TURKISH JOURNAL OF UROLOGY
Turk J Urol 2020; 46(2): 108-14 • DOI: 10.5152/tud.2019.19162
UROONCOLOGY
Original Article

Caprini score and surgical times linked to the risk for venous thromboembolism after robotic-assisted radical prostatectomy

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Cite this article as: Frankel J, Belanger M, Tortora J, McLaughlin T, Staff I, Wagner J. Caprini score and surgical times linked to the risk for venous thromboembolism after robotic-assisted radical prostatectomy. Turk J Urol 2020; 46(2): 108-14.

ABSTRACT

Objective: To evaluate the Caprini score as an independent predictor of venous thromboembolism (VTE) in patients undergoing robotic-assisted radical prostatectomy (RARP) and to identify appropriate cut-points for clinical use.

Material and methods: We performed a retrospective review of patients who underwent RARP for prostate cancer between December 2003 and February 2016. VTE cases developed the condition within 90 days of discharge. The control group was comprised of patients whose RARP most closely preceded and followed each VTE case in time and who were matched on lymph node dissection and surgeon. The Caprini score was calculated for each patient, and the groups were compared on a number of clinical variables. Multiple logistic regression was used to evaluate whether the Caprini score was an independent predictor of VTE. Receiver operating characteristics (ROC) curves were used to establish appropriate clinical cut-points.

Results: A total of 3719 patients underwent RARP during the study period. A total of 52 (1.4%) of patients met the criteria for cases. Data were available for 97 patients who met the criteria for controls. Multiple logistic regression indicated that the Caprini score and operative time were independently both significant predictors of VTE (p=0.005 and p=0.044, respectively). ROC indicated that the Caprini score showed a significant but moderate relationship to VTE (area under curve [AOC]=0.64; p=0.004). A Caprini score >6 was the best arithmetic balance for sensitivity (61.5; 95% confidence interval [CI]: 47.0–74.7) and specificity (59.8; 95% CI: 49.3–69.6).

Conclusion: The Caprini score predicts postoperative VTE in patients undergoing RARP.

Keywords: Prostatectomy; robotic surgical procedures; venous thromboembolism.

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Submitted:
07.08.2019

Accepted:
02.12.2019

Available Online Date:
06.01.2020

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Available online at
www.turkishjournalofurology.com

Introduction

Postoperative venous thromboembolism (VTE), encompassing deep vein thrombosis (DVT) and pulmonary embolism (PE), is associated with significant morbidity and mortality.[1] VTE is the leading cause of non-cancer death, following major abdominal or pelvic cancer surgery.[2] The incidence of VTE after radical prostatectomy is 0.3%–3.9%.[3,4] Given the risks of VTE associated with radical prostatectomy and the severity of such a diagnosis, a preoperative tool that could be used to predict the VTE risk in this patient population is required.

Caprini et al. developed a model to identify surgical patients at a greater risk for VTE based on a combination of published data and clinical experience.[5,6] The Caprini Risk Assessment Model (RAM) includes modified versions published in 2005[7] and 2010.[8] The Caprini RAM has been validated in otolaryngology, thoracic, gynecologic oncology, high-risk, reconstructive, and plastic surgery patients.[9-14] A modified version of the Caprini RAM was validated in a population of patients undergoing general, vascular, and urologic surgery, where patients undergoing urologic surgery represented 17% of the study population.[15]

Guidelines for thromboprophylaxis and preoperative VTE risk stratification have been developed for use in both general surgical and urologic patients. In 2012, the American Col-

lege of Chest Physicians (ACCP) developed a guideline for thromboprophylaxis in non-orthopedic surgical patients undergoing abdominal or pelvic surgery, which includes the Caprini score for risk stratification.[16] This set of guidelines stratifies risk based on the Caprini score into four groups, referring to them as very low, low, moderate, and high-risk.[16] Both the Caprini score alone and as part of the ACCP guidelines assigns the greatest risk stratification to patients with a score ≥5. Each risk group has an associated prophylactic regimen, with a score ≥5 recommended to receive combination prophylaxis.[15,16]

The American Urological Association produced a white paper in 2014 regarding anticoagulation therapy in urologic practice.[17] The utility of current guidelines in urologic surgery is uncertain; however, the vast majority of patients undergoing major abdominal or pelvic urological procedures fall under the high-risk category, despite having significantly different risks of VTE.[18] Further, the current guidelines are limited by a lack of procedure-specific risk stratification, including risk stratification for patients undergoing prostatectomy.[19]

While previous research including urological patients has suggested that the Caprini RAM could be a useful VTE risk stratification tool for those undergoing prostatectomy, its usefulness in this specific patient population has not previously been evaluated, to the best of our knowledge. In this study, we assessed the usefulness of the Caprini RAM as a predictor of VTE in patients undergoing robotic-assisted radical prostatectomy (RARP). The objectives were to compare VTE cases vs controls on the Caprini score and to evaluate the ability of the Caprini score to predict VTE in the presence of other potential predictive or confounding factors. If Caprini proved to be independently predictive, we sought to identify appropriate clinical cut-points.

Main Points:

- Previous work has sug¬gested that the Caprini Risk Assessment Model (RAM) could be useful in risk stratification for venous thromboembolism (VTE) in patients undergoing prostatectomy, however its usefulness in this specific patient population has not previously been evaluated.
- This study indicated that Caprini score and operative time were both independent predictors of venous thromboembolism within 60 days after robot-assisted radical prostatectomy, after controlling for other factors, including age and lymph node dissection.
- A Caprini sore >6 was identified as the critical cut-point, consistent with previous studies that have suggested a need for increased risk stratification in the higher-score ranges.
- The Caprini RAM is useful in predicting potential cases of VTE, however there is a need for a standard chemoprophylaxis protocol that can be initiated once VTE cases are identified.

Material and methods

Study design

The design is a retrospective case-control chart review contrasting cases of men with prostate cancer who experienced a VTE post RARP vs. controls who had no VTE post RARP during the study period, December 2003 through February 2016 (Institutional Review Board approval HHC-2016-0150).

Setting

A 867-bed regional referral center located in the northeastern region of the United States.

Participants

Cases: Inclusion criteria were patients (aged 18–89) with prostate cancer who underwent RARP between December 2003 and February 2016 and who developed a postoperative VTE within 90 days of discharge, defined as clinically significant PE, or DVT diagnosed with either computed tomography or sonography requiring treatment.

Controls: Patients whose RARP most closely preceded and followed each case in time, who were matched to the case considering lymph node dissection (yes/no), and for whom the same surgeon performed the operation were included in the study.

Exclusion criteria: Patients who had RARP with no VTE and who did not meet the criteria described for controls were excluded.

Bias

To address potential sources of bias (lymph node dissection, surgeon), the control group was matched to the VTE cases based on lymph node dissection (yes/no) and surgeon. To control for changes in surgical approaches and variation in chemoprophylaxis strategy over time, the control group was also chosen so that each control was the patient who had RARP most closely before or after one of the cases.

RARP and VTE prophylaxis

All patients undergoing RARP were prescribed sequential compression devices and were treated according to an early ambulation protocol for VTE prophylaxis; heparin prophylaxis was administered according to surgeon's preference. RARP was performed in the standard lithotomy position in all cases, and the extent of lymphadenectomy was tailored to the specific patient's risk of disease.

Data collection

After an approval by the Institutional Review Board, we queried our single-institution database of patients with prostate cancer and identified cases and controls as described above. The data-

Turk J Urol 2020; 46(2): 108-14
DOI:10.5152/tud.2019.19162

base includes surgeries performed by four surgeons and houses demographic, pathologic, and clinical data collected retrospectively. Clinical and pathologic data were collected for cases and controls, including diagnostic prostate-specific antigen (PSA), pathologic stage, Gleason grade, performance of lymphadenectomy, and operative times (operating [OR] and robotic surgery time). Data on comorbidities and medical history were extracted and a Caprini score was retrospectively calculated for cases and controls using the 2005 version of the Caprini RAM.[7,20,21] Comorbidities, medical history, and International Classification of Diseases (ICD)-9 and ICD-10 codes were incorporated into an algorithm to arrive at a more general indicator of medical history, the Charlson Comorbidity Index (CCI).

Sample size

Based on previous work,[20] we anticipated that we would have 30 patients with thromboembolic events and 60 patients with RARP without thromboembolic events as controls, yielding a total sample size of 90 patients. For the multiple logistic regression, standard guidelines indicate that this would give a sufficient sample size to allow us to include the Caprini score and up to three other predictors in the equation. As described below, the actual sample size exceeded this figure and allowed us to include a larger number of predictors than originally planned.

Statistical analyses

The main objective was to compare the VTE cases vs controls on the Caprini score. This objective was met using the Wilcoxon ranked sum test, a non-parametric test used as an alternative to the t-test when the data cannot be assumed to be normally distributed. This test was also used to compare the cases and the controls on other continuous variables. Chi-squared tests of proportion or Fisher's exact test was used to compare the groups on categorical variables.

A series of separate logistic regressions was run predicting VTE, including the variables that significantly made the cases vs. controls different in univariate comparisons ($p<0.10$). To obtain adjusted odds ratios, these factors were entered into a multiple logistic regression. If the Caprini score was predictive of VTE, this analysis would allow us to determine if it remained a predictor in the presence of other potential predictive or confounding factors (such as the extent of disease and overall comorbidity). Finally, once the VTE predictors were identified, ROC curves were used to establish appropriate clinical cut-points. A significance level of 0.05 was set for all analyses. The Statistical Package for the Social Sciences (SPSS, IBM) version 21 and MedCalc version 13.1.2.0 (MedCalc Software, Belgium) were used for the main and ROC analyses, respectively. Missing values were treated as missing and were not imputed.

Table 1. Clinical and operative factors

	VTE (n=52)	Control (n=97)	p
Age [years; median, (IQR)]	63.4 (58.6,66.4)	59.8 (56.5,65.9)	0.081[1]
PSA [ng/mL; median, (IQR)]	5.1 (4.1,6.7)	5.3 (3.9,7.6)	0.825[1]
OR time [in minutes; median, (IQR)]	216 (168,252)	188 (164,215)	0.012[1]
Robot time [in minutes; median, (IQR)]	166 (128,203)	147 (122,180)	0.089[1]
Lymph node dissection (n, %)	46 (88%)	73 (75%)	0.055[2]
Gleason grade (n, %)			0.917[3]
Grade 1	9 (18%)	20 (21%)	
Grade 2	32 (63%)	53 (55%)	
Grade 3	6 (12%)	15 (16%)	
Grade 4	2 (4%)	3 (3%)	
Grade 5	2 (4%)	5 (5%)	
Stage (n, %)			0.918[2]
pT2	39 (75%)	72 (74%)	
pT3, pT4, or LN +	13 (25%)	25 (26%)	
CCI [median, (IQR)]	3 (3,3.8)	3 (3,3)	0.709[1]
Caprini score [median, (IQR)]	7 (6,7)	6 (6,7)	0.003[1]

CCI: Charlson Comorbidity Index; IQR: interquartile range; LN: lymph node; OR: operating room; PSA: prostate-specific antigen; VTE: venous thromboembolism. Variations in sample sizes were as follows: {listed as variable (n for VTE group, n for control group)}: PSA (52, 96); OR time (50, 96); robot time (50,97); Gleason grade group (51,96). Tests for each p-value were as follows: [1]Wilcoxon ranked sum test; [2]Chi-squared test of proportions; [3]Fisher's exact test. Wilcoxon ranked sum test used to analyze continuous variables when distributions were not normal. A chi-squared test of proportions is used to analyze categorical data when expected cell counts are ≥5. Fisher's exact test is used to analyze categorical data when expected cell counts are <5.

Table 2. Multiple logistic regression predicting venous thromboembolic events

Factor	Adjusted odds ratio	95% CI for OR	p
Caprini score	1.95	1.22–3.12	0.005
Age	0.97	0.91–1.04	0.457
Time in operating room (each minute)	1.01	1.00–1.02	0.044
Lymph node dissection	2.13	0.75–6.07	0.156

95% CI: 95% confidence interval; OR: odds ratio

Table 3. ROC analysis predicting venous thromboembolism

Criterion	Sensitivity	95% CI	Specificity	95% CI
≥5	100.00	93.2–100.0	0.00	0.0–3.7
>5	98.08	89.7–100.0	6.19	2.3–13.0
>6	61.54	47.0–74.7	59.79	49.3–69.6
>7	23.08	12.5–36.8	91.75	84.4–96.4
>8	13.46	5.6–25.8	98.97	94.4–100.0
>9	7.69	2.1–18.5	100.00	96.3–100.0
>10	1.92	0.05–10.3	100.00	96.3–100.0
>13	0.00	0.0–6.8	100.00	96.3–100.0

ROC: receiver operating characteristic; 95% CI: 95% confidence interval

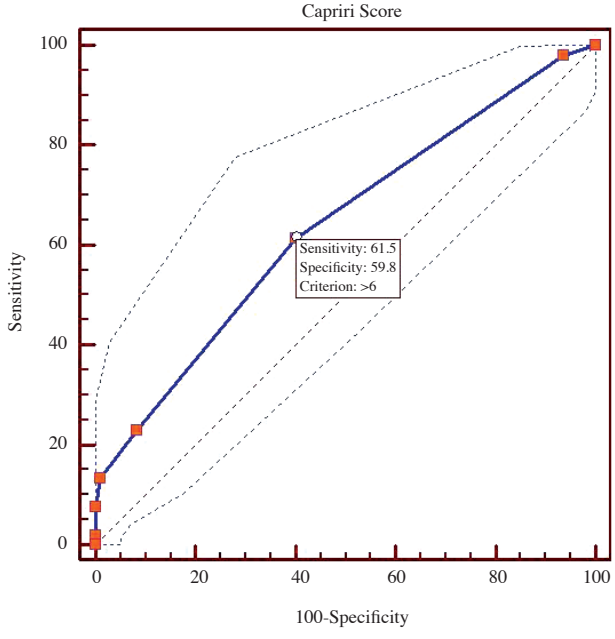

Figure 1. ROC curve using the Caprini score to predict VTE
ROC: operating characteristic; VTE: venous thromboembolism

Results

Descriptive statistics

A total of 3719 patients underwent RARP during the study period; 149 patients were included in the present analyses. A total of 52 (1.4%) met the criteria for cases. Data were available for 97 patients who met the criteria listed above for controls. Of the 52 cases, 25 presented with DVT, 18 presented with a PE, and 9 patients presented with both DVT and PE. Three potential controls were excluded because they did not match the cases on lymph node dissection. Four potential controls were excluded because of insufficient data to calculate the Caprini score. Overall, the median age and interquartile range (IQR) in years of the 149 patients included in the analyses were 61.35 (57.08, 66.28); and the median diagnostic PSA was 5.15 (3.92, 7.26) ng/mL. Gleason grades of the sample were as follows: Gleason 6 (29, 19.5%), Gleason 3+4 (85, 57.0%), Gleason 4+3 (21, 14.1%), Gleason 8 (5, 3.4%), and Gleason 9 or 10 (7, 4.7%). Two patients had missing data on the Gleason grade, and 119 (79.9%) had lymph node dissection. Overall, the median (and IQR) for the Caprini score was 6 (6,7). The median (and IQR) for CCI was 3 (3,3). The median OR time was 195 minutes (IQR, 165,228.5), and the median robot time was 150 minutes (IQR, 124, 181).

VTE cases vs. controls

No significant differences in age, robot time, CCI, PSA, the Gleason score, or stage were observed between the two groups (Table 1). The groups differed significantly in overall operating room (OR) times (p=0.012). Relative to controls, a higher proportion of the cases had lymphadenectomy (88.5% vs. 75.3%), but the difference was not statistically significant (p=0.055). The Caprini score ranged from 5 to 13 and was significantly higher for the VTE group (p=0.003).

Predicting VTE

A series of separate logistic regressions was run predicting VTE, including the variables that significantly differentiated the cases vs. controls in univariate comparisons (from Table 1): the Caprini score, age, OR time, and lymph node dissection. The robot time was not included due to its high correlation with the OR time (rho=0.88). Odds ratios, 95% confidence intervals, and p-values for the Caprini score, age, OR time, and lymph node dissection were 1.89 (1.29–2.77, p=0.001); 1.04 (0.98–1.07, p=0.207); 1.01 (1.00–1.02, p=0.013); 2.52 (0.95–6.63, p=0.061), respectively. When all four measures were included in a multiple logistic regression, the Caprini score and OR time were both independent predictors of VTE (Table 2). Table 3 presents the results of the ROC analysis using the Caprini score to predict VTE. The Caprini score was significantly associated with VTE (AUC=0.64, p=0.004). A Caprini score >6 was identified as the best arithmetic balance for sensitivity (61.5; 95% CI: 47.0–74.7) and specificity (59.8; 95% CI: 49.3–69.6) (Figure 1). The OR time was

Turk J Urol 2020; 46(2): 108–14
DOI:10.5152/tud.2019.19162

significantly associated with VTE (AUC=0.63, p=0.01). An OR time >204 minutes was identified as the critical cut-off point for sensitivity and specificity.

Discussion

The overarching goal of this study was to assess the usefulness of the Caprini RAM as a predictor of VTE in patients undergoing RARP. Our analysis indicated that the Caprini RAM is a significant predictor of VTE in patients undergoing RARP, even when the age, operating time, and lymph node dissection are accounted for in the multiple logistic regression. Derived RAMs, such as the Caprini score, must undergo validation for successful use in clinical practice.[21] As the 2005 version of the Caprini RAM is the best validated RAM in the general surgical and subspecialty populations, we chose to use this version in our analysis.[7,22,23]

The usefulness of the Caprini RAM as a predictor of postoperative VTE in urologic surgery patients has been a topic of debate, as it tends to group patients with significantly different risk factors into the same highest-risk group.[18] Pannuci and colleagues validated the Caprini RAM in reconstructive and plastic surgery patients and showed that patients with a Caprini score ≥7–8 were more likely to develop VTE.[14] Similarly, a recent study that included high-risk surgical patients validated the Caprini RAM and identified patients with a score ≥11 as a subgroup of patients at an "extremely high-risk" for whom standard prophylactic strategies may be inadequate.[13] One group validated an adapted Caprini RAM for general surgery patients and showed that the risk of developing VTE in the 5–6 score group was not significant as compared to those with a score ≥7, and therefore, recommended 7 as a possible cut-off for separate prophylaxis guidelines.[24] Several other studies have suggested need for further risk stratification within the Caprini RAM to develop more accurate prophylactic strategies, including patients undergoing esophagectomy[10] and gynecologic oncology surgery.[12] The critical cut-point for patients undergoing RARP in our study was a score >6, which is consistent with previous studies that suggest a need for increased risk stratification in the higher-score ranges. To precisely elucidate the critical cut-points for extremely high-risk patients undergoing RALP who may benefit from different guidelines for prophylaxis, comprehensive prospective clinical studies will be necessary.

Our study also showed that the total OR time was significantly longer in the VTE group. During the time period of this study, patients undergoing RALP were placed in the lithotomy position at the beginning of the procedure. The lithotomy position has been associated as an independent risk factor for an increased risk of VTE in surgical patients.[25] Furthermore, it has been proposed that pneumoperitoneum, which is necessary for robotic surgery, increases pressure on the venous system, resulting in flow disruptions.[26] A prolonged elevation of the intra-abdominal pressure may lead to conditions that favor thrombosis. A longer OR time may result in an increased time spent in the lithotomy position or prolonged pneumoperitoneum, which may account for the increased rate of VTE.

Currently, the ideal chemoprophylaxis strategy (e.g., administration of low-molecular weight heparin or low-dose unfractionated heparin) in patients undergoing robot-assisted prostatectomy has yet to be identified. According to the 2012 ACCP guidelines, an abdominal or pelvic surgery patient with a Caprini score ≥5 is considered being at high-risk and should receive combination therapy (pharmacologic and mechanical prophylaxis).[16] Using the Caprini RAM, almost all patients undergoing RARP have a total score of at least 5 (all in the current sample) and should therefore receive combination prophylaxis based on the ACCP guidelines. A high percentage of patients undergoing radical prostatectomy, however, do not receive combination prophylaxis.[27] Moreover, not all urologists agree that chemical prophylaxis is warranted in RARP; the Pasadena Consensus Panel, for example, recommended early mobilization and mechanical therapy instead of pharmacologic prophylaxis for RARP patients in the postoperative period.[28] Previous studies have shown that the incidence of postoperative VTE in patients undergoing robot-assisted prostatectomy was not significantly decreased by the administration of prophylactic heparin.[20,29]

Studies attempting to validate the Caprini RAM have addressed the need for evaluation of chemoprophylactic strategies in highest-risk patients. Bahl and colleagues demonstrated widely variable rates of VTE within the highest-risk group in a population of general, vascular, and urologic surgery patients.[15] Based on those results, modifications of the Caprini RAM suggest the addition of a separate "super high-risk group" for those with a Caprini score >8 and recommended extended duration of chemoprophylaxis for those patients.[23,30] Lobastov and colleagues administered a comprehensive VTE prophylaxis program to all patients in their prospective study of high-risk surgical patients, which they hypothesized accounted for the shifted Caprini score toward 11 as the boundary for patients at a significantly increased risk for VTE.[13] While our data show that the Caprini RAM is useful in predicting potential cases of VTE, there is a need for a standard chemoprophylaxis protocol that can be initiated once these cases are identified.

To the best our knowledge, this is the first study to use the Caprini RAM to predict outcomes in patients undergoing RARP. We analyzed other clinically relevant factors including CCI, PSA, stage, and the Gleason score. Supporting the idea that our results were not confounded by the extent of disease and overall comorbidity, none of these factors were found to be significant in univariate analyses that were comparing the VTE cases vs. controls.

We acknowledge several limitations to this study. First, inherent differences exist in the surgical technique from surgeon to surgeon, including differences in administering heparin prophylaxis. However, prior studies demonstrate no difference in the VTE rates with the administration of prophylactic heparin.[20,29] Second, the study period spanned 13 years, and thromboembolism prophylaxis has changed over time. To attempt to control for changes over time, we chose as controls patients who underwent RARP immediately before or after each VTE case. Third, while the matched control group was designed to minimize the differences between surgeons by using cases from each surgeon immediately preceding and following the VTE case, this design likely did not eliminate all sources of bias. The study was a retrospective review of medical records, which itself is influenced by charting errors, memory, and inconsistency in event identification. Records that were reviewed may have been missing relevant information, which could have resulted in underreporting of a patient's Caprini score.

Our results further support the use of the Caprini score as a risk assessment tool in the prediction of postoperative VTE for patients undergoing robotic prostatectomy. A Caprini score of >6 was identified as the critical cut point for statistically significant increased risk of VTE. This threshold is consistent with previous studies and highlights the need for further analysis of risk stratification in the higher-score ranges.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee Institutional Review Board of Hartford Hospital (HHC-2016-0150).

Informed Consent: This study was approved by the Hartford Hospital Institutional Review Board with a full waiver of consent.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – J.F., J.W., M.B., I.S.; Design – J.F., J.W., M.B., I.S., J.T.; Supervision – J.W.; Data Collection and/or Processing – J.T., I.S., M.B.; Analysis and/or Interpretation – J.F., M.B., I.S., T.M., J.W.; Literature Search – J.F., M.B., T.M.; Writing Manuscript – J.F., M.B., J.T., T.M., I.S., J.W.; Critical Review – J.F., M.B., J.T., T.M., I.S., J.W.

Conflict of Interest: J.W. serves on the speaker's bureau for Genomic Health and as a consultant for Medtronic.

Financial Disclosure: The authors declared that this study has received no financial support.

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