Part 1 data were derived from one hundred consecutive patients who presented for primary breast augmentation consultations to the first author between February 2020 and March 2022. All patients presenting for discussion of primary breast augmentation were included; no patient was screened and removed. Before consultation, patient care coordinators prescreened patients and declined consultation for active smokers, body mass index (BMI) greater than 35 kg/m^2, or those with unrealistic expectations.

Detailed history, physical examination, and proposed operation were used to calculate a patient-centric 2005 Caprini score. Completed scoring sheets contained a randomly assigned patient number, but no protected health information, and included yes/no answers to all Caprini-centric risk factors. Face-to-face risk stratification was completed, as previous studies have shown that electronic record review[12] and patient-reported scores[13] may incorrectly risk stratify patients. Deidentified data, including individual risk factors and aggregate 2005 Caprini scores, were compiled in an Excel spreadsheet for analysis using univariate statistics.

The goal of part 1 was to examine baseline VTE risk, calculated using the 2005 Caprini score, among patients presenting for breast augmentation while concurrently identifying the proportion of patients eligible for risk modification. As the expected VTE rate was rare (~0.02%),[2,3] and as not all consultations result in surgery, VTE rate was not tracked as an outcome of interest. No patient was declined for surgery based on baseline VTE risk.

For part 2, we utilized the 100 patient samples generated in part 1 as source data. A Monte Carlo approach was applied to generate 1 million simulations in which cohorts of 100,000 patient-procedure encounters were constructed through random selection (with replacement) from a set of 100 patients.[14] The Caprini risk scores for these 100 patients were predetermined in accordance with the specified risk profiles of the part 1 population (eg, using a 4% occurrence of Caprini ≥7 patients and 96% occurrence of Caprini ≤6 patients, the associated patient set would consist of 96 patients with "low"-risk profiles and four patients with "high"-risk profiles). Relative, rather than absolute, event risks were used. Each "low"-risk patient was assigned a

relative risk of 1, and each "high"-risk patient was assigned a relative risk of 5.96. Relative risk was determined from Venous Thromboembolism Prevention Study (VTEPS) data for plastic surgery inpatients who received no anticoagulation, embedded in a larger meta-analysis, which showed that Caprini ≥7 patients had a 5.96-fold increased risk for 60-day symptomatic VTE when compared with Caprini ≤6 patients (10 events/1519 Caprini ≤6 versus 14 events/356 Caprini ≥7).[15,16] For each simulation, the relative event incidence was calculated as the integral sum of relative risk values for each sampled patient, and the fraction of total events ascribed to "Caprini ≤6" and "Caprini ≥7" risk patients was determined. The initial Monte Carlo simulation, using population characteristics of 4% Caprini ≥7 patients and 96% Caprini ≤6 patients, did not perfectly explain the findings of Keyes et al, who reported that 89.5% (179 out of 200) of patients with VTE had Caprini ≤6. Subsequent Monte Carlo simulations were performed with variation in the ratios of Caprini ≥7 and Caprini ≤6 patients, to determine population characteristics which could better reproduce the findings of Keyes et al.[9]

RESULTS

Face-to-face 2005 Caprini scores were calculated for 100 consecutive new patient breast augmentation consultations between February 2020 and March 2022. Patients had a mean age of 35.7 years and mean BMI of 23.8 kg/m^2. The majority (94%) of patients were White (Table 1). The median 2005 Caprini score was 3, with a minimum score of 2 and maximum of 8. No patients corresponding to the Caprini >8 group were identified among 100 consecutive consultations. Proportions of individual risk factors are shown in Table 2.

Twenty eight percent (n = 28) of patients had at least one potentially modifiable risk factor or risk factor potentially benefiting from further investigation identified. These included 18% (n = 18) with exogenous hormone use, 5% (n = 5) with family history of VTE, 3% (n = 3) with three or more lost pregnancies, 3% (n = 3) with varicose veins, 1% (n = 1) with personal history VTE, and 1% (n = 1) with known genetic hypercoagulability.

Twenty three percent (n = 23) of patients had exactly one potentially modifiable risk factor or risk factor potentially benefiting from further investigation identified, and 5% of patients had two. In total, 28% of breast augmentation patients were potential candidates for risk factor modification or further investigation based on preoperative Caprini risk stratification.

Current data for surgery inpatients suggest that only those with 2005 Caprini score ≥7 have a favorable risk/benefit with anticoagulation.[15] The authors provide this number for context, but do not suggest that it is directly applicable to aesthetic or ambulatory surgery patients. In this consecutive series of breast augmentation patients, 4% (n = 4) of breast augmentation patients had a 2005 Caprini score ≥7 (Fig. 1).

Monte Carlo simulations were used to generate probabilistic distributions for the expected baseline Caprini score profiles among cosmetic surgery patients experiencing VTE based on different population prevalence estimates. In this approach, the fractions of overall VTEs that correspond to low-risk patients depend upon both the prevalence of low-risk profiles in the candidate surgical population and the relative VTE risk among patients at each Caprini score stratification. Using the distribution

Table 1. Demographics for 100 Primary Breast Augmentation Patients

Demographic	(N = 100)
Female gender (%)	100% (n = 100)
Age, mean (range) in years	35.7 (20–62)
Body mass index, mean (range) in kg/m^2	23.8 (16.5–34.2)
Ethnicity, % of total (n)	
White	94 (94)
African American	1 (1)
Asian	2 (2)
Native American or Alaskan Native	3 (3)
Other/did not report	0
Caprini score, median (range)	3 (2–8)

Table 2. Frequency of Individual Caprini RAM Risk Factors in 100 Breast Augmentation Patients

Risk Factor	(N = 100)
One-point risk factors	
Age, 41–59	24% (n = 24)
Minor surgery planned	0
Major surgery within 30 d	0
Varicose veins	3% (n = 3)
History of IBD	0
Swollen legs (current)	0
BMI >25	35% (n = 35)
Acute myocardial infarction <3 mo	0
Congestive heart failure <1 mo	0
Sepsis <1 mo	0
Serious lung disease (inc. pneumonia) <1 mo	0
Chronic obstructive pulmonary disease	0
Two-point risk factors	
Age 60–74 y	1% (n = 1)
Arthroscopic surgery	0
Malignancy (present or previous)	3% (n = 3)
Major surgery >45 min	100% (n = 100)
Laparoscopic surgery >45 min	0
Central venous access	0
Three-point risk factors	
Age ≥75	0
History of DVT/PE	1% (n = 1)
Family history of DVT/PE	5% (n = 5)
Positive Factor V Leiden	0
Positive prothrombin 20210A	1% (n = 1)
Positive lupus anticoagulant	0
Heparin induced thrombocytopenia	0
Elevated serum homocysteine	0
Elevated anticardiolipin antibodies	0
Other congenital or inherited thrombophilia	0
Polycythemia vera	0
Five-point risk factors	
Elective major lower extremity arthroplasty	0
Hip, pelvis, or leg fracture <1 mo	0
Stroke <1 mo	0
Multiple trauma <1 mo	0
Acute spinal cord injury or paralysis <1 mo	0
Females only	(N = 100)
One-point risk factors	
Oral contraceptives	18% (n = 18)
Pregnancy or postpartum (<1 mo)	0
History of unexplained stillborn infant recurrent spontaneous abortion (≥3), premature birth with toxemia or growth-restricted infant	3% (n = 3)

DVT, deep vein thrombosis; P, pulmonary embolus.

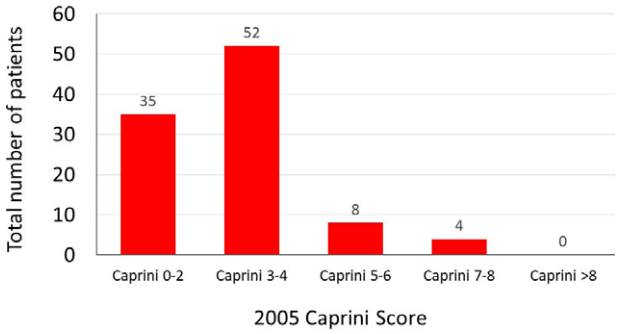

Fig. 1. 2005 Caprini scores among 100 consecutive patients presenting for primary breast augmentation.

of Caprini score profiles found in part 1 of our study, in conjunction with a risk cutoff of Caprini ≤6 versus ≥7, and a 5.96-fold increase in projected VTE incidence among patients with scores ≥7 based on prior work,[15,16] we found that 80.1% of predicted VTE occurrences among the resulting simulated populations were derived from patients in the Caprini ≤6 category (Fig. 2A). This figure was considerably lower than that observed in the Keyes study, in which 89.5% of VTEs occurred in cosmetic patients with low-risk Caprini scores. To backfit the 89.5% number, we reparameterized our model using a 98%/2% Caprini ≤6/Caprini ≥7 profile background prevalence among cosmetic surgery patients, with all other assumptions unchanged, and found the resulting simulations to more closely mirror the findings described by Keyes et al[9] (Fig. 2B).

DISCUSSION

Despite the low risk (0.01%–0.02%) in breast augmentation,[2,3] abdominoplasty (0.2%),[3] and aesthetic surgery as a whole (0.09%),[3] individualized VTE risk stratification is still relevant for the aesthetic population; risk stratification provides the opportunity to identify and potentially intervene upon high-risk individuals nested within the overall low-risk group. In this series of 100 consecutive primary breast augmentation consultations, the overwhelming majority (96%) of patients had Caprini ≤6. Individualized VTE risk stratification identified modifiable risk factors or risk factors potentially benefiting from further workup in 28% of patients.

This article helps surgeons to better understand population-level risk among aesthetic surgery patients, and augments and clarifies existing literature,[9] which only provides Caprini scores for patients with postoperative VTE. Monte Carlo simulation, based on the presented data, clearly demonstrates why the majority of VTE events after aesthetic surgery will occur in patients with lower risk scores. Specifically, a rare event in a common population (one-fold risk in 96% of the population) will occur approximately four times more frequently than a more common event in a rare population (5.96-fold risk in 4% of the population).

Justification of Risk Minimization in Already Rare Events

Surgeons generally believe that the aesthetics population is at low risk for VTE. This is based on clinical experience, as well as claims data demonstrating 0.09% risk for postoperative VTE among 129,032 aesthetic surgery patients in CosmetAssure.[3] Lower extremity duplex ultrasound for all aesthetic surgery patients, with or without symptoms, supports that deep vein thrombosis (DVT) may develop in 0.9% of the postoperative population,[17] although the relevance of detecting these asymptomatic events is unclear. The expected risk for symptomatic VTE among breast augmentation patients is 0.01%–0.02%.[2,3] Some procedures, such as thigh lift (0.25%), lower body lift (0.23%), and abdominoplasty (0.2%), carry higher risk,

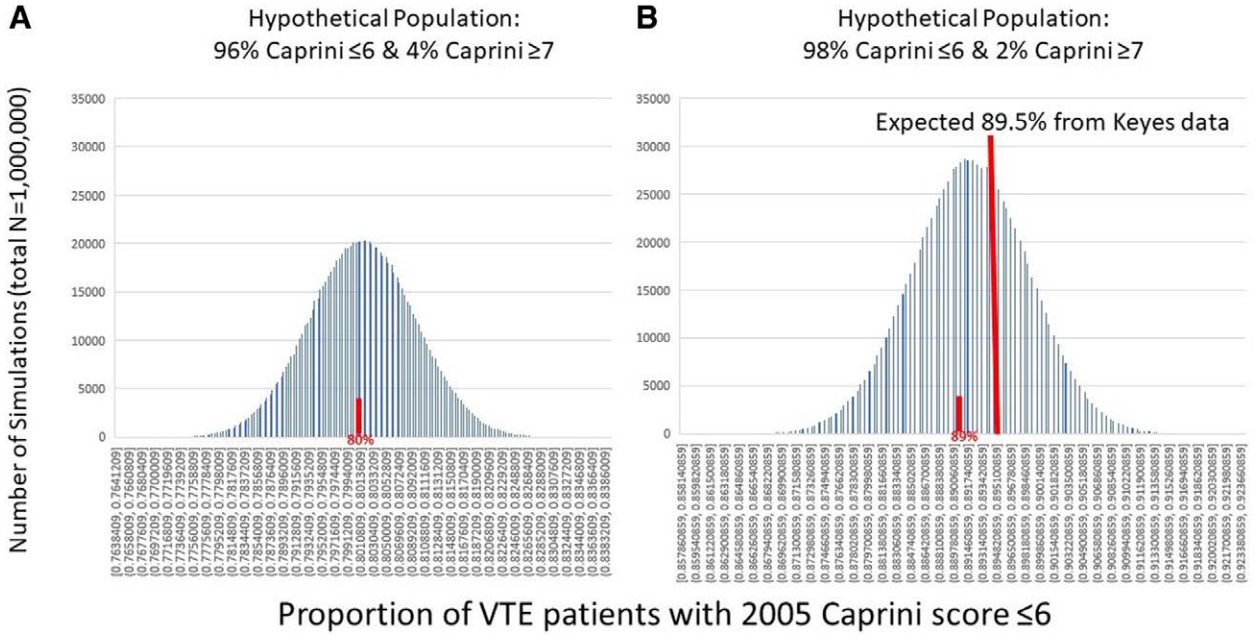

Fig. 2. Monte Carlo results (1 million simulations) showing the expected proportion of patients with VTE who have Caprini ≤6, derived from a hypothetical population of 96% Caprini ≤6/4% Caprini ≥7 (A) and 98% Caprini ≤6/2% Caprini ≥7 (B).

but still in the 1:400–1:500 range.[3] Given the low risk, some clinicians may not perform individualized VTE risk stratification, a practice suggested (but not mandated) for the ambulatory and aesthetic population in the 2011 American Society of Plastic Surgeons VTE Task Force Guidelines.[6]

Why, then, should surgeons bother with risk stratification or modification at all? The argument for risk stratification is that individualized risk stratification is a rapid and low-cost strategy that may help to prevent a very rare catastrophic event.

Motor vehicle safety provides an excellent comparison. National Safety Council 2019 data support an expected annual death rate of 11.9 per 100,000 drivers.[18] The expected death rate for motor vehicle drivers is 0.012%, essentially identical to the 0.01%–0.02% expected rate of VTE after breast augmentation.[2,3] Despite the very low risk of death, drivers are required to wear safety belts. This is because, like individualized VTE risk stratification, safety belts are a rapid and low-cost strategy that may help to prevent a very rare catastrophic event.

This study reports that 28% of primary breast augmentation patients have potentially modifiable risk factors or risk factors that may benefit from additional workup before surgery. However, this study and others suggest that the majority of breast augmentation patients are at low risk for VTE, and thus, risk modification may decrease baseline risk by a fraction of the already low 0.01%–0.02% risk.[2,3] This is relevant because risk modification may have its own disadvantages, for example, undesired pregnancy with oral contraceptive cessation. This study shows that 18% of patients reported hormone-based contraceptive use. In a study of 1254 aesthetic surgery patients, Valente et al[19] used multivariable logistic regression to show that perioperative hormone use and smoking were each independent predictor of postoperative VTE, when controlling for other factors. However, surveys of clinical practice suggest that less than one-third of surgeons discontinue oral contraceptives before aesthetic surgery.[20] Haveles et al,[21] speaking of hormone cessation in the male-to-female surgical population, suggest that "in the absence of definitive VTE risk factors…we conclude that surgeons may engage MTF patients in a joint decision-making process to determine the most optimal [hormone] management plan on a case-by-case basis." The authors agree with this logic, as it pertains to risk modification in an already very low risk breast augmentation or aesthetic surgery population.

Previous work from Keyes et al[9], using the Internet Based Quality Assurance Program (IBQAP) database, reports that the majority (89.5%) of VTE occurs in abdominoplasty patients with Caprini scores ≤6. As a result, the authors questioned the utility of Caprini scores in aesthetic surgery. Of note, the article reports on 200 abdominoplasty patients with VTE and states that Caprini scores were retrospectively calculated after events occurred. Caprini scores were not routinely calculated on non-VTE patients, and thus, the baseline population characteristics were unknown. This article adds to existing literature by providing information on the baseline population characteristics in the aesthetic surgery population. The presented Monte Carlo simulation of VTE in aesthetic surgery patients clearly shows that a rare event in a common population (one-fold risk in 96% of the population) is expected to occur approximately four times more often than a common event in a rare population (5.96-fold risk in 4% of the population). In addition, Monte Carlo simulation was used to demonstrate that the likely population from which Keyes' IBQAP was drawn was 98% Caprini ≤6 and 2% Caprini ≥7. These predicted ratios are in line with the presented data, as well as data from rhinoplasty[22] and body contouring.[23]

Caprini risk stratification has been examined in the aesthetic surgery population. Moubayed et al[22] performed individualized VTE risk stratification on 412 consecutive rhinoplasty patients, showing that an extreme minority (2%) had Caprini ≥7. Similarly, Sarhaddi et al[23] published a series of 492 body contouring patients, where 2% had Caprini ≥7, and Vasilakis et al[24] published a consecutive series of 600 abdominal body-contouring patients with 9% Caprini ≥7. Thus, data from breast augmentation, body contouring, and facial aesthetic surgery support that the extreme minority of aesthetic surgery patients has Caprini scores ≥7; this cut point is relevant because inpatient plastic surgery and inpatient surgery data suggest that only patients with Caprini ≥7 benefit from anticoagulation.[15,16] Inpatient data are not directly relatable to the ambulatory population, and this article does not suggest or prove that Caprini ≥7 aesthetic surgery patients benefit from anticoagulation—but this article does suggest that no more than 4% of breast augmentation patients have any plausible reason to even consider blood thinners for postoperative VTE prevention.

Although several large case series of routine anticoagulation for the overall body contouring population have been published,[23–26] these retrospective studies were performed in nonrisk stratified patients, the majority of whom were at low VTE risk. This study and others suggest that only 2%–9% of the aesthetics population have Caprini ≥7, and may potentially benefit from anticoagulation—but the benefits of anticoagulation for Caprini ≥7 patients have only been shown among the hospitalized, inpatient surgery population. At present, there are no data examining the risks or benefits of anticoagulation among the ambulatory or aesthetic population with 2005 Caprini scores ≥7, and this would be an important direction for further research.

Limitations

This study reports clinical data derived from primary breast augmentation patients in a single surgeon's practice, and has limitations as a result. Study data are not necessarily relevant to nonbreast augmentation populations, which may have different baseline characteristics. However, other published series of rhinoplasty[22] and body-contouring[23] patients have shown comparable proportions. Patients were representative of those typically seen in the Inland Northwest, and this study's demographics (Table 1) are not necessarily representative of other metropolitan areas. As noted above, the authors do not report VTE rate in this series, because the sample size (N = 100) is too small for an expected VTE event rate of 0.01%–0.02%[2,3] and because not all consultations led to surgical procedures.

Presented Monte Carlo simulations made several assumptions, based on the best available data, and have limitations

as a result. The expected 5.96-fold increased VTE risk in the Caprini ≥7 population was derived from inpatient plastic surgery data in the VTEPS study.[15,16] Whether this expected increase is the same in the ambulatory or aesthetic population is unknown, as no study has validated the 2005 Caprini score among these populations; specifically, no large study can provide both a numerator and denominator for patients with and without VTE events at different levels of Caprini risk. In addition, this article compares prospectively calculated 2005 Caprini scores from primary breast augmentation patients without VTE to the retrospectively calculated Caprini scores from Keyes et al's abdominoplasty population with VTE.[9] Whether the Caprini scores of primary breast augmentation patients in Spokane, Washington, are representative of the aesthetic surgery population as a whole is unknown. Caprini risk data from Keyes were retrospectively obtained, and not all VTE events may be reported to the IBQAP database. For these reasons, we first performed the Monte Carlo simulation using our own prospectively obtained data, and then retro-fit a similar model to estimate Keyes' initial population; thus, two independent data sources were used to suggest that between 80% and 89.5% of patients with VTE should have 2005 Caprini scores ≤6.

CONCLUSIONS

Twenty-eight percent of breast augmentation patients have VTE risk factors that are potentially modifiable or potentially benefiting from additional workup, detected by preoperative individualized VTE risk stratification. The overwhelming majority of primary breast augmentation patients (96%) have 2005 Caprini scores of ≤6. Predictive modeling supports that the majority of VTE events in aesthetic surgery patients will occur in Caprini ≤6 patients.

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