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The Use of venous thromboembolism prophylaxis in relatioN to patiEnt risk profilINg (TUNE IN) Wave 3 study

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Background. Thromboprophylaxis significantly reduces the risk of venous thromboembolism (VTE) in hospitalised medical and surgical patients. Nonetheless, the implementation of thromboprophylaxis in South Africa (SA) and worldwide is low.
Objective. The TUNE-IN (The Use of venous thromboembolism prophylaxis in relatioN to patiEnt risk profilINg) Wave 3 study is an extension of TUNE-IN Wave 1 and 2. This prospective, cross-sectional study assessed the use of VTE thromboprophylaxis in hospitalised medical, surgical and orthopaedic patients.
Methods. Over a 9-month period, 451 consenting patients >18 years of age hospitalised at Charlotte Maxeke Johannesburg Academic Hospital in Gauteng, SA, were systematically included. Patients were assessed and risk stratified according to the IMPROVE (International Medical Prevention Registry on Venous Thromboembolism) bleeding risk and Caprini risk assessment tools. Data on the use of VTE thromboprophylaxis, agent and dose were collected from the hospital records.
Results. The study identified 180 (40%) medical, 198 (44%) surgical and 73 (16%) orthopaedic participants. VTE thromboprophylaxis was administered in 263 (58%) study participants. In accordance with the American College of Chest Physicians guidelines on VTE prevention, adequate thromboprophylaxis was administered in 233 (52%). The most common thromboprophylaxis agent was low molecular weight heparin. Subsequently, the Caprini risk assessment tool identified 337 participants (75%) with a VTE risk score >2, whereas the IMPROVE risk assessment tool identified 22 participants (5%) with a high bleeding risk score (≥7). In accordance with the risk assessment tools, recommended thromboprophylaxis was administered in 68% of medical, 59% of surgical and 79% of orthopaedic high-risk participants ($p<0.012$). The proportion of medical and surgical participants at high VTE risk was similar to that in the Wave 1 and/or 2 studies; however, the rates of VTE thromboprophylaxis in the present study were lower ($p=0.097$ for medical and $p<0.001$ for surgical participants).
Conclusion. This study shows a significant gap between evidence-based thromboprophylaxis recommendations and clinical practice in a large sample of hospitalised medical, surgical and orthopaedic participants. It is recommended that an institutional VTE risk assessment tool be implemented to standardise risk evaluation and improve the administration of appropriate thromboprophylaxis for hospitalised patients.

Keywords: Venous thromboembolism, thromboprophylaxis, Caprini risk assessment, IMPROVE bleeding risk, hospitalised patients, South Africa

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Venous thromboembolism (VTE) is an important cause of morbidity and mortality in hospitalised, medical and surgical patient populations.[1] In Africa, the incidence of deep vein thrombosis (DVT) has been reported to range from 2% to 10% in surgical patients. In medical patients, the incidence of pulmonary embolism (PE) has been reported to range from 18% to 62%, with mortality rates of 40% to 70%.[2] Thromboprophylaxis significantly reduces the risk of VTE in hospitalised medical and surgical patients, and is recommended by clinical practice guidelines.[3-7] The updated American College of Chest Physicians (ACCP) guideline for the prevention of VTE identifies medical and surgical patients at risk of VTE, and provides recommendations for the type (mechanical and/or pharmacological), dose and duration of thromboprophylaxis.[6,7] It is also recommended to use risk stratification tools for VTE risk assessment in this setting. Several models including the Caprini, IMPROVE (International Medical Prevention Registry on Venous Thromboembolism), Kucher, Geneva, 4 elements and Padua model have been validated.[8,9] In particular, the Caprini score, which is based on the ACCP guideline, is a simple and comprehensive risk assessment model for surgical and medical hospitalised patients. The Caprini Risk Assessment Model (RAM) incorporates a total of 39 risk factors, each assigned a specific scoring point. Moreover, it has been extensively validated in nearly 5 million patients and has garnered over 200 peer-reviewed publications.[9] Although these risk assessment models are associated with inherent limitations, as clinical tools they help to stratify hospitalised patients according to thrombotic and bleeding risks.

Despite the presence of updated guidelines and risk assessment models, many hospitalised patients at risk for VTE either do not receive VTE prophylaxis or receive inadequate VTE prophylaxis. The earlier multi-national ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study showed that 50% of hospitalised patients were at risk for VTE, yet only 58% of surgical and 40% of medical patients received recommended VTE prophylaxis according to guidelines.[10,11] Locally, in South Africa (SA), the thromboprophylaxis rates have been described in the TUNE-IN (The Use of VTE prophylaxis in relatioN to patiEnt risk profilINg) Wave 1 and 2 studies, which compared favourably with worldwide trends.[12,13] Patients were stratified according to a modified Caprini risk score (2005). In the Wave 1 study conducted among private hospitalised patients, adequate VTE prophylaxis was administered

in 68% of surgical and 70% of medical patients, whereas in the Wave 2 study in both the private and public sectors, adequate VTE prophylaxis was only administered in 59% of surgical patients, of whom all were at risk. The Wave 2 study, however, did not include an assessment of medical patients.

The aim of the current Wave 3 study was to assess the utilisation of VTE thromboprophylaxis in hospitalised medical, surgical and orthopaedic patients within the public sector, risk stratified according to the IMPROVE bleeding risk and Caprini risk assessment tools. Moreover, the study aimed to compare the current utilisation of VTE thromboprophylaxis to the previous Wave 1 and 2 studies to identify changes in clinical practice.

Methods

Study design and population

In this cross-sectional study, consecutive medical, surgical and orthopaedic patients hospitalised at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in Gauteng, SA, were recruited over a 9-month period between July 2023 and April 2024. Consenting patients >18 years of age were included. CMJAH is a 1 080-bed facility. There are 330 beds for medicine inpatients, and subspecialist units include endocrinology, gastroenterology, rheumatology, neurology, cardiology, infectious diseases, pulmonology, nephrology, oncology and intensive care. There are also 360 beds for surgical inpatients, and subspecialist units include acute care surgery, cardiothoracic surgery, vascular surgery, trauma care, hepatobiliary surgery and endocrine surgery. There are an additional 180 beds for orthopaedic inpatients.

Ethical clearance

Written informed consent was obtained from all study participants, and the study protocol was approved by the University of the Witwatersrand Human Ethics Research Committee (ref. no. M-230146).

Data collection

Data were systematically collected from consecutive hospital records and patient interviews. The following patient information was collected: demographics; the use of VTE thromboprophylaxis; pharmacological or mechanical agent; and dose. Appropriate agents and dosing were determined in accordance with the ACCP guidelines on VTE prevention.[6] Patients were assessed and risk scores calculated with the Caprini risk assessment model and the IMPROVE bleeding risk assessment tool according to clinical signs and symptoms, relevant medical and surgical histories and laboratory investigations during the current admission (Table S1 and S2, appendix: http://coding.samedical.org/file/2359). According to the Caprini risk assessment model, patients were classified as low (0 - 1), middle (2), high (3 - 4), or super high risk (≥5) for VTE. Additionally, according to the IMPROVE bleeding risk assessment tool, patients were classified as low (<7) or high risk (≥7) for bleeding.

Data analysis

A sample of 385 patients was estimated, assuming a 1.0% incidence of VTE, at a confidence interval (CI) of 95%. The estimated incidence of VTE in hospitalised patients receiving thromboprophylaxis is 1% - 5%.[10] Moreover, the sample size was aligned with the original studies, to allow for meaningful comparison of results. Statistical analysis was performed using Statistica software version 13.2 (Statistica, USA). Normally distributed continuous data were presented as mean (standard deviation (SD)), and variables with non-Gaussian distribution as median (interquartile range (IQR)). Categorical data were presented as frequencies and percentages. Comparisons between medical, surgical and orthopaedic participants were performed using the χ^2 test or Fisher's exact test when necessary. Comparisons between the Wave 1, 2 and 3 studies were performed using a one-way analysis of variance (ANOVA). Statistical significance was set at a $p<0.05$.

Results

Characteristics

During the study period, 451 adult medical, surgical and orthopaedic participants were included (Fig. 1). Table 1 shows the baseline characteristics of the study group. The mean (SD) age of the study group was 47 (16) years. There was a higher proportion of surgical male participants than medical male participants ($p<0.010$). The median (IQR) hospital length of stay, which was recorded in 248 participants, was 7 (12) days.

Scores

According to the Caprini risk assessment model, 337 (75%) participants had a VTE risk score >2 (Table 2.) The proportion of orthopaedic participants (n=71, 97%) with a VTE risk score >2 was higher compared with medical (n=120, 67%, $p<0.001$) and surgical participants (n=146, 74%, $p<0.001$). There was no significant difference in gender according to risk score (Table 3) Fig. 2 shows the frequency of VTE risk factors in the study group. In medical and surgical participants, the most common VTE risk factors were age (41 - 60 years) and sepsis. In orthopaedic participants the most common VTE risk factors were age (41 - 60 years) and pelvic/leg fracture within the last month.

The IMPROVE bleeding score was assessed in 128 (71%) medical, 144 (73%) surgical and 36 (49%) orthopaedic participants. Of the study group assessed (n=308), 22 (7%) participants had a high bleeding score (≥7) and were considered to have a contraindication to pharmacological prophylaxis. In these participants, dose-reduced low molecular weight heparin (LMWH) was administered. There was no significant difference in high and low bleeding scores between the medical, surgical and orthopaedic participants (Table 4). The bleeding risk factors in the study group are listed in Fig. 3, of which the most frequent risk factors were age 40 - 84 years and (glomerular filtration rate) GFR 30 - 59 mL/min/m^2.

Thromboprophylaxis

VTE thromboprophylaxis was administered in 263 (58%) study participants. VTE thromboprophylaxis was inappropriately administered to 5 (2.8%) low-risk medical participants and 6 (3%) low-risk surgical participants. The most frequently used anticoagulant for VTE prophylaxis was LMWH in medical, surgical and orthopaedic participants (n=261, 99.7%). Only 1 (0.4%) participant received rivaroxaban. Among the orthopaedic participants, 56 (77%) received VTE thromboprophylaxis, which was higher than among medical and surgical participants ($p<0.006$ and $p<0.001$, respectively). VTE thromboprophylaxis was administered at the appropriate dose in 233 (52%) participants. The administration of dose-appropriate thromboprophylaxis was highest among orthopaedic participants (n=53, 73%), as compared with medical (n=90, 50%, $p<0.001$) and surgical participants (n=90, 46%, $p<0.001$). According to the modified Caprini risk assessment model, 146 (73.7%) participants at high risk in the study group received thromboprophylaxis (Fig. 4A). Among orthopaedic, medical and surgical participants at high risk (score >2), the use of recommended thromboprophylaxis was 79% (n=56), 68% (n=82) and 59% (n=86), respectively ($p<0.012$). (Figs 4B - D). Thromboprophylaxis was increasingly administered in high-risk orthopaedic participants as compared with surgical participants ($p<0.004$).

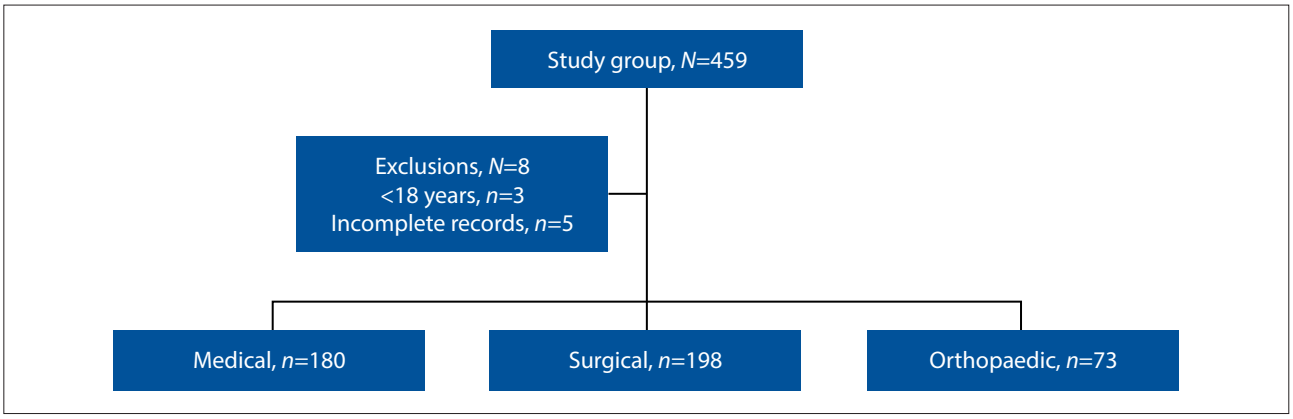

Fig. 1. Flow of study participants.

Table 1. Baseline characteristics according to hospital unit

Characteristic	Total, *n*=451	Medical, *n*=180 (40%)	Surgical, *n*=198 (44%)	Orthopaedic, *n*=73 (16%)	*p*-value
Age at study entry (years), *n* (%)					0.660
18 - 40	178 (39.0)	72 (40.0)	77 (38.9)	29 (39.7)	
41 - 60	174 (38.6)	65 (36.1)	76 (38.4)	33 (45.2)	
61 - 75	81 (18.0)	37 (20.3)	35 (17.7)	9 (12.3)	
>75	18 (4.0)	6 (3.3)	10 (5.1)	2 (2.7)	
Sex, *n* (%)					0.035
Male	251 (55.6)	88 (48.9)	123 (62.1)*	40 (54.8)	
Female	207 (44.4)	92 (51.1)	75 (37.9)	33 (45.2)	
VTE thromboprophylaxis, *n* (%)	263 (58.3)	105 (58.3)	102 (51.0)**	56 (76.7)*	<0.001
Appropriate VTE thromboprophylaxis dose, *n* (%)	233 (51.7)	90 (50.0)**	90 (45.5)**	53 (72.6)	0.002

VTE = venous thromboembolism.
*p<0.01 v. medical; **p<0.001 v. orthopaedic.

Table 2. Caprini risk-assessment model for study group, according to risk score

Risk	Total, *n*=451	Medical, *n*=180 (40%)	Surgical, *n*=198 (44%)	Orthopaedic, *n*=73 (16%)
Low (0 - 1), *n* (%)	47 (10.4)	29 (61.7)	18 (38.3)	0
Middle (2), *n* (%)	67 (14.9)	31 (46.3)	34 (50.7)	2 (3.0)
High (3 - 4), *n* (%)	139 (30.8)	63 (45.3)	66 (47.5)	10 (7.2)
Super high risk (≥5), *n* (%)	198 (43.9)	57 (28.8)	80 (40.4)	61 (30.8)

Table 3. Participant characteristics according to Caprini risk scores

		Caprini risk score			
Characteristics	Total, *n* (%)	Low (0 - 1), *n* (%)	Middle (2), *n* (%)	High (3 - 4), *n* (%)	Super high risk, (≥5), *n* (%)
Demographics					
Age at study entry (years), *n* (%)					
18 - 40	178 (39.5)	43 (91.5)	39 (58.2)	42 (30.2)	54 (27.3)
41 - 60	174 (38.6)	4 (8.5)	24 (35.8)	67 (48.2)	79 (39.9)
61 - 75	81 (18.0)	-	4 (6.0)	27 (19.4)	50 (25.3)
>75	18 (4.0)	-	-	3 (2.2)	15 (7.6)
Sex, *n* (%)					
Male	200 (44.4)	22 (11.0)	32 (16.0)	57 (28.5)	89 (44.5)
Female	251 (55.7)	25 (10.0)	35 (52.2)	82 (59.0)	109 (55.1)

Recommended thromboprophylaxis was administered in 85% of participants with stroke or paralysis, 83% of participants with a history of elective major surgery (2 - 3 hours), 90% of participants with serious trauma and 90% of participants with pelvis or leg fracture within the last month (Fig. 5).

Comparison with Wave 1 and 2 studies

The proportions of medical and surgical participants at high VTE risk were similar in this study to the Wave 1 and/or 2 studies (Table 5). The proportion of medical participants receiving VTE prophylaxis was non-significantly lower in this study in comparison with the

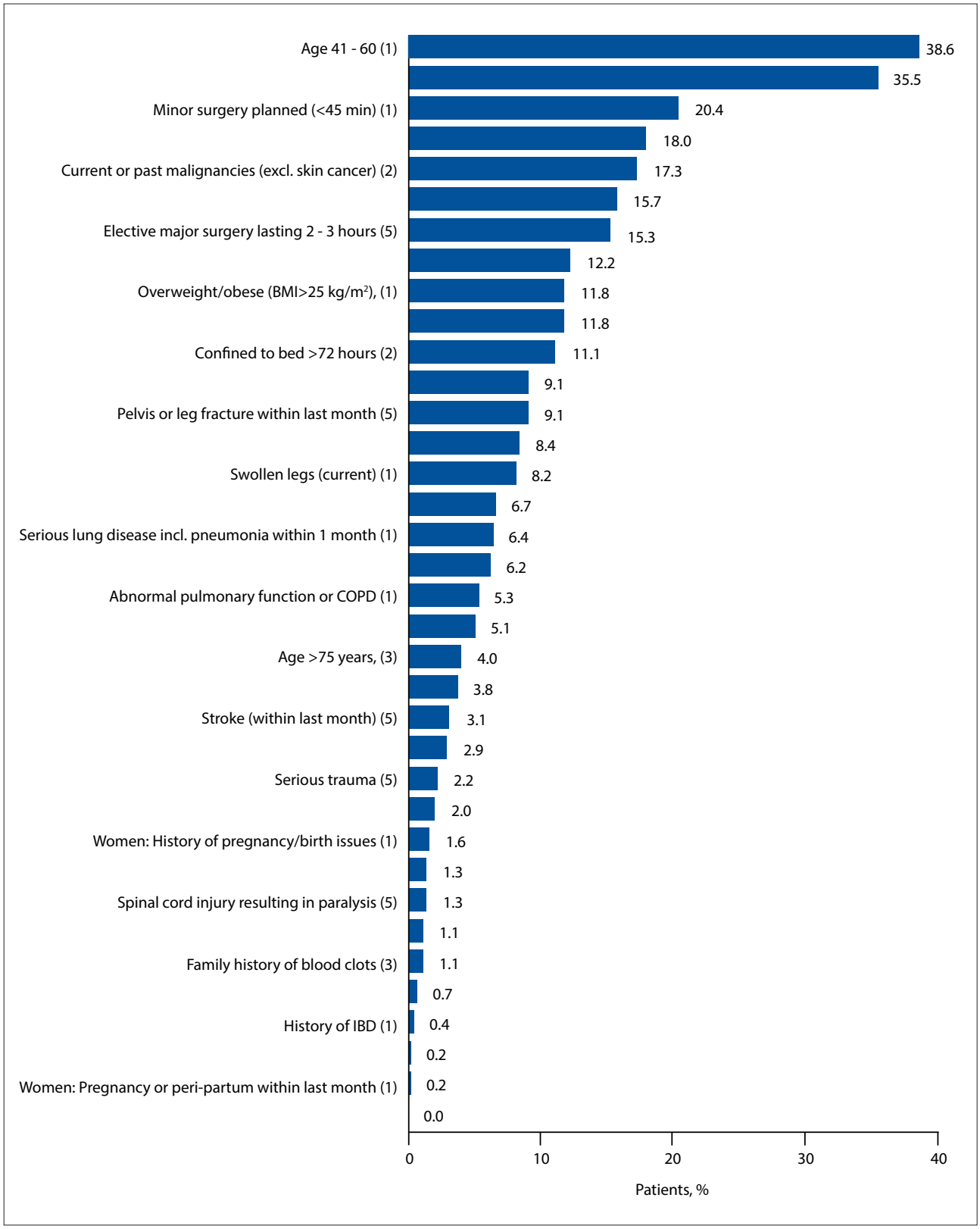

Fig. 2. Frequency of VTE risk factors (according to the Caprini risk assessment model) in study group, N=*451. (BMI = body mass index; COPD = chronic obstructive pulmonary disease; HRT = hormone replacement therapy, DVT = deep vein thrombosis; PE = pulmonary embolus; MI = myocardial infarction; IBD = inflammatory bowel disease; CVC = central venous catheter; PICC = peripherally inserted central catheter).*
**Risk score in parentheses.*

Table 4. IMPROVE bleeding risk assessment for participants at high risk of bleeding according to Caprini risk scores

Caprini risk score	Total, *n*=22	Medical, *n*=9 (41%)	Surgical, *n*=13 (59%)	Orthopaedic, *n*=0
Low (0 - 1), *n* (%)	1 (45)	1 (11)	0	0
Middle (2), *n* (%)	3 (14)	1 (11)	2 (15)	0
High (3 - 4), *n* (%)	9 (41)	6 (67)	3 (23)	0
Super high risk (≥5), *n* (%)	9 (41)	1 (11)	8 (62)	0

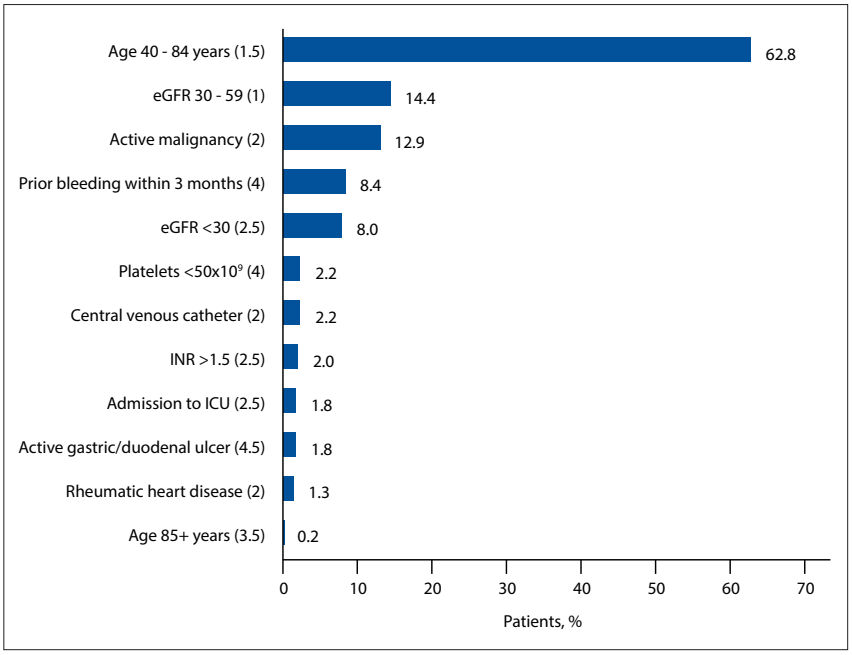

Fig. 3. Frequency of bleeding risk factors in the study group according to the IMPROVE bleeding risk score, N=*451). (eGFR = estimated glomerular filtration rate; INR = international normalised ratio; ICU = intensive care unit.)*

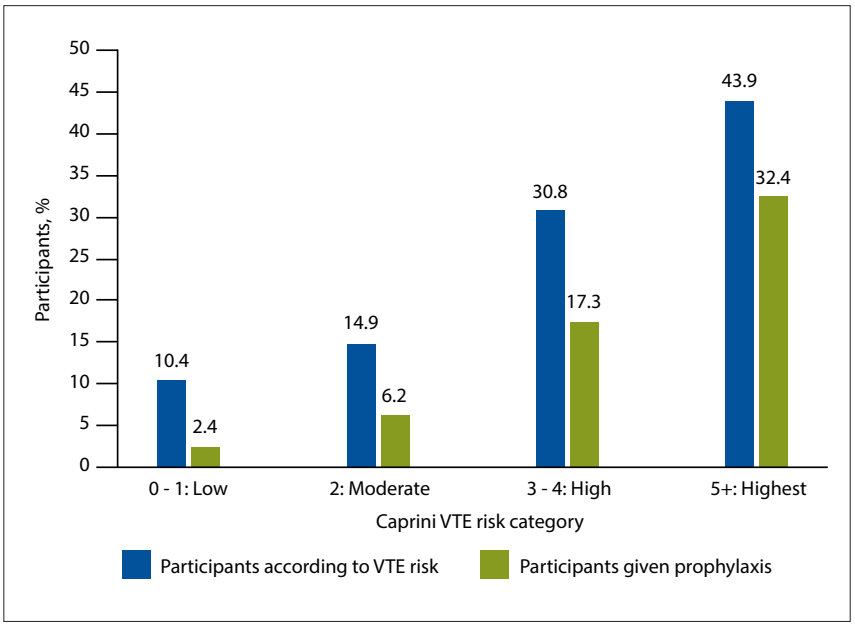

Fig. 4A. VTE prophylaxis administered in study group according to Caprini risk assessment, N=*451. (VTE = venous thromboembolism.)*

Wave 1 study. The proportion of surgical participants receiving VTE prophylaxis was lower in this study than in the Wave 2 study ($p<0.001$).

Discussion

In this large, prospective study of the public sector, we observed a low rate (58%) of VTE thromboprophylaxis. Additionally, rates of recommended VTE thromboprophylaxis in accordance with the ACCP guidelines[6] were low (52%). These findings are consistent with the earlier ENDORSE international study. The rates of recommended thromboprophylaxis in the present study were significantly higher for orthopaedic participants (73%), followed by medical (50%) and surgical participants (46%).[10] Major orthopaedic surgeries, including lower-limb fracture repair, and total hip and knee arthroplasty, are well-recognised risk factors for VTE. It is noteworthy that, despite ongoing debates regarding the choice of preventive agents, LMWH was the most commonly used option in this setting.[14] In keeping with reports in the literature, the present study shows an ongoing concern regarding the use of evidence-based thromboprophylaxis for hospitalised patients.

The Caprini risk assessment tool was applied to the study population. This revealed that a high proportion (75%) of the study population had a VTE risk score >2. Thromboprophylaxis rates, as recommended by the Caprini risk assessment tool,[9] were significantly higher among orthopaedic participants (79%), followed by medical (68%) and surgical participants (59%). Specifically, in medical participants, recommended thromboprophylaxis was administered in >75% with neurological conditions, including stroke or paralysis; pulmonary disease, including serious lung disease and chronic obstructive pulmonary disease; and cardiovascular disease, including acute myocardial infarction and congestive heart failure. Among surgical participants, recommended thromboprophylaxis was administered in >80% for elective major surgery (2 - 3 hours) and serious trauma. Among orthopaedic participants, recommended thromboprophylaxis was administered in >90% for pelvis or leg fracture within the last month, and serious trauma. A small proportion of participants (5%) had a high bleeding risk score (≥7)

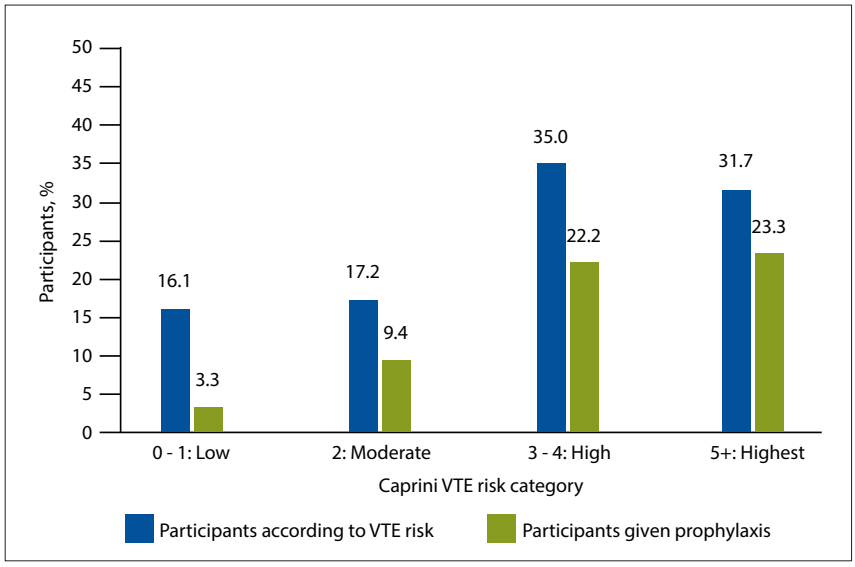

Fig. 4B. VTE prophylaxis administered in medical participants according to Caprini risk assessment, N=180. (VTE = venous thromboembolism.)

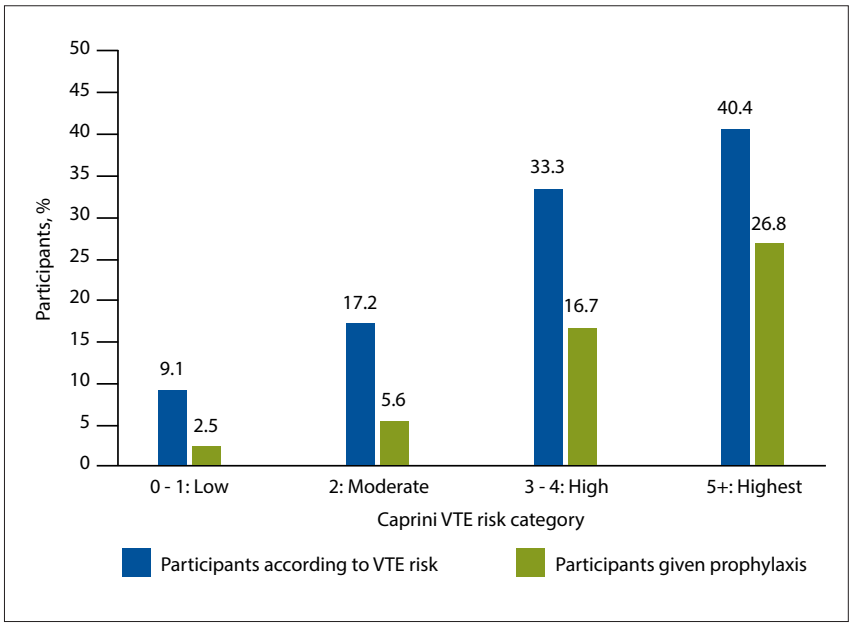

Fig. 4C. VTE prophylaxis administered in surgical participants according to Caprini risk assessment, N=198. (VTE = venous thromboembolism.)

based on the IMPROVE risk assessment tool, which suggests that bleeding risk was not the primary factor behind the low rates of thromboprophylaxis. This study observed lower rates of thromboprophylaxis among participants with the following risk factors: malignancy, obesity, smoking, sepsis, and diabetes requiring insulin. Nonetheless, these represent small numbers, which limit the statistical power for subgroup analysis. Further studies are warranted to validate these findings.

The findings of the Wave 3 study are consistent with the earlier Wave 1 and 2 studies.[12,13] Firstly, a similar proportion of medical and surgical participants at high VTE risk were observed compared with the Wave 1 and 2 studies. In the Wave 3 study, medical participants at high risk accounted for 67.0%, surgical participants at high risk accounted for 74.0% and, as expected, orthopaedic participants at high risk accounted for 97.0%. The high proportion of at-risk participants highlights the importance of conducting such a study. Secondly, we observed no significant difference in the proportion of medical participants at high risk who received VTE prophylaxis in comparison with the Wave 1 study. In the Wave 3 study, only 68% of high-risk medical participants received VTE prophylaxis, with a notable disparity observed in certain high-risk categories, e.g. malignancy, that were less likely to receive appropriate prophylactic measures. Of further concern, the proportion of surgical participants at high risk receiving VTE prophylaxis was significantly lower in this study in comparison with the Wave 2 study, which compared both the private and public sectors. These findings suggest that VTE risk may be underestimated by surgeons in clinical practice in certain types of surgeries. Moreover, there may

Table 5. Comparison of thromboprophylaxis characteristics between Caprini high-risk participants in the Wave 1, 2 and 3 studies[1,2]

	Wave 1 study	Wave 2 study	Wave 3 study	*p*-value
Study participants, *n*	608	453	451	
Caprini high-risk score (score >2)				
Medical participants, *n* (%)	154 (70)	-	120 (67)	0.923
Surgical participants, *n* (%)	328 (84)*	372 (82)	146 (74)	0.086
Orthopaedic participants, *n* (%)	-	-	71 (97)	-
VTE thromboprophylaxis (score >2)				
Medical participants, *n* (%)	119 (77)	-	82 (68)	0.097
Surgical participants, *n* (%)	223 (68)	349 (94)	86 (59)	<0.001
Surgical participants (public sector), *n* (%)	-	95 (86)**	86 (59)	<0.001
Orthopaedic participants, *n* (%)	-	-	56 (79)	-

*Includes orthopaedic participants.
**Of 110 participants.

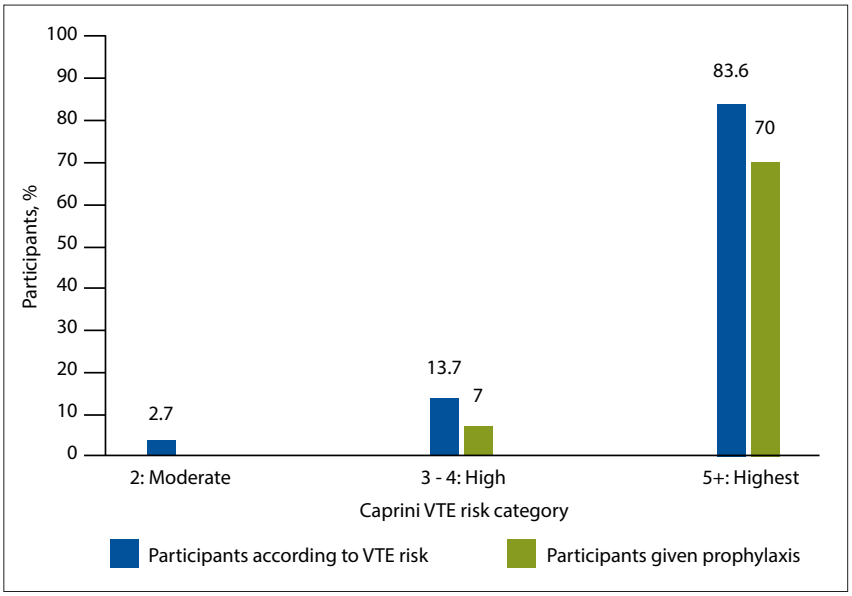

Fig. 4D. VTE prophylaxis administered in orthopaedic participants according to Caprini risk assessment, N=73. (VTE = venous thromboembolism.)

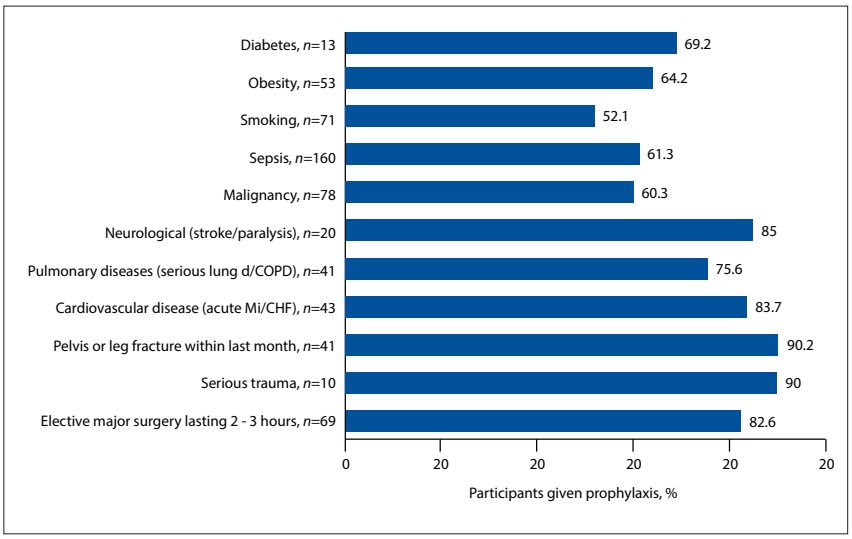

Fig. 5. Recommended VTE prophylaxis administered according to clinical condition. (CHF = chronic heart failure; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; serious lung d = serious lung disease.)

be hesitancy around administering prophylaxis postoperatively due to concerns about bleeding complications. Cases with multiple comorbidities add further complexity, as factors such as renal impairment, liver dysfunction and abnormal platelet counts can significantly influence bleeding risk. This highlights the importance of implementing standardised risk assessment tools such as the Caprini and IMPROVE models.

There are several limitations to this study. Firstly, this was a cross-sectional study, and as such, the length of stay was only recorded in 45% of participants. While length of hospital stay is not included in the Caprini risk assessment model, future studies are warranted to correlate length of stay and VTE risk post discharge, in particular in medical patients. Furthermore, only postoperative VTE thromboprophylaxis was prescribed to surgical and orthopaedic participants, which may have underestimated the rates of thromboprophylaxis in the study group. Secondly, it was not possible to perform a bleeding risk assessment according to the IMPROVE bleeding risk score in 143 (32.0%) participants who did not have a prothrombin time test performed. In hospitalised patients at low risk of bleeding, routine prothrombin time test testing as an assessment of liver function may negatively contribute to healthcare costs. Thirdly, medical participants from the intensive care unit (ICU) were under-represented (*n*=8, 2.0%), despite the hospital ICU capacity of 55 beds. Critically ill ICU participants were unable to give informed consent to participate in the study. Orthopaedic participants were also under-represented, owing to fewer hospital admissions during the study period, which may introduce bias. At CMJAH there are 330 medical and 360 surgical beds, as compared with 180 orthopaedic beds. Lastly, data on HIV status were not collected for this study population, despite a high burden of infection. According to a study of postoperative surgical patients at Universitas Academic Hospital, HIV status alone did not influence the decision to administer postoperative VTE prophylaxis.[15] However, more recent updates to the Caprini RAM have included HIV as a risk factor.[16] This inclusion reflects increasing evidence that chronic inflammation, immune dysregulation and endothelial activation associated with HIV infection predispose to thrombosis.

In conclusion, this study confirms the significant gap between evidence-based thromboprophylaxis recommendations and clinical practice in a large sample of hospitalised medical, surgical and orthopaedic participants. A considerable proportion of participants in this study were at high risk of VTE. Nonetheless, recommended VTE thromboprophylaxis was only prescribed in approximately half of the participants at high risk of VTE. Future studies are warranted to investigate the underlying factors contributing to the decline in VTE prophylaxis use. Understanding these barriers – whether related to clinical decision-making, patient characteristics, institutional protocols, or resource limitations – will be essential in identifying gaps in practice. Such insights can help to improve adherence to prophylaxis guidelines, particularly among high-risk patient populations. It is recommended that an institutional VTE risk assessment tool be implemented to standardise risk evaluation and improve the administration of adequate thromboprophylaxis for hospitalised patients.

Data availability. The data is available from the authors on request.

Declaration. This study was undertaken by Dr Jason Bassett as part of the requirements for the Masters of Medicine (MMed) degree in Internal Medicine at the University of the Witwatersrand.

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Author contributions. JB was responsible for study design, data collection and analysis and

writing the manuscript. ES contributed to study design, data analysis, writing and editing the final manuscript. BJ conceptualised the study and contributed to study design and editing of the final manuscript.

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Conflicts of interest. None.

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