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The Limited Utility of Currently Available Venous Thromboembolism Risk Assessment Tools in Gynecologic Oncology Patients

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Abstract

BACKGROUND—Use of risk assessment tools, such as the Caprini score or Rogers score, is recommended by national societies to stratify surgical patients by venous thromboembolism (VTE) risk and guide prophylaxis. However, these tools were not developed in a gynecologic oncology patient population and their utility in this population is unknown.

OBJECTIVE—To examine the ability of both the Caprini and Rogers score to stratify gynecologic oncology patients by risk of VTE.

STUDY DESIGN—Patients undergoing surgery for cervical, ovarian, uterine, vaginal and vulvar cancers between 2008 and 2013 were identified from the National Surgical Quality Improvement Database using ICD-9 codes. Caprini and Rogers scores were calculated for each patient based upon recorded demographic and procedure data. VTE events were recorded for 30 days postoperatively. Patients were categorized into risk groups based on calculated Caprini and Rogers scores and the incidence of VTE and 95% confidence interval was estimated for each of these groups. The relationship between risk score and VTE incidence was examined with Pearson's correlation coefficient.

RESULTS—Of 17,713 patients, 1.8% developed a VTE. No patients were classified by the Caprini score as low risk, 0.1% were moderate risk, 3.0% were higher risk (score 4), and 96.9% were highest risk (score >=5). The Caprini score groupings did not correlate with VTE. The high-risk group had a paradoxically higher incidence of VTE of 2.5% compared to the highest risk group, 1.7% (p=0.40). However, when the highest risk group of the Caprini score was sub-stratified, it was highly correlated with VTE (R^2=0.93). For the Rogers score, only 0.2% of

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patients were low risk (score <7), 36.9% were medium risk (score 7–10), and 63.0% were high-risk (score >10). When the highest risk group of the Rogers score was sub-stratified, it was also highly correlated with VTE (R^2=0.99).

CONCLUSIONS—Gynecologic oncology patients score very high on current VTE risk assessment models. The Caprini score is limited in its ability to discriminate relative VTE risk among gynecologic oncology patients as 97% are in the highest-risk category. Sub-stratification of the highest risk groups allows for relative VTE risk stratification among gynecologic oncology patients suggesting that further evaluation of risk stratification is needed in gynecologic oncology surgery.

Keywords

venous thromboembolism; risk assessment model; Caprini score; Rogers score; gynecologic oncology surgery

INTRODUCTION

Venous thromboembolism (VTE) is the second most common complication and third most common cause of excess mortality after surgery (1). Patients with gynecologic cancer are at an increased risk of thromboembolism. National organizations, such as the American College of Chest Physicians (ACCP), have published guidelines for the appropriate use of postoperative mechanical and pharmacologic prophylaxis (2). Within these guidelines, risk stratification is used to determine the appropriate degree of prophylaxis for each individual patient. Those patients at the highest risk (~6% risk of VTE) are recommended to receive dual prophylaxis with both mechanical and pharmacologic prophylaxis including extended duration pharmacologic prophylaxis for those with pelvic cancers. Populations at low risk (~1.5% risk of VTE) are recommended to receive only mechanical prophylaxis.

The risk stratification tools used in the ACCP guidelines are the Caprini score and the Rogers score (3–5). Both the Caprini and the Rogers models assign points to various risk factors for VTE and use those point totals to place patients into risk strata. The Caprini score is the most widely used VTE risk assessment tool (6–8). The Rogers score was developed from vascular and general surgery cases recorded in a large Veterans Administration quality database and is used less frequently (3). The authors of ACCP guidelines note that although risk stratification models have not been validated in gynecologic surgery patients, gynecologic surgery patients are likely sufficiently similar to other patients undergoing abdominal and pelvic surgery for extrapolation (2). However, neither score was developed in a gynecologic oncology patient population and the validity of this extrapolation hypothesis is unknown.

Two studies have examined the use of the Caprini score in gynecologic oncology patients. Both found that gynecologic oncology patients score high using the Caprini risk assessment model with >92% and >96% falling into the highest risk category, suggesting a limited ability to risk stratify as the vast majority of patients are categorized in a single stratum (9, 10). However, further examination into the possibility of risk stratification within this

highest risk category has not been performed and the Rogers score has yet to be examined in a gynecologic oncology patient population.

Our objective was to examine the utility of the Caprini and Rogers scores to risk stratify gynecologic oncology patients undergoing surgery by their risk of postoperative VTE.

MATERIALS AND METHODS

This was a secondary analysis cohort study of prospectively collected surgical quality data. The primary outcome was the association between risk assessment score in two different risk assessment models and the incidence of VTE. The study population was patients who underwent surgery for cervical, ovarian, uterine, vaginal and vulvar cancers between 2008 and 2013 who were identified from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Database using International Classification of Diseases, Ninth Revision (ICD-9) codes. The Institutional Review Board at the University of North Carolina at Chapel Hill reviewed this study and declared it exempt from formal review as it does not constitute human subjects research.

The ACS-NSQIP database is a national surgical quality improvement project. Participation is voluntary and participating institutions are able to track their own risk-adjusted outcomes after surgery. Trained clinical reviewers prospectively collect variables such as patient demographics, operative variables and post-operative outcomes for each individual procedure for 30 days following surgery. The data is then de-identified of patient, hospital, and location-specific information and placed into the NSQIP database. Periodic auditing ensures high quality data, including that for data points occurring after hospital discharge. Details of methods of data collection and reliability have been previously reported (11).

Our primary outcome was VTE which was defined as either a pulmonary embolism or a deep vein thrombosis diagnosed within 30-days postoperatively. Both were defined as per the NSQIP participant use file (12). Demographic, operative and disease characteristics were also recorded. Site of malignancy was defined by postoperative ICD-9 code. Procedure type was defined as laparotomy, minimally invasive and external. Patients were placed into these categories based on primary procedure Current Procedural Terminology (CPT) codes. Minimally invasive procedures were defined as laparoscopic or vaginal approaches with abdominal cavity entry, such as a vaginal hysterectomy or operative laparoscopy. External procedures were defined as procedures in which the abdominal cavity was not entered, such as vulvar/vaginal resections, or cervical excisional procedures. Charlson comorbidity score was calculated for each patient as previously described (13, 14). Surgical complexity was defined by the work relative value unit (wRVU) which is an estimate of the amount of physician work per CPT code. The wRVU for each procedure is the sum of the assigned value to each CPT code for the procedure, thus higher wRVU is associated with increasing surgical complexity.

A Caprini score and a Rogers score was calculated for each patient by assigning points to each risk factor present for a given patient. The Caprini score model was used to calculate a Caprini risk score for each patient based on the variables available in the NSQIP database

(Supplementary Table 1). Risk factors that are assigned points in the Caprini score, but are unavailable in NSQIP, include swollen legs, varicose veins, history of unexplained abortions (>3), use of hormonal contraceptives or replacement, history of inflammatory bowel disease, central venous access, history of VTE or family history VTE, and congenital or acquired thrombophilias. Data was missing for less than 5% of patients for all available risk factors in the Caprini model. The Rogers score model was used to calculate a Rogers risk score for each patient based on the variables available in the NSQIP database (Supplementary Table 2). All risk factors included in the Rogers score are available in NSQIP. For the Rogers model, data was missing for less than 5% for all risk factors with the exception of serum albumin and bilirubin which were missing for ~40% of patients. Patients missing these laboratory values were given zero points for that risk factor. As there are 18 measured risk factors in the Rogers score worth 1–4 points and both hyperbilirubinemia and hypoalbuminemia are worth only 1 point and are relatively rare in the population (17% and 5% respectively), having the additional data for these two variables should not alter the total Rogers score sufficiently to change our conclusions.

Data regarding mechanical or pharmacologic prophylaxis is not available in the NSQIP database. However, Surgical Care Improvement Project (SCIP) guidelines that were implemented in 2008 require the use of VTE prophylaxis or documentation of why prophylaxis was not provided (15). We assume that the compliance with these guidelines was very high (>95%) due to the penalties imposed on hospitals and thus, the majority of the patients in this cohort likely received VTE prophylaxis (16).

After risk scores were calculated for each patient, patients were categorized into the American College of Chest Physicians risk stratification groups based upon their Caprini or Rogers score individually. Patients were also categorized into risk categories by their individual scores. The incidence of VTE for each of these risk groups was estimated along with a 95% confidence interval. The relationship between risk score and VTE incidence was examined using Pearson's correlation coefficient. For bivariable analysis, 2-tailed t-tests were used for continuous variables and Pearson's chi square tests for categorical variables. A p value of less than 0.05 was considered significant for all analyses. SPSS version 20.0 (IBM Corp, Armonk, NY) was used for all analyses.

RESULTS

We identified 17,713 patients with the demographic and operative characteristics as listed in Table 1. The majority of the patients in this cohort had uterine cancer (59.5%) followed by ovarian cancer (27.2%), cervical cancer (8.8%) and vulvar/vaginal (4.5%) cancer. Surgical approach was laparotomy (52.3%), minimally invasive (43.0%) and external procedures (4.7%). This cohort also represents a group of patients undergoing surgically complex procedures. The median work relative value unit was 31.5 (interquartile range 19.3–38.0). For reference, the number of work relative value units assigned to a total abdominal hysterectomy is 17.3. Therefore, the majority of these procedures were complicated oncologic procedures.

Of 17,713 patients with gynecologic cancer, 1.8% (n=313) developed VTE. One hundred and thirty one patients experienced a PE, 149 experienced a DVT and 33 experienced both a PE and a DVT. There were 143 deaths recorded in the 30-day postoperative period and VTE was associated with an increased risk of death. Patients with VTE experienced a 4.7% 30-day mortality compared to 0.7% for patients without VTE ($p<0.001$). On bivariable analysis, cancer site was associated with VTE. Patients with ovarian cancer had the highest VTE incidence (3.0%) followed by vulvar/vaginal cancer patients (1.5%), uterine cancer patients (1.3%) and cervical cancer patients (1.2%)($p<0.001$).

Surgical approach was also associated with VTE. Laparotomy patients had the highest VTE incidence (2.7%), followed by patients undergoing external procedures (1.1%) and those undergoing minimally invasive procedures (0.7%) ($p<0.001$). However, surgical approach is not factored into the Caprini score; thus, patients undergoing minimally invasive surgery had almost identical mean Caprini scores as patients undergoing laparotomy (6.5 versus 6.4, $p=0.06$). Rogers scores were significantly lower for patients undergoing minimally invasive surgery as compared to laparotomy, although the magnitude of the difference was small (10.6 versus 11.6, $p<0.001$).

Patients were classified into ACCP Guideline risk groups based first on their Caprini risk score and then by their Rogers risk score (Table 2). These guidelines classify patients undergoing non-orthopedic surgical procedures into 4 groups based on the risk of VTE and corresponding Caprini and Rogers scores for each group are given. The category patients were placed in was different depending on whether the Caprini score or the Rogers score was used. For the Caprini score, no patients were classified low risk, 0.1% were moderate risk, 3.0% were higher risk and the remaining 96.9% were highest risk. For the Rogers score, only 0.2% of patients were low risk, 36.9% were medium risk, and 63.0% were high risk (score >10).

Patients were then classified into the conventional risk groups described by the Caprini and Rogers score (Table 3). For the Caprini score, the higher risk group had a paradoxically higher incidence of VTE of 2.5% compared to the VTE incidence of the highest risk group, 1.7% ($p=0.40$). For the Rogers score, VTE incidence increased with each increase in risk category and patients in the high risk group had a higher incidence of VTE (2.2%) than those in the moderate risk group (1.0%) ($p<0.001$).

Given the large number of patients in the highest risk groups for each score, these groups were substratified by score. VTE incidence rates were calculated for each score (Table 4). Among the patients in the highest risk groups VTE incidence was highly correlated with increasing risk score. For the Caprini score, this relationship was linear ($R^2=0.93$) (Figure 1). Those with a score of 8 or greater had an increased odds of experiencing a VTE compared to those with a score of 5 (OR 2.1). For the Rogers score, the relationship between score and VTE incidence was also linear and highly correlated ($R^2=0.99$) (Figure 2). The odds of experiencing a VTE also increased for each increasing risk score. Those with a score of 15 or greater have 5.3 times the odds of experiencing a VTE as those with a score of 11.

COMMENT

Gynecologic oncology patients score very high on currently available VTE risk assessment models. Using the conventional Caprini risk score groupings, 96.9% of gynecologic oncology patients are classified in the highest risk group with a score of ≥5. This finding is supported by two previous studies which found that >92% and >96% of patients operated on by a gynecologic oncologist were categorized in the highest Caprini risk groups (9, 10). For the Rogers score, 63.0% of patients are classified in the high-risk group with a score of ≥11. Given that the majority of gynecologic oncology patients score in the highest risk group, in the current groupings we cannot distinguish between gynecologic oncology patients at higher relative VTE risk and those at lower relative risk.

Risk stratification is a central principle of VTE prophylaxis in the current ACCP Guidelines (2). When we placed our gynecologic oncology patients into the ACCP risk categories, patients were categorized differently depending on whether the Caprini score or the Rogers score was used. Using the Caprini score, only 0.1% of the patients were very low or low risk, whereas for the Rogers score, 37.1% were classified as very low or low risk. This discrepancy makes it difficult for clinicians to use these ACCP recommended groupings in gynecologic oncology patients. Our data suggests the ACCP statement that the gynecologic surgery population is similar enough to those undergoing other abdominal or pelvic surgery to use the same risk groups is not valid among gynecologic oncology surgical patients. Thus, in the current ACCP paradigm, risk stratification, a fundamental principle of VTE prophylaxis, is not possible for gynecologic oncology patients.

However, when we examined the highest risk group for each of the risk assessment models by score we found that an increasing score is highly associated with VTE incidence. This suggests that these risk assessment models, while incorporating important risk factors for VTE, may not be assigning some risk factors appropriate weight. If these risk assessment models are altered by creating stratified scores within the highest risk groups, they may be more effective in discriminating the relative risk of VTE between different gynecologic oncology patients.

One possible variable that may unduely influence the risk calculation is the score assigned to minimally invasive surgery. Currently available risk assessment models also do not distinguish between minimally invasive surgery and laparotomy in terms of VTE risk, although studies have shown that the VTE risk is lower with minimally invasive surgery (17–19). In this study, although the observed incidence of VTE was markedly different between minimally invasive surgery patients and laparotomy patients, their mean Caprini and Rogers scores were not. The lack of differentiation between minimally invasive surgery and laparotomy is a target for improvement in future VTE risk assessment models for gynecologic oncology patients.

Risk stratification is needed for gynecologic oncology patients as modern VTE prophylaxis is not one size fits all, and prophylaxis has both risks and costs. Perioperative VTE prophylaxis for high-risk cancer patients can include the four following components: mechanical prophylaxis, preoperative pharmacologic prophylaxis, postoperative

pharmacologic prophylaxis and extended duration pharmacologic prophylaxis for 28 days. The use of preoperative pharmacologic prophylaxis is associated with both a decrease in VTE incidence and in some studies, an increase in bleeding (20, 21). Although studies specific to gynecologic oncology and a recent large quality improvement project that included gynecologic oncology patients have not found a statistically significant increase in perioperative bleeding (22, 23). Extended duration prophylaxis has been shown to decrease the incidence of VTE among patients with cancer undergoing laparotomy, but is associated with significant costs and inconvenience and the trial supporting its use only contained a small percentage of gynecologic oncology patients (24, 25). Additionally, gynecologic oncology surgery is increasingly being performed with a minimally invasive approach (26, 27). There are few who would argue that a healthy 45 year old with an early stage endometrial cancer undergoing laparoscopic hysterectomy would require all four of the prophylaxis components. In fact, some have argued that patients undergoing minimally invasive surgery for cancer do not require any prophylaxis as data to demonstrate benefit is not available for this population (28, 29). Strategies such as risk stratification within the highest risk group of both the Caprini or Rogers score or development of gynecologic oncology specific risk scores could allow us to tailor our VTE prophylaxis regimen to the VTE risk of our individual patients. Those at highest risk could be given all four components of perioperative prophylaxis whereas those at the lower risk could receive only mechanical prophylaxis. Improved risk stratification allows for appropriate utilization of the various methods of prophylaxis available while minimizing risks and costs.

Strengths of this study include a large cohort of gynecologic oncology patients in which to measure VTE incidence. Additionally, our data source is a large national quality database focused on measuring postoperative complications up to 30 days after surgery and thus has robust data regarding VTE events. This data source has been used to study VTE in the many surgical disciplines and was the data source used for the highly cited validation of the Caprini score in general surgery patients (7, 17, 19, 30, 31). Limitations of the study include the lack of data regarding VTE prophylaxis within NSQIP. Although, it is likely that as cancer patients undergoing surgery, nearly all patients received some form of prophylaxis as per the Surgical Care Improvement Guidelines. The use of prophylaxis is likely responsible for the relatively low incidence of VTE we observed. Additionally, NSQIP does not contain information regarding some of the Caprini model inputs and thus our calculated Caprini scores may underestimate the true Caprini score for a given patient. However, given that 96.9% of patients were in the highest risk group, adding the data for these additional risk factors would only increase the percentage of patients in the highest risk group and enhance our hypothesis that risk stratification is limited if all patients are in the highest risk stratum.

Currently available risk assessment models with conventional risk groups have limited utility in a gynecologic oncology patient population as the majority of patients are in the highest risk groups. However, sub-stratification within the highest risk groups may provide valuable information about the relative risk of VTE between different groups of gynecologic oncology patients. Risk assessment model development specific to the gynecologic oncology patient that incorporates route of surgery will likely improve risk stratification.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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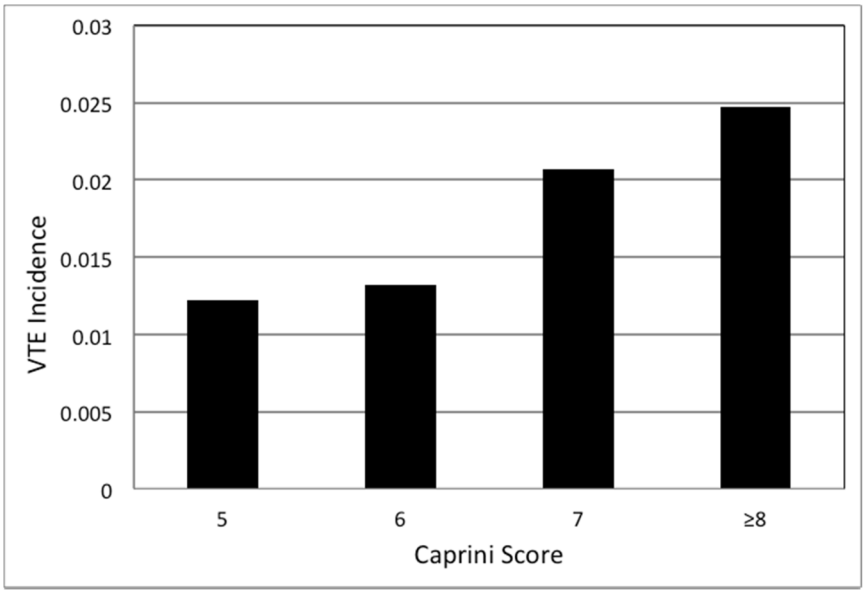

Figure 1. Highest-risk Caprini Group Stratified by Score and Venous Thromboembolism Incidence

The relationship between increasing Caprini score and VTE incidence is linear with R^2=0.93.

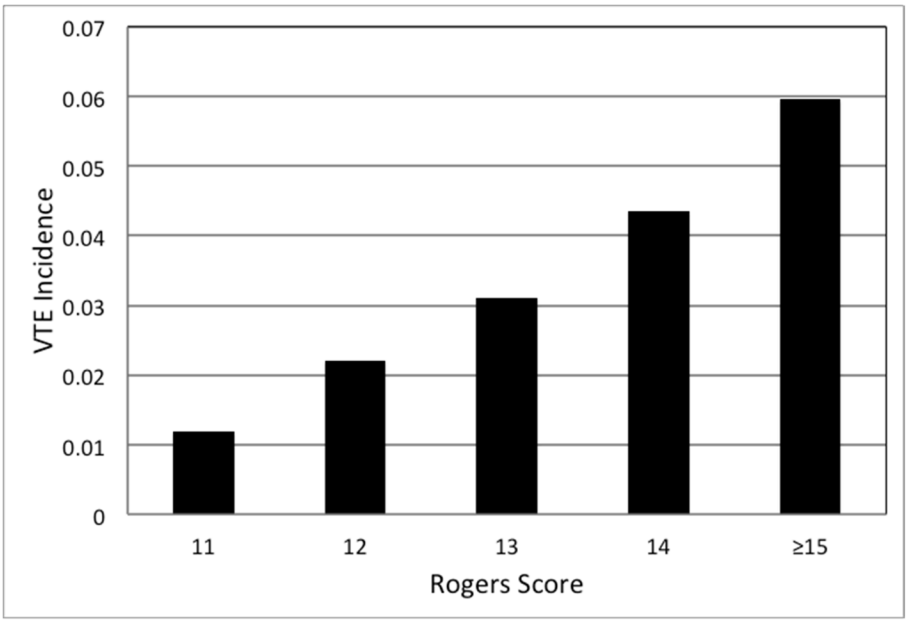

Figure 2. High-risk Rogers Group Stratified by Score and Venous Thromboembolism Incidence

The relationship between increasing Rogers score and VTE incidence is linear with R^2=0.99.

Table 1

Demographic and Operative Characteristics

Age (years)	62 (53–70)
BMI (kg/m^2)	30.4 (25.1–37.4)
Race	
White	13744 (77.6)
Black	1358 (7.7)
Asian	657 (3.7)
American or Alaskan Native	140 (0.8)
Unknown	1814 (10.2)
Site of Malignancy	
Uterus	10543 (59.5)
Ovary	4812 (27.2)
Cervix	1560 (8.8)
Vulva/vagina	793 (4.5)
GTN	5 (0.01)
Procedure type	
Laparotomy	9263 (52.3)
Minimally-Invasive	7624 (43.0)
External	826 (4.7)
Charlson comorbidity index score	
0	11923 (67.3)
1	2890 (16.3)
2	1435 (8.1)
3+	1465 (8.3)
Operating time (min)	159 (112–221)
Length of hospital stay (days)	2.5 (1–4)
Work relative value unit	31.5 (19.3–38.0)

Data is presented as n(%) for categorical variables and median (interquartile range) for continuous variables.

External procedures were defined as procedures in which the abdominal cavity was not entered, such as vulvar/vaginal resections and cervical excision procedures.

Table 2

Patient Categorization into American College of Chest Physicians Risk Groups

Patients were categorized into the ACCP risk groups first by Caprini score and then by Rogers score. The group patients were placed in differed depending on which score was used.

ACCP Risk Group	Patients Categorized by Caprini Score		Patients Categorized by Rogers Score	
	Caprini Score	Patients in Risk Group	Rogers Score	Patients in Risk Group
Very Low Risk	0	0 (0.0)	<7	29 (0.2)
Low Risk	1–2	18 (0.1)	7–10	6532 (36.9)
Moderate Risk	3–4	527 (3.0)	>10	11152 (63.0)
High Risk	≥5	17168 (96.9)	**	**

ACCP – American College of Chest Physicians

Data is presented as n(%).

** Rogers scores are not listed for the high risk ACCP group, only a Caprini score is provided.

Table 3

Observed Venous Thromboembolism Incidence by Risk Group in Currently Available VTE Risk Assessment Models

Patients were placed into conventional risk groups defined by the currently available VTE risk assessment models themselves.

	Observed VTE	95% Confidence interval for VTE incidence (%)
Caprini Score		
Low (0–1)	0	--
Moderate (2)	0 (0/18)	--
Higher (3–4)	2.47% (13/527)	1.1–3.8
Highest (≥5)	1.75% (300/17168)	1.6–1.9
Rogers Score		
Low <7	0 (0.0)	--
Medium 7–10	1.03% (67/6532)	0.8–1.3
High >10	2.21% (246/11152)	1.9–2.5

VTE – venous thromboembolism

Table 4

Observed Venous Thromboembolism Incidence for Highest Risk Groups Sub-stratified by Score

	Observed Incidence of VTE	95% confidence interval for VTE incidence estimate	Odds ratio	95% confidence interval for OR
Caprini score				
5	1.22% (31/2539)	0.79–1.65%	referent	--
6	1.32% (80/6049)	1.03–1.61%	1.08	0.71–1.65
7	2.07% (121/5849)	1.70–2.43%	1.71	1.15–2.54
≥8	2.47% (68/2749)	1.89–3.05%	2.07	1.35–3.17
Rogers score				
11	1.19% (61/5124)	0.89–1.49%	referent	--
12	2.21% (70/3171)	1.70–2.72%	1.87	1.33–2.65
13	3.11% (44/1414)	2.21–4.02%	2.67	1.80–3.95
14	4.35% (35/839)	2.94–5.76%	3.61	2.37–5.51
≥15	5.96% (36/604)	4.07–7.85%	5.26	3.45–8.01