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DEEP VENOUS THROMBOSIS PROPHYLAXIS, STANDARDS AND PRACTICES.

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ABSTRACT

BACKGROUND: Deep venous thrombosis is life life-threatened critical vascular condition in which the formation of blood clots occurs in deep veins, especially in lower limbs that may lead to pulmonary embolism and post-thrombotic syndrome. Despite standardized guidelines and protocols for the assessment of DVT risk and its prophylaxis, utilization remained suboptimal, especially in developed or underdeveloped countries **OBJECTIVE:** The current study aimed to evaluate current practices regarding DVT risk assessment by using the Caprini Risk Assessment Model (RAM) in hospitalized patients. Moreover, it also aimed to investigate the implementation of prophylaxis. **METHODS AND MATERIAL:** A prospective clinical study was held in two phases across multiple wards of tertiary care hospitals (Prime Teaching Hospital & Kuwait Teaching Hospital) in Peshawar. A total of 271 patients were recruited in Phase I and 340 patients in Phase II. Healthcare professionals received education about the dangers of DVT and the significance of prompt prophylaxis. Posters were also displayed in the ward for underlining the necessity of VTE prophylaxis. Data was collected through a structured checklist based on Caprini RAM protocols and SPSS v.22 was used for data analysis. **RESULTS/FINDINGS:** The findings revealed that in both phases of the clinical study, the majority of patients were observed to be at moderate risk followed by a high risk of DVT. Preoperative risk assessment was conducted for 84.1% of patients in Phase I and 86,2% in Phase II but a small percentage of patients received prophylaxis in the first phase (22.1%). Then in the second phase of study, a significant improvement was observed up to 56.5%. Regarding the type of prophylaxis, mechanical prophylaxis was a commonly used intervention in both phases. **CONCLUSION:** Significant improvements observed in phase II highlighted the potential of structured interventions and also enhanced awareness among health care providers. Furthermore, it may benefit patients' quality of life and overall, well-being by reducing the burden of complications associated with DVT.

KEYWORDS: Intermittent Pneumatic Compression, Prophylaxis, Thrombosis, Pressure stocking, venous thromboembolism

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INTRODUCTION

Deep venous thrombosis (DVT), is a serious obstructive medical ailment of vascular origin in which blood clots are frequently formed within the deep veins of the lower limbs of an individual. It is a multi-causal condition that poses a significant increase in adverse health outcomes, induces functional impairments due to post-thrombotic syndrome, and can lead to death due to pulmonary embolism if left untreated[1,2]. Deep venous thrombosis greatly contributes to the disease burden with an estimated occurrence of 80 cases per 100,000 and a frequency of lower limb DVT at 1 per 1000 cases[3]. In the United States, it is markedly observed that more than 200,000 individuals are under the influence of DVT, of whom approximately 50,000 cases suffer from pulmonary embolism [4,5,6].

In DVT, clots usually develop in the deep veins of the calf region but then spread in the proximal direction. Thrombus formation substantially depends on anatomical location, making a specific pattern in which distal calf veins are commonly affected and account for 40% of its occurrence rate, followed by popliteal vein behind the knee for 16%, femoral and common femoral vein in the thigh region by 40%, and by extending further upward in the pelvis region, iliac veins constitute only 4% of cases[7]. Based on risk factors DVT can be classified as provoked and unprovoked, of which provoked DVT has clear and identifiable risk factors. In contrast, unprovoked DVT is idiopathic i.e. without any known risk factors [8]. Risk factors are further classified as genetic or acquired which include patients with inherited thrombophilia, Antithrombin deficiency, Factor XII deficiency, Prothrombin gene mutation, surgeries that involve prolonged post-surgical immobilization particularly orthopedic or neurovascular surgeries, immobilization due to prolonged travel, prior DVT, advancing age, male gender,malignancies associated with hypercoagulability, pregnancy, obesity and overweight, hormone replacement therapy in postmenopausal women, chronic medical condition like stroke, heart failure, sepsis, hematological disorders are responsible for DVT occurrence and reoccurrence [8,9]. DVT is characterized by key signs and symptoms that are uneven and asymmetrical swelling, pain, and warmth in an extremity [10].

Hospitalized patients are generally more prone to develop thrombosis due to one of the following 3 reasons i.e. vessel wall damage, hypercoagulability, and venous stasis moreover failure to accurately assess the risk of DVT could have a huge burden on the healthcare system as well as on the economy with an estimated $20,000 management cost on per patient annually This rising burden calls for the necessity of evidence-based guidelines for the prevention of thrombosis in hospitalized patients. Therefore, organizations in healthcare sectors developed standardized protocols and clinical guidelines for the assessment and prophylaxis of DVT and these guidelines are based on the assessment of risk factors, proper dosage, choice of therapy, and duration of prophylaxis[11,12].

DVT prevention/prophylaxis options can be mechanical and pharmacological therapy which refers to the use of anticoagulant medications. Mechanical therapy includes several options likeanti-embolism stockings, early mobilization, vena cava filters, leg elevation, and intermittent pneumatic compression (IPC) [13]. Selecting appropriate therapy is highly based on risk factor identification that can be done through the Caprini risk assessment model which is the most widely used and valid tool and through the NICE (National Institute for Health and Care Excellence) guidelines [14,15]. Additionally, the American College of Chest Physicians (ACCP)

recommends using Padua and IMPROVE bleeding scores that aid in decision-making. According to ACCPand the SIGN (the Scottish Intercollegiate Guidelines Network) guidelines, prophylaxis treatment with anticoagulants is recommended if the Padua score is ≥ 4 and the IMPROVE bleeding score is < 7 [16, 17].

Several researches have shown that despite the availability of well-defined standardized protocols and guidelines, risk assessment of deep venous thrombosis prophylaxis is often ignored or inadequately practiced in developing countries. This non-compliance can result in increased rates of morbidity and mortality. Moreover, it poses a negative impact on healthcare costs due to prolonged hospital stays and on interventions applied. Therefore, a structured clinical study is conducted that aims to assess and evaluate current practices related to DVT risk assessment, prophylaxis implementation, and documentation accuracy. Additionally, this study also aims to identify gaps in practices, in determining the barriers affecting adherence and will enhance healthcare provider awareness. This study is crucial in ensuring improvement in patient outcomes and quality of life.

Current practice was compared to the Caprini risk assessment model[14] that ensures all hospitalized patients should undergo DVT risk assessment upon admission and prophylaxis using the assessment protocols described in the standard tool.

METHODOLOGY

A prospective clinical study was conducted in two phases from multiple departments including Urology, Gynecology, General Surgery Neurosurgical, and Medical wards of selected tertiary care hospitals including Prime Teaching Hospital (PTH) and Kuwait Teaching Hospital (KTH) in Peshawar. This study was carried out to assess compliance and adherence of DVT prophylaxis to current practices with Caprini (RAM) guidelines, and based on cumulative risk scores, patients were classified into different risk categories, for guiding appropriate prophylaxis decisions. The study population comprised hospitalized patients (a total of 271 in Phase I and 340 patients in Phase II) who were at risk of developing Deep Venous Thrombosis (DVT).

The patients of both genders (male & female), aged >18 years, hospitalized for at least 24 hours, not on anticoagulative therapy, and had no contraindication to medicine-based interventions were included in the study. In contrast, patients<18 years of age, with any contraindications to prophylactic measures [e.g., bleeding disorder, hemorrhagic stroke, hypertension (bp>230/120)], and those who were on pre-existing anticoagulant drugs did not recruit in the inclusion criteria.

Data was collected using a structured study checklist based on Caprini RAM recommendations. For that purpose, a multidisciplinary team, including physicians, medical officers, trained medical officers, internees, and nursing staff reviewed medical records, admission notes, and treatment protocols. Further, Data was analyzed through SPSS software version 22. Descriptive statistics including frequency and percentages were presented in tabularand bar chart form. Ethical approval was obtained from the institutional review board (IRB) and strict precautions on patient confidentiality were ensured.

RESULTS

The dataset in *Table 1* is a comprehensive analysis of demographics obtained from the patients at DVT risk according to the Caprini Risk Assessment Model score in two phases of a study. In Phase I, out of a total of 271 patients, 97(35.8%) patients were from the general surgery ward, followed by the Medicine ward (26.6%), urology (16.2%), surgery (17.0%), gynecology (15.5%), and neurosurgery (5.9%). Whereas in Phase 2, among 340 patients, 82(24.1%) were admitted to the Urology department, followed by the

gynecology 81(23.8), general surgery (23.2%), medicine 72(21.2%), neurosurgery 26(7.6). Age distribution showed that most patients were between 41-60 years old. The distribution of age categories, gender, and BMI is shown in Table 1.

Table 1: Demographic Characteristics

Variable	Category	study phase I	study phase II
		Frequency (%) N=271	Frequency (%) N=340
Age	≤40	97(35.8)	102(30.0)
	41-60	101(37.3)	130(38.2)
	61-74	63(23.2)	100(29.4)
	≥75	10(3.7)	8(2.4)
Gender	Female	136(50.2)	167(49.1)
	Male	135(49.8)	173(50.9)
BMI	Underweight	10(3.7)	12(3.5)
	Normal	205(75.6)	250(73.5)
	Overweight	41(15.1)	56(16.5)
	Obese Class 1	12(4.4)	20(5.9)
	Obese Class 2	3(1.1)	2(0.6)
Hospital	KTH	163(60.1)	206(60.6)
	PTH	108(39.9)	134(39.4)
Unit/Ward	Gynae	42(15.5)	81(24.0)
	Urology	44(16.2)	82(24.1)
	Medicine	72(26.6)	72(21.1)
	General Surgery	97(35.8)	79(23.2)
	Neurosurgery	16(5.9)	26(7.6)

The study findings in *Table 2* represented the risk level of DVT according to Caprini RAM, pre-operative assessment of DVT, and administration of DVT across both phases. The majority of patients reported a moderate level of DVT risk in both phases [phase I = 110(40.6%), phase II = 150(44.1%)], followed by a high risk of DVT [phase I=84(31.0%), phase II= 108(31.8%)]. Pre-operative risk assessment revealed that in phase I, from 271 patients, 228(84.1%) went under risk assessment. The frequency of patients requiring and receiving prophylaxis in both of the phases are shown in table 2.

Table 2: frequency distribution of DVT risk & Prophylaxis

Variable	Category	Frequency (%) N=271	Frequency (%) N=340
DVT Risk Level	Low Risk	77(28.4)	82(24.1)
	Moderate Risk	110(40.6)	150(44.1)
	High Risk	84(31.0)	108(31.8)
Pre-Op Assessment	Not Done	43(15.9)	47(13.8)
	Done	228(84.1)	293(86.2)
Prophylaxis Required	No	100(36.9)	126(37.1)
	Yes	171(63.1)	214(62.9)
Prophylaxis Received	Not Received	211(77.9)	148(43.5)
	Received	60(22.1)	192(56.5)

N=271(phase I), N=340(phase II), DVT=Deep Venous Thrombosis, pre-op=preoperative

Table 3 illustrates the type of prophylaxis used in both phases of clinical study for preventing DVT, which was categorized into mechanical prophylaxis, pharmacological prophylaxis, and a combination of both mechanical and pharmacological. It was observed that in phase I, out of 271 patients, 41 patients

received mechanical prophylaxis including TED stocking (8.9%, n=24) and pressure/compression stocking (6.3%, n=17). pharmacological prophylaxis was administered in 16 patients [LMWH (5.9%)], and only 3 patients received combined therapy [LMWH+ Mechanical (1.1)], while 211 (77.8%) did not receive any prophylaxis. The type of prophylaxis used in phase 2 is also shown in Table 3.

Table 3: Type Of Prophylaxis Received

Prophylaxis Type	Category	Frequency (%) N=271	Frequency (%) N=340
Mechanical Prophylaxis	TED stocking Pressure Stocking	24(8.9) 17(6.3)	60(17.6) 56(16.5)
Pharmacological Prophylaxis	LMWH	16(5.9)	53(15.6)
Combination	LMWH+ Mechanical	3(1.1)	25(7.4)
No Prophylaxis Received		211(77.8)	146(42.9)

N=271(phase I), N=340(phase II), TED=Thromboembolism Deterrent, LMWH=Low Molecular weight heparin

A comparison of the mean between the requirement of prophylaxis and prophylaxis received has been demonstrated in *Table 4*, which showed that the mean difference of prophylaxis required remained the same in both phases. In contrast, the mean comparison of prophylaxis received showed a difference in both phases, which revealed improved adherence to guidelines to prevent DVT. This ensured that higher-risk patients received appropriate treatment during the second phase of the study.

Table 4: Mean Comparison of Prophylaxis Required or Prophylaxis Received

Variable	Mean ± S.D N=271	Mean ± S.D N=340
Prophylaxis Required	1.63±0.48	1.63±0.48
Prophylaxis Received	1.22±0.416	1.56±0.49

N=271(phase I), N=340(phase II), S.D=standard deviation.

Table 5 presents the detailed distribution of DVT risk levels and the administration of prophylaxis. It was found that in phase I, the majority of patients were at moderate risk 89(32.8%) and High risk 82(32.3%), and they required prophylaxis for the prevention of DVT but only 60 (22.1%) received it while a large number of patients remained unattended. In contrast to phase I, phase II showed improvement in prophylaxis administration with 192(56.5%) of patients receiving treatment.

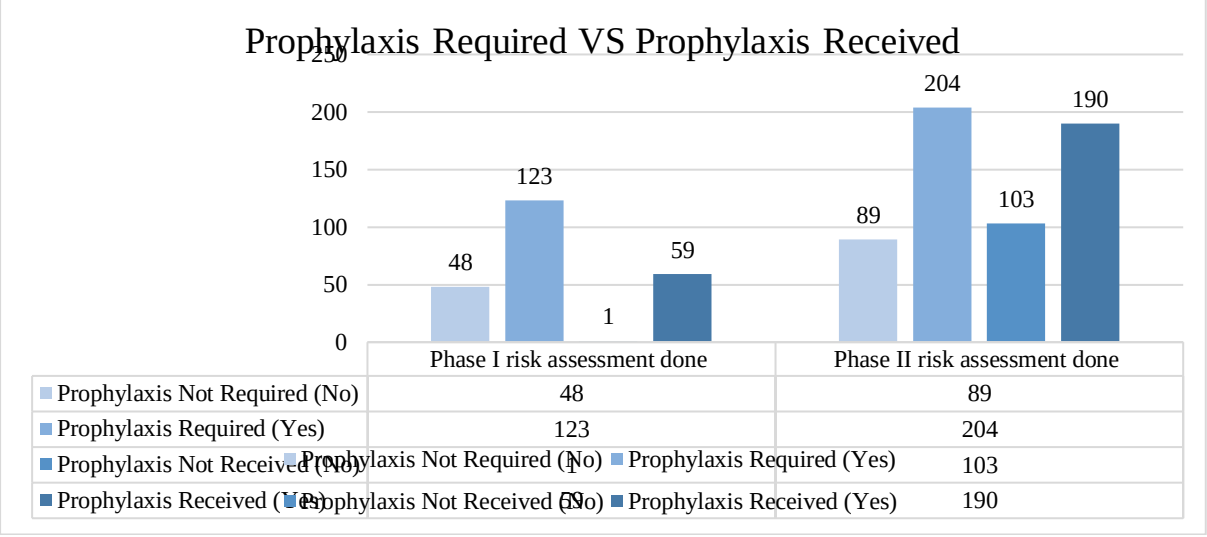
Table 5: Comparison of DVT Risk & Prophylaxis Administration Across Two Phases of study

Phase		Prophylaxis Not Required N (%)	Prophylaxis Required N (%)	Prophylaxis Not Received N (%)	Prophylaxis Received N (%)
Phase I (N=271)	Low (1-2)	77(28.4)	0(0)	77(28.4)	0(0)
	Moderate (3-4)	21(7.75)	89(32.8)	94(34.9)	16(5.9)

	High (≥5)	2(0.74)	82(32.2)	40(14.7)	44(16.24)
	Total	**100(36.9)**	**171(63.1)**	**211(77.9)**	**60(22.1)**
Phase II (N=340)	Low (1-2)	76(22.4)	6(1.76)	76(22.4)	6(1.76)
	Moderate (3-4)	47(13.8)	103(30.3)	62(18.2)	88(25.9)
	High (≥5)	3(0.9)	105(30.9)	10(2.9)	98(28.8)
	Total	**126(37.1)**	**214(62.9)**	**148(43.5)**	**192(56.5)**

Figure 1 represents the bar chart and it illustrates the relationship between prophylaxis requirement and administration in different phases of assessing the risk for DVT development. Phase II showed a significant improvement in prophylaxis administration as compared to Phase I. In Phase I, only 59 out of 123 patients requiring prophylaxis received it, whereas in Phase II, indicating better adherence in such a way that of 204 patients for whom prophylaxis was required, 190 patients had received it. Additionally, the number of patients who did not receive prophylaxis despite being required decreased in Phase II, demonstrating improved implementation after risk assessment. These improvements suggest that an organized risk assessment played a central role in ensuring that more patients receive the necessary prophylaxis, thus reducing gaps in administration.

Figure 1: Comparison of Prophylaxis Requirement and Prophylaxis Received



N=271 (Phase I), n=340 (Phase II)

DISCUSSION

The findings of the current study provided valuable insights into DVT prophylaxis adherence and demonstrated substantial improvement in DVT prophylaxis adherence, as compared to a previous study conducted in a Palestinian Teaching Hospital. That prior study utilized the Padua and IMPROVE risk models for the assessment of clotting and bleeding risks and primarily focused on medically ill hospitalized patients. Of the hospitalized patients, 112 (27.5%) had reported a high risk of VTE (Padua score ≥ 4), and 73 patients were eligible for VTE pharmacological prophylaxis; but, only 44 (60.3%) received the appropriate prophylaxis. In addition, 296 patients had low Padua scores, indicating that pharmacological prophylaxis was not indicated. Further 80.18% of cases reported inappropriate prophylaxis. In contrast, the present study applied the Caprini Risk Assessment Model (RAM) providing a more generalized risk assessment. The findings revealed a substantial increase in prophylaxis administration, from 22.1% in Phase I to 56.5% in Phase II, demonstrating improvement in guideline adherence. Moreover, the preoperative assessment of DVT development, which was not assessed in that previous study, remained steadily high at 84.1% in Phase I and 86.2% in Phase II. The proportion of patients receiving no prophylaxis decreased significantly from 77.8% in Phase I to 43.0% in Phase II, in contrast to the prior study, where only 60.3% of high-risk patients received appropriate prophylaxis. This suggested a more refined approach to risk categorization in the current study, aligning prophylaxis decisions with individual patient needs[18].

Another study recruited NICE guidelines to assess the risk for VTE and that study was also conducted in two phases. It had been noticed that, in Phase A, only 5% of patients were risk assessed for VTE, and of those eligible for prophylaxis only 22.2% received the prescription and in Phase B, 100% of patients were risk assessed for VTE and 75% received the prophylaxis. These previous findings were consistent with our study in such a way that both were prospective and the second phase provided more adherent results to clinical guidelines (15). In the cross-sectional and multi-centered study, an observational study in Jordan and Lebanon in 40 centers to investigate VTE cases according to ACCP 2016 guidelines 59% of the patients received prophylaxis treatment in the form of pharmacological anticoagulant prophylaxis and/or mechanical prophylaxis. Low molecular weight heparin was the most commonly used anticoagulant for VTE prophylaxis in 366 out of the total 704 (51.9%) patients in the analysis and showed poor compliance but the current study was conducted in 2 phases and assessment was done through Caprini score which represented that among 271 patients in pase16 (5.9%) of the patients received pharmacological prophylaxis and this ratio had been increased in phase II up to 53(15.3%) from 340 patients and LMWH was used as a common anticoagulant prophylactic and reported increased compliance from phase II as compared to phase I. Further, the current study did not find any of the risk factors associated with DVT while prior studies like Hajj et al observed that only age was a significant predictor of appropriate VTE prophylaxis (odds ratio [OR] 1.05, $P < 0.001$), and Ismai et al Identified that associated risk factor for VTE was advanced age (>60 years), history of prior major surgery, Major surgery lasting > 60 minutes, obesity, and immobilization ($P \leq 0.05$), with enoxaparin; the most commonly used anticoagulant agent in VTE risk patients (92%). Further, that study also identified that most of the patients were from medical and surgical wards where our study utilized a generalized approach and included patients from gynecology, urology,

medical, general surgical, and neurosurgical units which was one of the key strengths[19,20]. A retrospective observational analysis was done from four hospitals under Hamad Medical Corporation, Patients over the age of 18 who were hospitalized were included. The mean age was 51.25 years and 54.5% were males. Whereas, our study was a prospective observational, conducted from two hospitals and it investigated that, phase I had 135(49.8%) males and phase II had 173(50.9%) male population. The previous study observed Hypertension and diabetes mellitus being the most common comorbidities found in the overall group while our observation did not include any comorbidities. In addition, the present study only focused on DVT patients while a study done by Ambra et al found 86 subjects had DVT,109 had PE, and 14 had both. And, 67.5% of the patients developed VTE during admission while 32.5% developed it within 1 month of discharge and 69.7% received VTE prophylaxis under guidelines. Both studies were consistent in a way that they did not find any risk factors. [21].

Kharaba et al used ACCP criteria for risk assessment and 292 (70.5%) patients at high risk and 73 (17.6%) at moderate risk. As per the ACCP criteria, 375 (90.5%) patients were at risk for VTE and qualified for prophylaxis. Although 227 (60.5%) received some form of prophylaxis, only 144 (38.4%) of them received ACCP-recommended VTE prophylaxis. In their hospital, most of the patients are at high risk for developing VTE. While in the present study, 77(28.4%) were at low risk [1-2], 110(40.6%) at moderate risk [3-4], and 84(31.0%) at High risk [≥5] in phase 1 and in phase II of an study, 82 (24.1%) were at low risk, 150(44.1%) at moderate risk, and 100 (31.8%) at High risk. Overall, the majority of patients were at moderate risk for developing DVT in that study. Kharaba et al reported that VTE prophylaxis guidelines were not properly implemented therefore, proper strategies should be developed and implemented to ensure patient safety our study showed some improvement in prophylaxis adherence[22].

Another study by Gafter-Gviliet al conducted a retrospective analysis on high-risk VTE patients and aimed to assess the benefit and safety of venous thromboembolism prophylaxis. In that total of 18,890 patient-unique episodes were included in the analysis. Of them, 3206 (17.0%) received prophylaxis, 1309 (6.9%) died, 540/3206 (16.8%) of those who received venous thromboembolism prophylaxis and 769/15,864 (4.9%) of those who did not. This past study observed that prophylaxis neither sowed clinical benefits in mortality reduction nor in VTE reduction but showed adverse effects of major bleeding. On the other hand, the current study lacked these findings.[23]

This clinical study underscores the persistent gaps in DVT risk assessment and prophylaxis compliance, despite established guidelines. However, adherence to evidence-based guidelines and standardized risk assessment are critical in optimizing patient outcomes and minimizing disease burden and complications from DVT. The current study did not observe risk factors and their association that might be influenced by DVT prophylaxis. Further, the current study included a limited number of hospitals thereby reducing the generalized approach. Besides that, training and awareness programs for healthcare providers are recommended to enhance compliance with DVT prophylaxis protocols.

CONCLUSION

Substantial progress was observed in phase II which highlighted the potential of structured interventions and also enhanced the awareness among healthcare providers. To withstand further improvements in these outcomes, training and learning programs, workshops, and hands-on practices on DVT risk assessment and prophylaxis should be incorporated into the medical setting

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ETHICS APPROVAL: The ERC gave ethical review approval.

CONSENT TO PARTICIPATE: written and verbal consent was taken from subjects and next of kin.

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AUTHORS' CONTRIBUTIONS:

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated in the work to take public responsibility of this manuscript. All authors read and approved the final manuscript.

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