

# Caprini Scores, Risk Stratification, and Rivaroxaban in Plastic Surgery: Time to Reconsider Our Strategy

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Summary: Limited data are available regarding the pathophysiology of venous thromboembolism in plastic surgery patients. In an effort to identify patients at greater risk, some investigators promote individual risk assessment using Caprini scores. However, these scores do not correlate with relative risk values. Affected patients cannot be reliably predicted (97% false positive rate). Caprini scores make many body contouring patients candidates for chemoprophylaxis, an intervention that introduces risks related to anticoagulation. Caprini has financial conflicts with several companies that manufacture products such as enoxaparin, commonly used for chemoprophylaxis. Rivaroxaban, taken orally, has been used by some plastic surgeons as an alternative to enoxaparin injections. However, this medication is not United States Food and Drug Administration approved for venous thromboembolism prophylaxis in plastic surgery patients, and a reversal agent is unavailable. This article challenges the prevailing wisdom regarding individual risk stratification and chemoprophylaxis. Alternative methods to reduce risk for all patients include safer anesthesia methods and Doppler ultrasound surveillance. Clinical findings alone are unreliable in diagnosing deep venous thromboses. Only by using a reliable diagnostic tool such as Doppler ultrasound are we able to learn more about the natural history of this problem in our patients. Such knowledge is likely to better inform our treatment recommendations. (Plast Reconstr Surg Glob Open 2016;4:e733; doi: 10.1097/GOX.000000000000660; Published online 13 June 2016.)

he American Society of Plastic Surgeons Web site highlights venous thromboembolism (VTE). A featured article asks, "Are you current with VTE prevention techniques?" and tells the cautionary tale of a plastic surgeon whose patient died of a pulmonary embolism after undergoing a mommy makeover.<sup>1</sup> The surgeon's competitors rallied against him. The surgeon's medical license was suspended, in part (other grounds were cited too) for failing to

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perform a risk assessment and perioperative care "to prevent DVT/PE occurrence."<sup>1</sup> The surgeon lost his hospital privileges and his practice, his wife filed for divorce, and he attempted suicide. The catastrophe of a patient death was compounded by the tragedy of the professional and very nearly physical destruction of the surgeon. Such an outcome underscores the importance of critical evaluation of our present methods to reduce risk. This issue is essential not only to patient safety but to medical malpractice defense. With stakes this high, we need to get it right.

#### INDIVIDUAL RISK ASSESSMENT

Pannucci<sup>2</sup> and other proponents of chemoprophylaxis believe that individual risk assessment using Caprini scores is now part of the standard of care

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for plastic surgery inpatients. The Venous Thromboembolism Prevention Study (VTEPS)<sup>3</sup> evaluated only plastic surgery inpatients. It is risky to extrapolate any conclusions to the outpatient population because of differences in patient characteristics, types of surgery, anesthesia, and level of mobility.<sup>4</sup>

According to its proponents,<sup>3,5</sup> plastic surgeons who do not subscribe to risk stratification are noncompliant, uninformed, and their practices are "inadequate." The points in Caprini's scoring system add up quickly. A healthy 60-year-old woman (2 points) with a body mass index of  $26 \text{ kg/m}^2$  (1 point) undergoing surgery lasting >45 minutes (2 points) is assigned 5 points. The American Society of Plastic Surgeons Venous Thromboembolism Task Force Report<sup>6</sup> recommends that plastic surgeons consider chemoprophylaxis for patients with 2005 Caprini scores between 3 and 6. To its credit, this Task Force<sup>6</sup> does not conclude that individual risk stratification and chemoprophylaxis represent the standard of care. However, using the word "consider" indicates a preference for Caprini scores and anticoagulation, obligating those who disagree with these methods (and therefore do not consider them) to defend their practices.

## UNDISCLOSED FINANCIAL CONFLICTS

In their 2009 publication, Venturi et al<sup>7</sup> discuss risk factors for VTE. The disclosure paragraph states that "the authors have no financial interest in and received no compensation from manufacturers of products mentioned in this article." The article mentions such products as enoxaparin, fondaparinux, heparin, and sequential compression devices.<sup>7</sup> However, a separate article by Caprini dated November 4, 2006, and posted on his "venousdisease.com" Web site,<sup>8</sup> reveals that this coauthor received writing support and funding from Sanofi-Aventis (Bridgewater, N.J.) and is on the speaker's bureau and a consultant for Tyco, Sanofi-Aventis, GSK, and Eisai pharmaceuticals. Covidien (formerly Tyco, Dublin, Ireland) manufactures Kendall sequential compression devices; Sanofi U.S. (Bridgewater) produces Lovenox (enoxaparin) and GlaxoSmithKline (Brentford, London, United Kingdom) manufactures Arixtra (fondaparinux).

Another 2006 article posted on Caprini's Web site was funded by Sanofi and GlaxoSmithKline, and includes a disclosure paragraph stating that Caprini and coauthors served as consultants and paid speakers for "all companies involved in the development of antithrombotic agents." Surprisingly, this paragraph is missing in the published article.<sup>10</sup> Eisai (Tokyo, Japan) manufactures Fragmin (dalteparin). Other nondisclosed sponsors include Pfizer (New York City, N.Y.), maker of Eliquis (apixaban),<sup>11</sup> Leo Pharma (Ballerup, Denmark), maker of heparin,<sup>12</sup> AstraZeneca (London, United Kingdom),<sup>13</sup> manufacturer of a withdrawn warfarin alternative, and Boehringer Ingelheim (Ingelheim, Germany),<sup>14</sup> maker of tissue plasminogen activator. Remarkably, Caprini's 2005 and 2010 publications<sup>15,16</sup> and the majority of the articles available on his Web site include no disclosure of any conflicts of interest. There is no longer any doubt that a financial conflict influences investigators.<sup>17,18</sup>

## THE ORIGIN OF CAPRINI SCORES

The Caprini scoring system<sup>15</sup> was published in Disease-A-Month, a journal for primary care physicians, with an impact factor of 0.945.19 Forty proposed risk factors are assigned values ranging from 1 to 5 points.<sup>15</sup> No relative risk data are provided to support the point assignments. Only 24 references are cited.<sup>15</sup> Caprini's follow-up 2010 publication<sup>16</sup> contains 14 references and, again, no relative risk data. In determining risk scores, Caprini admits that he applies logic, emotion, experience, and intuition.<sup>15,16</sup> The inadequacy of such nonscientific considerations is the very raison d'être for evidence-based medicine.<sup>20</sup> The use of this scoring system in articles published subsequently in high-impact journals such as the Journal of the American College of Surgeons,<sup>21</sup> Journal of Plastic and Reconstructive Surgery,3 and Chest<sup>22</sup> cannot compensate for the lack of a scientifically sound foundation.

## **GUIDELINES OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS**

Caprini scores were not referenced in the 2004 or 2008 ACCP guidelines. The 2012 Guidelines for prevention of VTE in surgical patients were divided into 2 sections: orthopedic and nonorthopedic, with different authors and different recommendations.<sup>22,23</sup> Caprini scores were referenced in the guidelines published by Gould et al,<sup>22</sup> which were intended for the prevention of VTE in nonorthopedic patients. Surgeons familiar with patient risk assessment forms are aware of the lack of compliance in filling them out. Today, guidelines used in hospitals and surgery centers, including those credentialed by the American Association for Accreditation of Ambulatory Surgery Facilities,<sup>24</sup> often call for the inclusion of a risk assessment score in the medical record. However, surgeons are still free to use their judgment in deciding whether to prescribe anticoagulation.

Caprini scores are not referenced in the 2012 Guidelines for prevention of VTE in orthopedic patients.<sup>23</sup> This omission is notable because joint replacement patients have traditionally been considered at high risk for VTE. The 2012 guidelines<sup>23</sup> conclude that for major orthopedic surgery the surgery-specific risk far outweighs the contribution of patient-specific factors. Falck-Ytter et al<sup>23</sup> recognize that although individualized risk factor assessment carries considerable appeal, this method is limited by a lack of validation and is "not sufficiently secure to mandate different risk strata"; and the interaction of risk factors in a given patient is not well understood. The 2012 ACCP guidelines<sup>25</sup> recognize ultrasound surveillance as an accepted form of management for patients who develop distal venous thromboses. There are no general recommendations regarding its use as a screening tool.

#### VALIDITY OF CAPRINI SCORES

Table 1 compares Caprini scores with known levels of relative risk.<sup>26–29</sup> Advancing age is by far the most important risk factor.<sup>26</sup> The mean relative risk for other factors assigned Caprini scores between 3 and 5 is 5.1-fold. For patients with lower scores, between 0 and 2, the mean relative risk is 6.3-fold. Using Pearson correlations, the correlation co-efficient is 0.07, and the *P* value is 0.81, indicating no correlation between individual Caprini scores and relative risk values.

Both the VTEPS and a recent publication using a large national database identify high risk patients whose likelihood of a VTE is approximately 3%,<sup>3,30</sup> as opposed to an overall risk of  $\leq 1\%$ . Almost half of all VTEs occur in patients deemed less risky (Caprini scores < 7) because these patients are more numerous.<sup>31</sup> Wilkins and Pannucci<sup>32</sup> suggest that there is "predictive value" in risk assessments, which is true only if one accepts that 97% of such predictions are wrong.

Caprini's assignment of 5 points for a >3-hour operation is inexplicably high, matching his point assignment for a recent hip, pelvis, or leg fracture; elective major lower extremity arthroplasty; or an acute spinal cord injury.<sup>16</sup> Pannucci et al<sup>33</sup> agree with Caprini's 2010 updates but favor his older 2005 scoring system because the newer scores are less supportive of individual risk assessment.

The Caprini scoring system overrates several risk factors. A positive family history (3 points) or prothrombin G20210A mutation (3 points) are modest risk factors for VTE, raising the risk 2 to 3 times.<sup>27-29</sup> Factor V Leiden (3 points) raises the risk 2–5 times.<sup>27,29</sup> Serum homocysteine is given 3 points despite a barely measurable relative risk.<sup>27</sup> Advanced age is grossly underrated. Three points are assigned for age >75 years despite a 90-fold increased risk between ages 45 and 80 years.<sup>26</sup> Immobilization and bed rest (1 point) are underrated.

Table 1.	Comparison of 2010 Caprini Scores with
Relative	Risk Factors

	Caprini Score*	Relative Risk†
Age $\geq 75 \text{ yr}_{\infty}^{26}$	3	90
Postpartum <sup>28</sup>	1	20
Major trauma <sup>28</sup>	5	13
Hospitalization on a medical service <sup>28</sup>	0	8
Cancer <sup>28</sup>	3	6.5
Surgery <sup>28</sup>	3	6
Pregnancy <sup>28</sup>	1	5.5
Prolonged bed rest <sup>28</sup>	1	5.5
Oral contraception <sup>28</sup>	1	4
Factor V Leiden <sup>27,29</sup>	3	4
Hormone replacement therapy <sup>28</sup>	1	3
Prothrombin 20210G <sup>27,29</sup>	3	2.5
Obesity $(BMI > 30 \text{ kg}/\text{m}^2)^{28}$	1	2.5
Family history <sup>28</sup>	3	2.5
Travel > 4 $h^{28}$	0	2
Elevated homocysteine level <sup>27</sup>	3	1.1

BMI indicates body mass index.

\*Zero values are assigned if Caprini does not include the parameter as a risk factor.

†Mean values are used when ranges are provided.

Hospitalization and long periods of travel are omitted. The Caprini scoring system does not recognize the type of anesthesia as a factor despite strong empirical evidence.<sup>34–38</sup> Pannucci<sup>2</sup> acknowledges the importance of anesthesia as a risk factor, particularly in its effect on the calf muscle pump, but this vital consideration is not considered in this risk assessment model.

## PATHOPHYSIOLOGY OF VTE IN PLASTIC SURGERY

Recent evidence reveals that the incidence (very low), timing (>24 hours after surgery), and location (distal) of thromboses in plastic surgery patients<sup>39,40</sup> are much different (and more favorable) than patients undergoing joint replacement. "Chemoprophylaxis" implies prevention, like a vaccine. However, risk stratification and chemoprophylaxis are not comparable with a vaccine in either efficacy or safety.<sup>4</sup> Anticoagulation does not affect any of the 3 elements of Virchow's triad.<sup>40</sup> Enoxaparin does not prevent venous stasis.

## STATISTICAL ADJUSTMENTS TO FIT THE THEORY

The actual number of affected patients among treated and control patients was not reported in the VTEPS.<sup>3</sup> Pannucci,<sup>41</sup> however, recently conceded that the VTE rate was identical (1.2%) in both groups. Pannucci et al<sup>3</sup> controlled for small differences in lengths of hospital stays (3.1 versus 3.8 days) and median Caprini scores (4 versus 5) between the control and treated patients. Many investigators will

be skeptical of an adjustment that finds a significant treatment difference when the complication rate starts out equal. There are problems in the authors' adjustments. The investigators neglected to consider the duration of anticoagulation, which Pannucci<sup>2</sup> candidly recognizes as a weakness of the VTEPS. By making adjustments in the direction favored by the investigators, and disregarding a factor that opposes it, the authors just barely find significance, citing a *P* value of 0.042.<sup>3</sup> Moreover, controlling for the Caprini score is unjustified because there is no known linear relationship between such scores and risk. Controlling for length of hospitalization is questionable because Caprini believes that length of hospitalization is not a risk factor.<sup>15</sup> Regardless, the sample sizes are too small to make reliable conclusions regarding independent risk factors for VTE.<sup>31</sup>

The VTEP investigators<sup>3</sup> would have done well to trust their data and conclude that there was no significant treatment effect.<sup>41</sup> Certainly, a negative outcome is not what these investigators expected, but such a conclusion would have been a valuable contribution and one that would help to open a new chapter in the management of this serious problem.

#### RIVAROXABAN

Rivaroxaban (Xarelto, Janssen Pharmaceuticals, Titusville, N.J.) is appealing to surgeons and patients because it is orally administered. However, this anticoagulant has not been shown to be effective in reducing VTE risk in plastic surgery patients. Dini et al<sup>42</sup> report numerous hemorrhages in abdominoplasty patients treated with rivaroxaban. Hunstad et al43 implicate the simultaneous use of the antiinflammatory medication tenoxicam42 and report a lower incidence of this complication in their own study -3 hematomas requiring evacuation among 132 patients (2.3%), excluding 2 hematomas that were evacuated before the patients received rivaroxaban. By contrast, in my own study<sup>44</sup> of 167 consecutive abdominoplasties treated with spontaneous breathing, avoid gas, face up, extremities mobile<sup>31</sup> anesthesia and no chemoprophylaxis, there were no hematomas. Both series43,44 identified 1 known VTE (0.76% and 0.60%, respectively). Although its use is approved in patients undergoing knee or hip replacement (different patients, surgery, and natural history of thromboses<sup>39,40</sup>), rivaroxaban is not approved by the U.S. Food and Drug Administration for deep venous thrombosis prophylaxis in plastic surgery.45 Unlike alternatives such as heparin, warfarin, and enoxaparin, no antidote is available.<sup>45</sup> This limitation may be overlooked in publications.<sup>43,46</sup>

Not surprisingly, studies show an increased risk of bleeding, hematomas, and blood transfusions in plastic surgery patients treated with low-molecularweight heparin.<sup>47,48</sup> In recognition of the risk of bleeding, the 2012 ACCP Guidelines now include aspirin as an acceptable form of prophylaxis for orthopedic patients undergoing joint replacement.23 Pannucci et al<sup>49</sup> conclude that enoxaparin does not increase the risk of reoperative hematomas. Ironically, these authors cite a *P* value that is lower (although still nonsignificant) than the nonsignificant P values used in the VTEPS<sup>3</sup> to support a treatment difference. Nevertheless, proponents of chemoprophylaxis seem to acknowledge an increased bleeding risk by asking, What would you rather treat, a hematoma or a VTE?<sup>50–52</sup> An increased risk of bleeding is expected because anticoagulation is not selective and is likely to affect clots in the operative field. In the case of excisional body contouring surgery, the dissection can be extensive.

#### **META-ANALYSES**

With the publication of new meta-analyses and guidelines,<sup>53</sup> it is important to note that such analyses are only as reliable as the constituent studies. Data derived from other surgical specialties are simply not applicable, regardless of whether they are based on over 17,000 patients.<sup>46</sup> Clinical diagnosis of a deep venous thrombosis is notoriously unreliable.<sup>7,40</sup> Analyses that do not include consecutive plastic surgery patients investigated using an objective tool cannot provide needed information regarding the true frequency, timing, and anatomic site of deep venous thromboses, which are likely to be affected by the procedure and type of anesthesia.<sup>4,7,31,38</sup> An analogy would be trying to investigate arrhythmias without performing electrocardiograms.

## IS DOPPLER ULTRASOUND SCREENING PRACTICAL?

Pannucci<sup>41</sup> questions whether performing ultrasound scans is feasible, citing the expense. However, for those surgeons who have encountered a VTE in practice, this extra safety measure is unlikely to represent a barrier. The expense is dwarfed by the cost of in-hospital treatment of a deep venous thrombosis (over \$20,000 as cited in the VTEPS<sup>3</sup>), plus the tremendous emotional cost to the patient, family, and plastic surgeon.

At present, I employ a full-time ultrasound technician. She also works part-time at a local hospital. Her salary is approximately \$30,000 annually. The equipment cost is \$30,000 or \$6000 per year over a 5-year period (the equipment is warranted for 5 years). In my practice, the cost per patient for 3 perioperative scans is <\$200, included in the surgical fee. This expense may be compared with the price of enoxaparin, at about \$250 for a 1-week course. Writing a prescription is easier than scanning patients, obviously. However, Doppler ultrasound scans are not as onerous as one might think and are well accepted by patients.<sup>40</sup>

## TREATING A DISTAL VENOUS THROMBOSIS

Some investigators may question whether knowledge of a thrombosis is even desirable, arguing that a distal thrombosis does not require treatment. It is true that most distal thromboses are likely to spontaneously resolve.<sup>54</sup> However, they may also propagate. A prudent course of management, and one supported by the ACCP guidelines, is weekly ultrasound scans to document resolution.<sup>25,40</sup> A hematologist is consulted regarding management, and the consultant decides whether or not to recommend anticoagulation, the specific medication, and the duration.

### DOPPLER ULTRASOUND SURVEILLANCE

Pannucci and Cuker<sup>46</sup> comment that spontaneous breathing, avoid gas, face up, extremities mobile anesthesia does not live up to its promise, referencing a 0.5% rate of deep venous thromboses detected by Doppler ultrasound.<sup>40</sup> On the contrary, ultrasound screening avoids needless anticoagulation and identifies patients with early subclinical thromboses (Table 2). The diagnosis comes first and treatment second rather than the reverse. The alternative is to simply wait for a thrombosis to become clinically evident and only then intervene. One need not wait for a large proximal thrombosis to propagate unseen and undetected. As proponents of chemoprophylaxis point out, the presenting clinical sign of VTE may be sudden death.<sup>21</sup>

Today, it is impossible to think of practicing cardiology without electrocardiograms. Similarly, any serious study of deep venous thromboses must include ultrasound scans. Doppler ultrasound imaging may prove to be as valuable as preoperative electrocardiograms that many plastic surgeons already order routinely. Ultrasound examinations are quick, accurate, and noninvasive. Negative scans are highly reassuring to the patient and surgeon.<sup>40</sup>

Important questions remain. Should all plastic surgery outpatients be screened perioperatively using Doppler ultrasound? Do certain procedures and operating times pose greater risk? When should patients be scanned? Not enough data are presently available to reliably answer these questions. My plan is to continue scanning all patients and then evalu-

	Ultrasound Surveillance	Individual Risk Stratification and Rivaroxaban
High sensitivity	1	
Few false positives	1	
High patient compliance	1	1
Low cost	1	1
No increased risk of bleeding	1	
No need for antidote	1	
No problem with FDA approval	1	
No concern for drug interactions	1	
Allows early, reliable detection of thrombosis	1	
Diagnosis before treatment	1	
Adds to understanding of natural history	$\checkmark$	
Convenient for patient and surgeon		$\checkmark$
No need for ultrasound equipment or the services of a trained sonographer		1

 Table 2. Comparison of Ultrasound Surveillance

 versus Individual Risk Stratification and Rivaroxaban

FDA indicates United States Food and Drug Administration.

ate the data once a larger study population has been collected (eg, >1000 patients). The contributions of other investigators are welcome. The more patients are scanned, the more we learn about the nature of this enigmatic complication in our patients.

"Doubt is the origin of wisdom." - René Descartes

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