

## Original Research Article

# Incidence, Predictors and Outcome of Venous Thromboembolism among Patients Undergoing Major Surgical Procedures at Bugando Medical Centre, Mwanza, Tanzania

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**Abstract: Background:** Venous thromboembolism (VTE) is the leading cause of morbidity and mortality worldwide among patients undergoing surgical procedures. This study aimed to determine the incidence, predictors, and outcome of VTE among patients undergoing major surgical procedures at Bugando Medical Centre (BMC). **Methods:** A descriptive longitudinal study involving 381 participants was conducted from February 2020 to July 2020 at BMC. Patients with a high modified Caprini and modified Wells score underwent doppler ultrasound and computed tomography pulmonary angiogram to confirm presence of VTE. Post mortem was performed on participants who succumbed to death prior to these investigations. Categorical variables significance calculated using Chi-square and Fisher's exact tests. Cox regression analysis was used to determine the predictors. Kaplan-Meier survival curve used to depict the occurrence of VTE. **Results:** The cumulative incidence of VTE was 11.8%. Age  $\geq 45$  years, body mass index  $\geq 25$ , hypertension and prolonged immobilization were significant predictors of VTE. Around 43.0% (n=164) were postoperatively classified as having a high risk of developing VTE. Of these, 27.7% (n=45) developed VTE (p<0.001) of which 14 patients died resulting in a mortality rate of 31.1%, and the mortality was significantly associated with males (p=0.013). Only 17.7% (n=29) of high-risk patients received VTE prophylaxis, however, prophylaxis was protective against development of VTE (p=0.023). **Conclusion:** Venous thromboembolism is not uncommon among postoperative patients and is associated with high mortality rate. Appropriate VTE screening and prophylaxis is of paramount importance in order to lower VTE morbidity and mortality.

**Keywords:** Venous thromboembolism, deep venous thrombosis, pulmonary embolism.

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## INTRODUCTION

Venous thromboembolism (VTE) represents a broad spectrum of disease, ranging from deep venous thrombosis (DVT) to pulmonary embolism (PE) which is a common complication following surgical procedures [1]. VTE is the leading cause of morbidity and mortality worldwide among patients undergoing surgical procedures with an annual incidence ranging from 0.75 to 2.69/1000 individuals [2]. The overall incidence of DVT following surgery in Africa ranges between 2.4% and 9.6% [1, 3-5]. In Sub-Saharan Africa, the incidence of postoperative DVT was reported to be 2.4%, 5%, and 9.6% in Nigeria, Uganda and Sudan [3-5]. Data on the incidence of postoperative PE in Africa is limited, a study done in Nigeria reported the mortality rate of PE as 60% among postoperative

neurosurgical patients [3]. In Tanzania, a study on prophylaxis practice and incidence of DVT among patients operated for hip fracture, showed that the incidence of DVT was 6.1% [6]. VTE is a multifactorial condition resulting from a complex interaction between genetic predispositions and acquired risk factors, leading to thrombosis and, subsequently, embolism [7]. Patients undergoing major surgery are at particular risk for VTE because major operations induce an inflammatory response and a hypercoagulable state, and necessarily create an endothelial vascular insult. Furthermore, the tendency for patients to limit mobilization due to postoperative pain may predispose to venous stasis [7]. The risk of DVT and PE after surgery is substantially increased within the first 4-6 weeks postoperatively and varies considerably by type of surgery [8,9]. Other commonly encountered risk

factors include older age, cancer, trauma, obesity, sepsis, and inherited coagulopathies [5,7–9].

The predictors of VTE in surgical patients varies according to patient-related factors and procedure-related factors [9]. The risk for VTE in surgical patients has been noted to be as high as 59% [1,7]. VTE prophylaxis has been reported to reduce the risk of VTE among surgical patients undergoing major operation [10–12]. Appropriate use of thromboprophylactic agents in high-risk individuals has the advantage of reducing morbidity and mortality and hospital stay. [11]. VTE prophylaxis remains underutilized in African hospitals, with at least one-quarter of patients at risk for VTE not receiving prophylaxis [1, 10, 12] which could explain the high incidence and fatality rate of VTE in Africa.

Although VTE has increasingly been recognized as a leading preventable cause of morbidity and sudden death worldwide [1, 2], still little information is available regarding this subject in Tanzania. Therefore this study aimed to determine the incidence, predictors, and outcome of venous thromboembolism among patients who underwent major surgeries at Bugando Medical Centre.

## MATERIALS AND METHODS

### Study Design and Setting

A descriptive longitudinal study carried out from February 2020 to July 2020 at the Emergency and Surgical Clinics and Wards of Bugando Medical Centre.

### Study Participants

An average of 2853 major surgical procedures are done quarterly at BMC.

The sample size was 381 participants calculated using the Yamane Taro formula [15];  $n = N/[1+N(e)^2]$

Where  $n$  = sample size,  $N$  = population under the study (2853),  $e$  = error margin (0.05)

All patients aged 18 years and above who underwent major surgery were included in the study. Patients who had concurrent VTE were excluded. Convenience sampling technique was used.

### Data Collection

All patients who met the inclusion criteria, signed a written informed consent and were consecutively included until sample size was reached.

Modified Caprini and Modified Wells score was used to risk categories patients and those with a score of  $>5$  and  $>6$  respectively were subjected to Doppler ultrasound (DUS) and Computed Tomography Pulmonary Angiography (CTPA). Participants who succumbed before these investigations underwent a post mortem to identify the cause of death. The pretested data sheet had the following variables; clinical presentation (unilateral or bilateral lower limb swelling, pain/tenderness, warm skin and bluish or reddish skin coloration around the affected area, chest pain, difficulty in breathing, coughing, hemoptysis, tachypnea, tachycardia and hypotension, preoperative characteristics (e.g. associated medical co-morbidities, body mass index, HIV status and prior history of VTE), Intra-operative characteristics (e.g. type of surgical procedure, type of anesthesia and duration of operation), Postoperative characteristics (e.g. duration of postoperative immobilization, duration to onset of VTE). The participants were followed up to the fourth week post operatively. Standard radiologic criteria were used to make a diagnosis of DVT or PE and during autopsy demonstration of adherent thread of thrombus in the right atrium and/or pulmonary arteries, with haemorrhagic edematous lungs were confirmatory for PE.

### Statistical Analysis

Data was analyzed using STATA version 13. The median with Interquartile Range (IQR), p-values were computed for categorical variables using Chi-square and Fisher's exact tests ( $p < 0.05$  being significant). Cox regression analysis was used to determine the predictors VTE and Kaplan-Meier survival curve to depict the occurrence of VTE.

### Ethical Consideration

Approval to conduct the study was sought from the Joint CUHAS/BMC Ethics and Review Committee (No. CREC/421/2020). Written informed consent was signed by all participants before recruitment into the study. Patient's refusal to consent or withdraw from the study did not alter or jeopardize their access to standard medical care at BMC. Confidentiality was maintained by using anonymous codes throughout the study.

## RESULTS

### Socio-demographic and clinical characteristics

A total of 381 patients were recruited into the study as shown in Table 1.

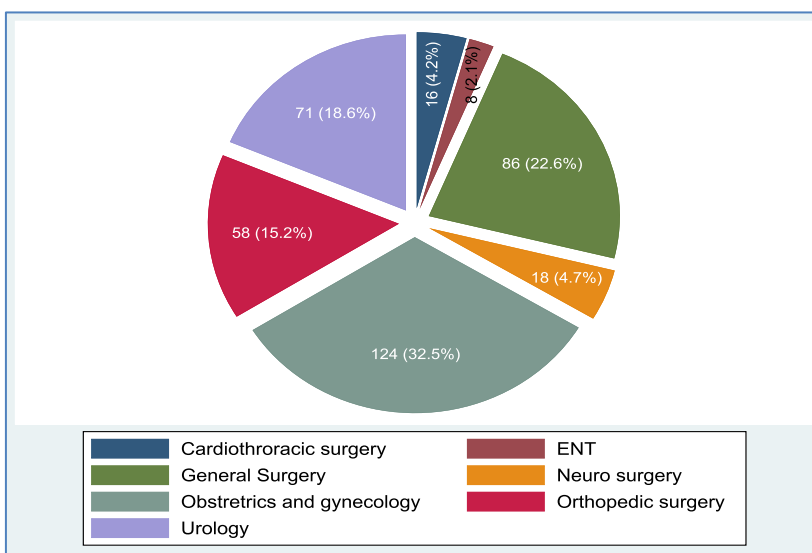
**Table-1: Socio-demographic and clinical characteristics**

Variable	Frequency (n=381)	Percent (%)
<b>Age in years</b>		
18-45	234	61.4
46-65	71	18.6
>65	76	20
<b>Gender</b>		
Male	182	47.8
Female	199	52.2
<b>Pre-existing medical illness</b>		
Yes	161	42.2
No	220	57.8
<b>BMI</b>		
Underweight<18.5	2	0.5
Normal 18.5-24.9	284	74.5
Overweight 25.0-29.9	60	15.7
Obesity>30	35	9.2
<b>HIV status</b>		
Reactive	35	9.2
Non-reactive	346	90.8
<b>History of smoking</b>		
Yes	36	9.5
No	345	90.5
<b>History of oral contraceptive use</b>		
Yes	80	20.0
No	301	80.0
<b>Prior history of VTE</b>		
Yes	2	0.5
No	379	99.5

**Major Surgeries Distribution**

Obstetrics and gynaecology had the number of highest participants at 32.5% (n=124) followed by General Surgery 22.6% (n=86) while Ear Nose Throat

Surgery (ENT) had the least participants as shown in Figure 1 below. The duration of surgical procedures ranged from 1 to 6 hours.



**Fig-1: Major Surgeries Distribution**

**Post-operative Risk of VTE**

Using modified Caprini and modified Wells score, 43.0% (n=164) patients were postoperatively

classified as having a high risk of developing VTE. Of these, 27.7% (n=45) went on to develop VTE (p<0.001) as shown in Table 2 below.

**Table-2: Post-operative Risk of VTE and VTE Occurrence**

Risk	VTE		p-value
	Yes	No	
High	45(27.4%)	119(72.6%)	<b>&lt;0.001</b>
Low	0(0.0%)	217(100.0%)	

All patients at high risk of developing VTE (n=164) were eligible for initiation of VTE prophylaxis with the low molecular weight heparin until fully ambulatory, however, only (17.7%, n=29) high-risk

patients received VTE prophylaxis which was shown to be protective (Table 3) against VTE occurrence (p=0.023).

**Table-3: Post-operative VTE Prophylaxis and VTE Occurrence**

Prophylaxis	VTE		p-value
	Yes	No	
Yes	3(6.7%)	42(93.3%)	<b>0.023</b>
No	26(21.8%)	93(78.2%)	

**Incidence of VTE**

Out of 381 patients enrolled, 45 patients developed VTE giving a cumulative incidence of 11.8%. Of which, 64.4% (n=29) had DVT only, 28.9% (n=13) had PE and 6.7% (n=3) had both PE and DVT.

**Predictors of VTE**

Factors associated with VTE during the study period among 381 patients included as shown in

**Table-4: Predictors of VTE on univariate and multivariate Cox Regression Analysis (n=381)**

Variables	VTE		Analysis			
	Yes	No	Univariate		Multivariate	
	n (%)	n (%)	HR[95% CI]	p-value	HR[95% CI]	p-value
<b>Age (years)</b>						
≤45	19 (8.1)	215(91.9)	1.0	<b>0.007</b>	1.7[1.2-5.4]	<b>0.020</b>
>45	26(17.7)	121(82.3)	2.2[1.2-4.1]			
<b>BMI</b>						
Normal <25	28(9.8)	258(90.2)	1.0	<b>0.040</b>	1.9[1.0-3.4]	<b>0.040</b>
Overweight ≥ 25	17(17.9)	78(82.1)	1.8[1.0-3.4]			
<b>HIV infection</b>						
Non-Reactive	37(10.7)	309(89.3)	1.0	<b>0.030</b>	1.4 [0.7 – 3.3]	0.300
Reactive	8(22.9)	27(77.1)	2.5 [1.1 – 5.0]			
<b>Immobilization days</b>						
< 14	22(6.7)	304(93.3)	1.0	<b>&lt;0.001</b>	6.4[3.5-11.7]	<b>&lt;0.001</b>
14-28	23(41.8)	32(58.2)	7.4 [4.1 - 13.4]			
<b>Co-morbidities</b>						
<b>Hypertension</b>						
No	25(7.9)	292(92.1)	1.0	<b>&lt;0.001</b>	2.6[1.3 – 5.2]	<b>0.006</b>
Yes	20(31.3)	44(68.7)	4.3[2.4 - 7.8]			
<b>Diabetes Mellitus</b>						
No	37(10.3)	321(89.7)	1.0	<b>&lt;0.001</b>	0.9[[0.4 – 2.2]	0.802
Yes	8(34.8)	15(65.2)	3.9[1.8 – 8.4]			
<b>Cancer</b>						
No	37(11.4)	281(88.4)		0.795		
Yes	8(12.7)	55(87.3)	1.1[0.5 – 2.4]			

**Key:** BMI= Body Mass Index; CI=Confidence Interval; HR=Hazard Ratio; HIV=Human Immunodeficiency Virus

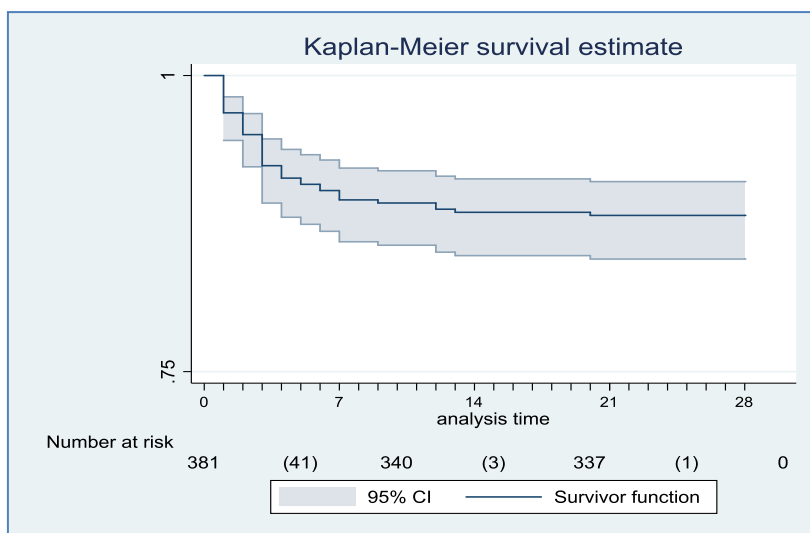
**Outcome of VTE**

Fourteen (31.1%) out of 45 patients with VTE died. 4 of 5 patients with VTE who died before radiological investigation, revealed evidence of VTE at autopsy. Mortality was significantly associated with

gender with males having a higher mortality (p=0.013). The Kaplan-Meier Survival Curve in Figure 2 below suggests that during follow-up (28 days) the risk of VTE occurrence was very high on day 1, then dropped gradually until day 14 where it plateaued till day 28.

**Table-5: Predictors of mortality among patients with VTE (n=45)**

Variable	Death		p-value
	Yes	No	
	n (%)	n (%)	
<b>Age</b>			
≤45	4 (21.1)	15 (78.9)	0.213
>45	10 (38.5)	16 (61.5)	
<b>Gender</b>			
Male	11 (47.8)	12 (52.2)	<b>0.013</b>
Female	3 (13.6)	19 (86.4)	
<b>Smoking</b>			
Yes	3 (50.0)	3 (50.0)	0.36
No	11 (28.2)	28 (71.8)	
<b>Contraceptives use</b>			
Yes	3 (27.3)	8 (72.7)	0.149
No	11 (32.4)	23 (67.6)	
<b>BMI</b>			
Normal <25	9 (33.3)	18 (16.7)	0.693
Overweight ≥ 25	5 (27.8)	13 (72.2)	
<b>HIV infection</b>			
No	10 (27.0)	27 (73.0)	0.195
Yes	4 (50.0)	4 (50.0)	
<b>Nature of Surgery</b>			
Elective	8 (42.1)	11 (57.9)	0.173
Emergency	6 (23.1)	20 (76.9)	
<b>Types of anesthesia</b>			
General	5 (33.3)	10 (66.7)	0.820
Regional	9 (30.0)	21 (70.0)	
<b>Immobilization days</b>			
<14	13 (33.3)	26 (66.7)	0.382
14-28	1 (16.7)	5 (83.3)	
<b>Prophylaxis</b>			
Yes	2 (25.0)	6 (75.0)	0.518
No	12 (32.4)	25 (67.6)	



**Fig-2: Kaplan-Meier Survival Curve: VTE event occurrence risk against time**

**DISCUSSION**

Venous thromboembolism is a well-known complication following major surgery [1]. In this study, the cumulative incidence of VTE was 11.8%, higher

than that reported in other studies [3–5]. The study from Sudan used 125 I-fibrinogen test which is less reliable in diagnosing venous thrombosis [16, 17], this may have resulted to its low incidence compared to this

study which used Doppler Ultrasound. The incidence of VTE in Africa appears to be lower than what has been found in most studies performed in the US population of African origin, probably due to underreporting of VTE, poor diagnostic techniques, and low incidence of inherited thrombophilia [1].

In this study, 43% were at high risk of developing VTE but only 17.7% received prophylaxis against VTE this may have contributed to the higher VTE incidence.

Majority (57.8%) of VTE patients were 45 years and older similar to other studies which showed that patients 40 years and older are at significantly high risk of developing VTE and the risk doubles every decade or following major surgical procedures [14,18-20]. Many mechanisms such as decrease mobility which leads to venous stasis and blood pooling, underlying co-morbid conditions and decreased activity of the fibrinolytic system have been proposed to explain why advancing age increases the risk of developing VTE [7].

High body mass index (BMI) was strongly associated with VTE occurrence postoperatively in this study, similar to other previous studies [17]. A high BMI has been associated with decreased levels of antithrombin III and fibrinolytic activity [21,22].

The overall HIV seroprevalence among the study participants in this study was 9.2% higher than that of the Tanzania general population at 5% [23]. This study showed that 22.9% of patients with VTE were HIV seropositive. HIV did not significantly predict the occurrence of VTE among patients undergoing major surgery. HIV has been reported in several studies as the main risk factor for postoperative VTE among patients undergoing major surgery [24, 25].

Prolonged immobilization of more than two weeks following major surgery in this study was a major predictor of an increased risk of VTE similar to previous the studies due to increased venous stasis [26, 27].

Only 17.7% of high risk postoperative patients in this study received VTE prophylaxis suggesting that the use of VTE prophylaxis against VTE is not a common practice in our resource limited setting as has been reported previously [1]. Only 10.3% (n=3) of the high risk postoperative patients demonstrating VTE prophylaxis key prevention role. This is supported by many studies which shows that VTE prophylaxis with LMWH reduces the risk of VTE among surgical patients by >60% [10, 12, 28, 29].

Co-morbidities such as Hypertension were also strongly associated with occurrence of VTE while Diabetes mellitus had a weak association (Table 4). In a meta-analysis of 21 studies with a total of 63,552

patients undergoing major surgery showed that VTE risk was higher in the presence of cardiovascular risk factors, which included obesity, hypertension, diabetes mellitus, tobacco smoking, and hypercholesteremia [21, 24, 30-33].

In the present study, mortality rate among patients with VTE was 31.1% of which majority (57.1%) was due to PE alone almost analogous to a Nigerian study reported a mortality rate of 60% among postoperative patients [3]. The higher mortality rate is a reflection of African resource limited settings demonstratable in this study we were unable to screen for asymptomatic VTE as well as hypercoagulable disorders which may have influenced the study results.

## CONCLUSION

Venous thromboembolism is not uncommon among postoperative patients and is associated with high mortality rate. Appropriate VTE screening and prophylaxis is of paramount importance in order to lower VTE morbidity and mortality.

## ACKNOWLEDGMENT

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## Conflict of Interest

All authors declare no conflict of interest.

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