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Original Research Article

Prospective Observational Study of Compliance to Venous-Thromboembolism Prophylaxis Guidelines as per the American College of Chest Physicians (ACCP) in Post-Operative Patients in a Tertiary Care Centre

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ABSTRACT

Venous thromboembolism (VTE) results in significant morbidity and mortality in post-operative patients. From various studies it is proven that prophylaxis for venous thromboembolism is preferred and effective in post-operative patients and American College of Chest Physicians (ACCP) has published evidence based guidelines for VTE prophylaxis. In this study compliance to these guidelines was studied in post-operative patients in a tertiary care centre. 500 postoperative cases were prospectively observed, risk stratification done according to Caprini Score and compliance was determined. Overall compliance to ACCP guidelines was low, only 19.8% patients. So there is need of proper identification of risk factors and aggressive implementation of ACCP guidelines for VTE prophylaxis in post-operative patients for effective control of burden of VTE including pulmonary embolism.

Key words: Compliance, Post-operative, Prophylaxis, Pulmonary embolism, venous thromboembolism.

INTRODUCTION

Venous thromboembolism (VTE) is a preventable occurrence that results in significant morbidity and mortality. One of the dominant characteristics of this disease is that for every symptomatic pulmonary embolism diagnosed, there are 2.5 cases of VTE that are asymptomatic and remain undetected. Moreover, 40 to 60% of the deaths from VTE occur in patients in whom there is no previous diagnosis of deep vein thrombosis (DVT) and 20% of the patients have a sudden death secondary to massive pulmonary embolism as their first and only symptom. ^[1] VTE events remain a relatively common cause of death in hospitalized patients and almost 75 per cent of all VTErelated deaths are from hospital-acquired VTE.^[2] Postoperative deep vein thrombosis (DVT) of the lower limbs is often asymptomatic and in many patients, fatal PE is the first clinical manifestation of postoperative VTE.

The evidence-based practice guidelines published by The American College of Chest Physicians (ACCP) incorporated obtained data from а comprehensive and systematic literature review of the most recent studies available at that time. Evidence-Based Guidelines (ACCP guidelines) help in the assessment of risk factors for VTE and recommend the appropriate use of prophylaxis to prevent VTE in patients at risk. ^[3] The newly developed consensus/clinical practice guidelines provide recommendations for the continued management of patients with VTE, addressing specifically the risk stratification of VTE, and the appropriate use of low molecular weight heparins (LMWHs) in the prophylactic management of this condition. ^[4]

ACCP Guidelines has Stratified patients into different risk groups according to Caprini Risk assessment score ^[5] for General and Abdominal-pelvic Surgery including those undergoing patients. gastrointestinal, urological, gynaecologic, bariatric, vascular, or plastic and reconstructive surgery in to Very Low Risk, Low Risk, Moderate Risk, High Risk and recommended prophylaxis guidelines for each group.^[6]

Many studies have been done to assess various risk factors and identify the patients with high risk of developing VTE. Caprini scoring system and American College of Chest Physicians (ACCP) consensus guidelines for VTE prophylaxis are one of the most widely accepted scoring systems for VTE risk assessment and prophylaxis advised. If used appropriately, such prophylaxis is cost effective because it reduces the incidence of symptomatic thromboembolic events, which require costly diagnostic procedures and prolonged anticoagulation therapy.^[7]

The occurrence of VTE increases in the immediate postoperative period due to prolonged immobilisation, muscle relaxation due to anaesthetic agents and increased thrombotic activity. Hence the prophylaxis should be commenced either 2 hours before or within 10 hours following surgery in high risk individuals.^[8]

Postoperative deep vein thrombosis (DVT) of the lower limbs is often asymptomatic; in many patients, fatal PE is the first clinical manifestation of postoperative VTE. Therefore, it is inappropriate to rely on early diagnosis and treatment of postoperative thromboembolism. Hence routine and systematic prophylaxis in patients at risk is the strategy of choice to reduce the burden of VTE after surgery.^[7]

Aim

To Study Compliance to Venousthromboembolism prophylaxis Guidelines as per The American College of Chest Physicians (ACCP) in postoperative patients in a Tertiary care centre.

Objectives

In Postoperative cases

- 1. To do Risk Stratification of patients for VTE in the tertiary care centre.
- 2. To Study method of VTE prophylaxis used in the tertiary care centre.
- 3. To Study compliance of VTE prophylaxis with ACCP Guidelines in the tertiary care centre.

MATERIALS AND METHODOLOGY

Present prospective observational study was carried out in tertiary care public hospital with an aim to study compliance to venous-thromboembolism prophylaxis guidelines as per The American College of Chest Physicians (ACCP) in postoperative patients. Present study was carried out in 500 patients who were admitted and satisfied the inclusion criteria. Patients were included in study after ethical committee clearance and valid informed consent.

All cases were studied in during their stay in the hospital and data was collected and analysed in Microsoft Excel.

Information in terms of surgery and Caprini Score was found out and the type of VTE prophylaxis which patient received (Mechanical, Pharmacological or both). According to Caprini Score, patients were stratified into different risk categories and it was recorded whether patients received VTE prophylaxis, if any and whether it was according to the ACCP guidelines or not.

Patients who were at high risk of bleeding due to thrombocytopenia, liver cirrhosis with coagulopathy, recent history of gastrointestinal bleeding, peptic ulcer, large wounds, liver trauma etc. were determined as their prophylaxis recommendation differed as per ACCP guidelines. Patients who developed complications related to the method of prophylaxis were studied.

Inclusion Criteria:

- 1. All Surgery cases in age group of more than 18 years done in a Department of General Surgery both Elective and Emergency.
- 2. Patient undergoing repeat surgery.
- 3. Repeat Surgery in same patient during study period is new case.

Exclusion Criteria:

- 1. Age less than 18 years.
- 2. Pregnant female.
- 3. Orthopaedic, Gynaecological Surgery, Neurosurgery, Cardiovascular Thoracic Surgery.

Risk Assessment

Several risk assessment models that stratify patients according to their risk of VTE have been published, the most notable being those developed by Caprini, Cohen, and Kucher. ACCP Guidelines has stratified patients into different risk groups according to Caprini Risk Assessment Score. ^[5] These risk assessment models consist of a list of exposing risk factors (presenting illness or procedure) and predisposing risk factors (genetic and clinical characteristics), each with an assigned relative risk score. The scores are summed to produce a cumulative score, which is used to classify the patient to 1 of the 3 or 4 risk levels and determine the onset, intensity, type, and duration of prophylaxis. an alternative. As the American College of Chest Physicians advocates a simpler approach by assigning risk according to the patient group to which an individual belongs. The patient group describes the primary reason the patient was hospitalized, such as major general surgery or major orthopaedic surgery, and each was tested in randomized clinical trials of thromboprophylaxis. Though some patientspecific, predisposing risk factors may be considered, this method does not promote individualized approach risk an to assessment and thromboprophylaxis.^[6]

Caprini Risk Assessment ^[5,9]

- Each Risk Factor Representing 1 point
- Age 41 to 60 years
- Minor Surgery Planned(<45 Minutes)
- History of Major Surgery (<1 Month)
- Varicose Veins
- History of Inflammatory Bowel Disease
- Swollen Legs (Current)
- Obesity (BMI >25)
- Acute Myocardial Infarction
- Congestive Heart Failure (<1 Month)
- Sepsis (<1 Month)
- Serious Lung Disease Including Pneumonia (<1 Month)
- Abnormal Pulmonary Function (COPD)
- Medical Patient at bed rest(< 72 hours)

Each Risk Factor representing 2 point

- Age 60 to 74 years
- Arthroscopic Surgery
- Malignancy (Present or Previous)
- Major Surgery (>45 minutes)
- Laparoscopic Surgery (>4 minutes)
- Patient Confined to bed (>72 hours)
- Immobilising Plaster Cast (< 1 month)
- Central Venous Access

Each Risk Factor representing 3 point

- Age over 75 years
- History of DVT/PE
- Family History of thrombosis
- Positive Factor V Leiden
- Positive Prothrombin 20210A
- Positive Serum Homocysteine
- Positive Lupus Anticoagulant
- Elevated Anticardiolipin Antibodies
- Heparin Induced Thrombocytopenia (HIT)
- Other Congenital or acquired thrombophilia
- For Women only (Each Represents 1 Point)
- Oral contraceptive or Hormonal Replacement Therapy
- Pregnancy or Postpartum (< 1 Month)
- History of Unexplained Still Births, Recurrent Spontaneous Abortion (≥3) Premature birth with toxaemia or growth restricted Infant

Caprini Score is addition of all the positive risk factor (points allotted to each factor) and according to that score patient is divided in different category according to ACCP Guidelines.^[6]

Risk Stratification	Caprini Score
Very Low Risk	0
Low Risk	1-2
Moderate Risk	3-4
High Risk	≥5

ACCP Recommendations

Patient Population	Intervention	Grade
General and abdominal-pelvic surgery	Recommend that no specific pharmacologic prophylaxis be	1B
patients at very low risk for VTE (Caprini score 0)	used other than early ambulation	
	Suggest that no specific mechanical prophylaxis be used other	2C
	than early ambulation	
General and abdominal-pelvic surgery	Suggest mechanical prophylaxis, preferably with	2C
patients at low risk for VTE (Caprini score 1-2)	intermittent pneumatic compression (IPC), over no	
	prophylaxis	
General and abdominal-pelvic surgery	Suggest LMWH over no prophylaxis	2B
patients at moderate risk for VTE (Caprini score 3-4) who	Suggest LDUH over no prophylaxis	2B
are not at high risk for major bleeding	Suggest mechanical prophylaxis, preferably with IPC, over no	2C
complications	prophylaxis	
General and abdominal-pelvic surgery	Suggest mechanical prophylaxis, preferably with IPC, over no	2C
patients at moderate risk for VTE (Caprini score 3-4)	prophylaxis	
who are at high risk for major bleeding complications or		
those whom the consequences of bleeding are thought to		
be particularly severe		
General and abdominal-pelvic surgery	Recommend pharmacologic prophylaxis with LMWH) over no	1B
patients at high risk for VTE	prophylaxis	
(Caprini score \geq 5)	Recommend LDUH over no prophylaxis	1B
who are not at high risk for major bleeding	Suggest that mechanical prophylaxis with elastic stockings or	2C
complications	IPC should be added to pharmacologic prophylaxis	
High-VTE-risk patients undergoing abdominal or pelvic	Recommend extended-duration pharmacologic prophylaxis(4	1B
surgery for cancer	weeks) with LMWH over limited-duration prophylaxis	
who are not otherwise at high risk for major bleeding		
complications		
High-VTE-risk general and abdominal-pelvic surgery	Suggest use of mechanical prophylaxis, preferably with IPC,	2C
patients who are at high risk major for bleeding	over no prophylaxis until the risk of bleeding diminishes and	
complications or those in whom the consequences of	pharmacologic prophylaxis may be initiated	
bleeding are thought to be particularly severe		
General and abdominal-pelvic surgery	Suggest low-dose aspirin over no prophylaxis	2C
patients at high risk for VTE (Caprini score \geq 5) whom both	Suggest fondaparinux over no prophylaxis	2C
LMWH and unfractionated heparin are	Suggest mechanical prophylaxis, preferably with IPC, over no	2C
contraindicated or unavailable and who	prophylaxis	
are not at high risk for major bleeding complications		
General and abdominal-pelvic surgery	Suggest that an inferior vena cava (IVC) filter should not be	2C
patients	used for primary VTE prevention	
	Suggest that periodic surveillance with venous compression	2C
	ultrasound should not be performed	

RESULTS

In the present study, 38.8% patients were female and Overall 47.6% patients were falling in age group of more than 40 years where risk of VTE increases rapidly.

Table 1: Risk Stratification			
VTE Risk Number of patients at risk of bleeding			
Low risk	0		
Moderate risk	6		
High risk	9		
Total	15		

Table 2: Patients at risk of bleeding

	Number Of Patients	Percentage
Very Low Risk	0	0%
Caprini Score 0		
Low Risk	170	34%
Caprini Score 1-2		
Moderate Risk	225	45%
Caprini Score 3-4		
High Risk	105	21%
Caprini Score ≥5		
Total	500	100%

Table 3: Type of prophylaxis used

Tuble 5. Type of prophylaxis used						
	Early Mobilisation	Mechanical	Pharmacological	Pharmacological	No	Total
				+ Mechanical	Prophylaxis	
Low Risk Group	157	13	0	0	0	170
Moderate Risk Group	150	65	1	0	9	225
High Risk Group	14	50	2	16	23	105
Total	321	128	3	16	32	500

Table 4: Compliance to Guidelines

Risk Group (Total Number of Patients in each group)	Prophylaxis According to ACCP Guidelines	
	Number of patients	Percentage
Low Risk (170)	13	7.64%
Moderate Risk(225)	65	28.89%
High Risk(105)	21	20%
Total(500)	99	19.8%

In Patients who received prophylaxis according to ACCP guidelines overall only 34.34% of them received highest recommendation as per the strength and quality of evidence. Amongst this proportion was more in Low risk group (100%) followed by High risk Group (80.95%) and least in moderate risk group (6.15%) [Table 5]

Table 5: Prophylaxis Of Highest Recommendation				
Risk Group	Number of Patients Receiving Prophylaxis	Prophylaxis Of High		
	according to ACCP guidelines	Number	Percentage	
Low Risk	13	13	100%	
Moderate Risk	65	4	6.15%	
High Risk	21	17	80.95%	
Total	99	34	34.34%	

Table 6: Side Effect of Mechanical Prophylaxis				
Side Effect of Mechanical Number of Percentage (Out of Patient who received				
Prophylaxis	Patients	Mechanical Prophylaxis; n=144)		
Oedema	1	0.01%		
Skin Lesions	0	0%		
Ulcerations	4	2.78%		
Total	5	3.47%		

Table 7:	Side Effect	of Pharmacolo	gical Prophylaxis

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Side Effect of Pharmacological	Number of	Percentage (Out of Patient who received		
Prophylaxis	patients	Pharmacological Prophylaxis; n=19)		
Bleeding	2	10.52%		
Heparin Induced Thrombocytopenia	0	0%		
Total	2	10.52%		

DISCUSSION

VTE is one of the common complications seen in postsurgical patients. Approximately one-third of the 150,000 to 200,000 VTE-related deaths per year in the United States occur following surgery. In India, the reported incidence of VTE is 17.46 per 10000 admissions and mortality in patients with VTE was 13%.The reported overall mortality for PE was 49.5% in India compared to 45.1% in the Western countries.^[10]

In present study, 34% patients were falling into Low risk Category,45% into Moderate risk category and 21% into High risk category according to Caprini Score and ACCP guidelines, but there was no patient with Very Low risk as Caprini Score of 0 is not possible in this study group of postoperative patients. ^[6,11] Majority of patients were in moderate to high risk group [Table 1]. There were 15 patients overall in the study group who were at high risk of bleeding, Their distribution as per Caprini VTE Risk stratification was 9 in high risk, 6 in moderate risk and none in low risk categories. Thus overall only 3% of patients in study group were at high bleeding risk

which is a small proportion of patients [Table2].

In our study, 64% of patients received early mobilisation post operatively as only prophylaxis. 25.6% received mechanical prophylaxis mostly with graded compression stockings; only 0.6% patients received pharmacological prophylaxis alone while 3.2% patients received combination of pharmacological mechanical and prophylaxis. 6.2% patient in this study didn't receive any prophylaxis [Table 3]. Thus majority of the patients received early mobilisation as the only prophylaxis and very small percentage of patients received pharmacological prophylaxis which could be due to overestimation or anxiety of bleeding risk in postsurgical patients.

In High risk subgroup 47.62% received mechanical Prophylaxis alone mostly with graded compression stockings, 1.9% patients received pharmacological prophylaxis alone while 15.2% patients received combination of mechanical and pharmacological prophylaxis and 21.9% patient did not receive any prophylaxis [Table 3]. Most of these patients should have ideally received pharmacological

prophylaxis unless contraindicated due to high bleeding risk. Thus large number of patients who deserved getting prophylaxis was deprived of any kind of prophylaxis predisposing them to a significant risk of VTE and PE. Amongst the patients receiving prophylaxis in this group; a very small proportion received prophylaxis as recommended by ACCP evidence based guidelines and all these patients who received suboptimal type of prophylaxis were predisposed to increased risk of postoperative VTE events. It was easily possible to reduce VTE risk in all these patients by strict adherence to ACCP VTE prophylaxis guidelines.

Higher number of patients received pharmacological prophylaxis in this high Caprini risk group compared to other risk groups. Out of these patients, 9 patients were having malignancy who required extended pharmacological prophylaxis for 4 weeks as per ACCP guidelines, but none of them got it for extended period.

In moderate risk group majority of patient received mechanical prophylaxis. Mechanical prophylaxis alone for this group was lower grade of prophylaxis as per ACCP guidelines unless pharmacological prophylaxis was contraindicated due to high bleeding risk. Only 0.44% patients received pharmacological prophylaxis in this group and all other patients except the ones with high bleeding risk received suboptimal or inferior prophylaxis.

In Low risk subgroup of patients 92.35% of patients received early mobilisation post operatively only as prophylaxis. 7.65% Mechanical Prophylaxis mostly with graded compression stockings and no patients received pharmacological or combination of mechanical and pharmacological prophylaxis [Table 3]. This attributed could be to failure of identification of risk factors for VTE and need of prophylaxis in this subgroup of patients.

Overall compliance to ACCP guidelines was low, only 19.8% patients, with maximum in moderate risk group

which is 28.89% and lowest in low risk group, with 20% in high risk group [Table 4]. In Patients who received prophylaxis according to ACCP guidelines overall only 34.69% of them received highest recommendation more in Low risk group (100%) followed by High risk Group (81%) moderate and least in risk group (6.25%)[Table 5].

The ENDORSE (Epidemiologic International Day for the Evaluation of Risk for Venous Patients at Thromboembolism in the Acute Hospital Care Setting) study aimed to assess the prevalence of VTE risk in acute hospital care setting and proportion of at-risk patients receiving effective prophylaxis. It was multicentric international study with study sites at various countries all over world. The Indian data from ENDORSE study revealed that despite a similar proportion of patients at risk in India and other participating countries, there is major underutilization of prophylaxis (17.4%) in India as compared to higher usage of prophylaxis globally (50.2%). ^[12,13] In case of at-risk surgical patients, Germany (92%), Hungary (87%), Spain (82%)and Switzerland (81%) showed high usage of ACCP-recommended prophylaxis.^[13]

Similar study by Sujay R. Belgod et al found that Appropriate VTE prophylaxis was given only in 42.03% of the postoperative patients (18.75% of low risk, 29.17% of moderate risk and 65.51% of high risk patients).^[14]

In our study group, 144 patient received mechanical prophylaxis with or without pharmacological prophylaxis out of which 3.47% patient developed some side effect (Ulceration 2.78% and Oedema 0.01%); 19 Patient received pharmacological prophylaxis out of which 2 (10.52%) patients had bleeding [Table 6,7].

B Wan, found that the incidence rates of hemorrhage complications was 5.4% in the LMWH group.^[15]

Study by Pavon, Juliessa M, Williams, John W 'Effectiveness of Intermittent Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis in High-risk Surgical and Medical Patients'. The incidence of bleeding did not differ significantly between the dose-adjusted heparin group (5.0%) and the IPCD group (3.6%; p=0.237). The incidence of major bleeding events was identical (1.8%) in the 2 study groups. ^[16]

As only 19 patients in our study group received pharmacological prophylaxis out of which 2 developed bleeding complication, due to small number of cases findings cannot be correlated. But above quoted studies suggest that incidence of complications of pharmacological prophylaxis is not unacceptable to avoid there use for VTE and PE prophylaxis.

Thrombophilia screening was not routinely done preoperatively which is the limiting factor of the present study.

CONCLUSION

- There utilisation was very low pharmacological prophylaxis 0.6% patients combination and of Pharmacological and mechanical in 3.2% patients overall. A large group of patient population remained deprived of well- deserved VTE prophylaxis as per ACCP guideline; thus exposing them to increased VTE risk.
- Complication rate of VTE prophylaxis were not unacceptably high; but due to very low utilisation rate of prophylaxis in our study a large volume study is required to estimate bleeding risk more accurately.
- Under- utilisation of VTE prophylaxis guidelines by ACCP could be due to;
 - Lack of knowledge of significance of VTE events in postoperative patients.
 - Lack of identification of risk factors.
 - Lack of Knowledge of VTE prophylaxis guidelines.
 - Due to lack of proper understanding of the guidelines.
 - Overestimating risk of complications of VTE prophylaxis.

- There is need of proper identification of risk factors and aggressive implementation of ACCP guidelines for VTE prophylaxis in postoperative patients which can be done by interventions like;
 - Creating awareness about VTE and its outcome.
 - Educating about effectiveness of VTE prophylaxis.
 - Educating about Risk benefit ratio for VTE prophylaxis and their bleeding complications.

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