

## A Prospective Analysis of Venous Thrombo-Embolism (VTE) Prophylaxis Using Intermittent Pneumatic Compression Devices in Intensive Care Patients in A Tertiary Care Hospital



### Medical Science

**KEYWORDS :** - Venous thrombo-embolism(VTE)/Pulmonary embolism(PE) prophylaxis, Intermittent pneumatic compression (IPC) devices, prevention guidelines)

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### ABSTRACT

*The aims of this study were to conduct an observational study to assess the existing practice of VTE [deep vein thrombosis (DVT) and pulmonary embolism (PE)] prophylaxis in surgical and medical in-patients in a major teaching service hospital intensive care unit (ICU) and using intermittent pneumatic compression devices in VTE prevention. **Materials & Methods :** Patients were randomized into two groups of 50 each Group A receiving existing protocol of VTE prophylaxis in ICU including compression stockings and pharmacological therapy while Group B patients received intermittent pneumatic compression device along with pharmacological therapy as per risk index. **Results :** There is evidence to support benefit of IPC (intermittent pneumatic compression ) compared to no compression or other mechanical methods for VTE prophylaxis in hospitalised patients.*

### INTRODUCTION

Venous thromboembolism (VTE) is a serious preventable cause of morbidity & mortality in the world. DVT & pulmonary embolism (PE) are distinct but related aspects of VTE. Being silent (80% DVT) and difficult to diagnose it poses great challenges in establishing diagnosis. Higher incidence, underestimation of risk, low level of clinical suspicion, under-used prophylaxis with high fatality has made DVT a world wide cause for concern. The immediate need of the hour is to have standard guidelines for management of DVT. These guidelines have to be practical, acceptable and implementable in institutions all over.

Despite the availability of effective, prophylactic, therapeutic options; venous thrombo-embolism continues to be under diagnosed and under treated. Awareness levels are low particularly of medically ill patients to this potentially life threatening killer disease. Though medical (non surgical) patients are at significant risk of developing DVT in India/other Asian countries is comparable to that in western countries serious challenges for our country in this regard are to find out prevalence of disease, maintaining standard protocols for its management and having high suspicion rate to decrease morbidity and mortality from the burden of this potentially fatal but preventable disease (deep vein thrombosis).

**Aims:** The aims of this study were to conduct an observational study to assess the existing practice of VTE [deep vein thrombosis (DVT) and pulmonary embolism (PE)] - prophylaxis in ICU patients and the use of intermittent pneumatic compression devices.

**Objectives:** The objective of this project is to improve outcomes related to VTE by raising awareness amongst the healthcare professionals in prevention of VTE/PE and encouraging application of proven methods for preventing DVT/ PE in ICU patients.

### Methods :

This work was approved by the hospital ethics committee and informed consent for the same was obtained from each patient. The study was carried out over 2 years. Patients were randomised into two groups: A & B . The total number of patients studied were 100 with 50 in each group.

**Group 'A'** – Surgical and medical in-patients subjected to the existing VTE prophylaxis practice in ICU. 50 patients who were satisfying all inclusion and exclusion criteria ( Table 1 & 2 ) were selected and treated in ICU. They were analysed for thrombosis risk factor assessment and Wells clinical prediction scoring system for DVT (Table 3) and placed under observation. Patients

were treated with existing VTE prophylaxis practice. Patients at low risk were observed and treated with early aggressive mobilization while bedridden patients with graduated compression stockings .Pharmacological therapy was given by physicians/ surgeons for moderate and high risk cases as per current ICU protocols. A daily clinical score for prediction of DVT was done and recorded . Patients having increasing score / clinically symptomatic were tested for d- dimer and Doppler ultrasonography. Patients positive for both were subjected to contrast venography / ECG, Chest radiography/ CT angiography as indicated.

**Group 'B'**- Specified at-risk surgical and medical in-patients subjected to VTE prophylaxis as per an evidence based clinical practice guideline provided in the ICU. All patients were analysed for thrombosis risk factor assessment and Wells clinical prediction scoring system for DVT ( Table 3) and placed under observation. Patients with a Wells score of 2 or more and all medium, high risk patients ( Table1) were placed on non-pharmacological therapy of intermittent pneumatic compression device and those satisfying criteria for pharmacological therapy were treated as per guidelines. A daily score was maintained and diagnostic tests as in group "A" patients and diagnostic tests for VTE/PE were carried out as in Group "A" .

All patients given pharmacological prophylaxis using Heparin/LMWH/ Warfarin were monitored with daily INR and platelet counts and observed for clinical signs of bleeding.

Following central data processing, statistical analysis was carried out. Diagnosis of VTE was made clinically and by available laboratory and imaging techniques as indicated for the individual patients in our hospital (ECG analysis, plasma D-dimer levels, chest X-ray, venous ultrasonography, and helical CT arteriography). VTE rates were determined from these assessable investigations and the results of the two groups were compared for statistical significance.



**Figure 1: AIRCAST VENAFLOW SYSTEM**

**TABLE – 1**  
**Inclusion Criteria for VTE prophylaxis**

Strong Risk Factors (odds ratio > 10)	Moderate Risk Factors ( odds ratio 2-9)	Weak Risk Factors ( odds ratio <2)
Fracture (hip or leg)	Arthroscopic knee surgery Previous VTE	Bed rest ≥ 3 days
Hip or knee replacement	Central venous lines Chemotherapy	Immobility due to sitting Prolonged car/air travel
Major general surgery	Congestive Heart/Respiratory Failure	Increasing Age
Major trauma	Hormone replacement therapy	Laparoscopic surgery
Spinal cord injury	Malignancy Oral contraceptive therapy	Obesity
	Paralytic stroke	Pregnancy
	Thrombophilia	Varicose veins

**Exclusion Criteria for VTE prophylaxis**

LMWH	Compression Stockings/ IPC device
Haemorrhage	PIVD
Bleeding diathesis	Gangrene
Extensive dissection	Recent skin graft
Haemorrhagic stroke	Gross oedema of legs
Allergy	Pressure sores to heels
Heparin induced thrombocytopenia	Cellulitis

The study was conducted on 100 patients divided into two groups admitted to the ICU. All subjects were explained the experimental protocol before the start of the study and consent taken from each subject. Selection of cases was done after fulfilling inclusion and exclusion criteria for the study ( Table 1 ).

**Table2 : Wells Clinical Prediction Rule for DVT**

Clinical feature	Points
Active cancer (treatment within 6 months, or palliation)	1
Paralysis, paresis, or immobilization of lower extremity	1
Bedridden for more than 3 days because of surgery (within 4 weeks)	1
Localized tenderness along distribution of deep veins	1
Entire leg swollen	1
Unilateral calf swelling of greater than 3 cm (below tibial tuberosity)	1
Unilateral pitting edema	1
Collateral superficial veins	1
Alternative diagnosis as likely as or more likely than DVT	-2
<b>Total points:</b>	

*Risk score interpretation (probability of DVT): 3 points: high risk (75%); 1 to 2 points: moderate risk (17%); <1 point: low risk (3%).<sup>27</sup>*

**Group A** patients were clinically observed and treated as per existing protocols for DVT prophylaxis . On admission to ICU thrombosis risk factor assessment was assessed and Wells prediction score for DVT was carried out. On assigning the risk patient was managed with early mobilisation for low risk cases and with appropriate mechanical compression stockings with or without pharmacotherapy with Heparin/LMWH . Patients were monitored clinically and biochemically for symptoms/signs of DVT and treated.

**Group “B”** patients were similarly clinically observed and treated as per existing protocols for DVT prophylaxis . On admission to ICU thrombosis risk factor assessment was done and Wells prediction score for DVT was carried out. All patients with Wells score of 2 or more and all patients with moderate or more risk status were managed with intermittent pneumatic compression device . Low risk cases were managed with early mobilisation . Pharmacotherapy with Heparin/LMWH was instituted as per protocol. Patients were monitored clinically and biochemically for symptoms/signs of DVT and treated.

Data were analyzed using statistical software. In each study group, comparisons were made in all measurements using Student’s t-test. P value <0.05 was regarded as statistically significant.

**IPC Device :** ICU Staff was given demonstration and training in the use of Intermittent pneumatic compression device ( AIRCAST Venaflo System ) . The device was used on patients of Group “B” in all moderate , high and very high risk cases along with pharmacotherapy where indicated. The IPC device was easy to use, well accepted by Nursing staff and paramedics. The device requires minimal training and maintenance. It was found to be easy to apply and for continuous use for patients. The patient compliance to the devices was extremely good and the devices could be used in all indicated cases.

**RESULTS**

**Incidence of Symptomatic deep venous thrombosis:**

One patient in Group “A” had clinical signs of VTE . On investigations d-Dimer and Doppler venous ultrasonography was positive. Chest X ray and CT was unremarkable. Patient was aggressively treated for VTE and followed up. He responded well to treatment . However, being an operated case for recurrent Astrocytoma, he succumbed to his primary condition after 89 days. There was no evidence of pulmonary embolism . Two patients of Group “A” had symptomatic leg swelling with oedema. However , in both cases d- dimer and venous ultrasonography was negative.

No patients of Group “B” had symptomatic or clinical signs of VTE. However, since the number of cases was small in a study in which IPC cannot be blinded, the results were not statistically significant. More studies are required to come to a conclusion about effectiveness of protocols followed and advantage of IPC device in conjunction with pharmacotherapy for VTE prophylaxis.

**Incidence of Pulmonary embolism/ fatal PE :**

None of the patients of both groups had Pulmonary embolism / fatal PE in this study. This could be attributed to small number of cases in each group , exclusion criteria and protocols followed for both the groups. The study did increase awareness amongst Medical, Nursing and paramedical staff about symptoms , early warning signs and high index of suspicion for diagnosis.

**Incidence of all bleeding events:**

Incidence of major bleeding events was defined as decrease in Hb levels requiring blood transfusion of greater than 2 units or life threatening bleeding at critical site .None of the patients in both groups had a major bleeding event. In two patients receiving heparin therapy had to be modified / stopped due to INR >3.

**Effects of mechanical prophylaxis on skin:** Use of IPC device had no adverse effects on the skin on patients in our study.

## DISCUSSION

In spite of the availability of guidelines for VTE prevention and prophylaxis and the availability of safe and effective prophylactic agents, numerous audits have demonstrated that appropriate thromboprophylaxis is not being offered to large numbers of surgical patients.

There are numerous risk factors for the development of VTE in surgical patients, including the type and extent of surgery or trauma, duration of hospital stay, a history of previous VTE or cancer, immobility, recent sepsis, presence of a central venous access device, pregnancy or the postpartum period, and inherited or acquired hypercoagulable states

The risk of post-operative VTE depends upon a number of factors related to the surgical procedure itself (eg, degree of invasiveness, type and duration of anaesthesia, requirement for immobilization, as well as a number of patient-related adverse risk factors

ACCP Guidelines have divided patients undergoing surgical procedures into low, moderate, high and very high risk groups (15). Although there have been many attempts to develop means of quantitating these risks, none has been found to be universally acceptable. In preparing guidelines for the prevention of VTE, the caveat is usually added that if the patient has additional risk factors, consideration should be given to either increasing the intensity or the duration of the prophylactic agent (18).

**Low risk patients** — Low risk surgical patients are under the age of 40, have no adverse patient-related or surgery-related risk factors, and will require general anaesthesia for less than 30 minutes. Without prophylaxis their risk of proximal vein thrombosis is less than 1 percent and the risk of fatal pulmonary embolism is less than 0.01 percent (18).

In most cases, low risk surgical patients are those who are undergoing minor elective abdominal or thoracic surgery. However, in some settings the risk of VTE is uncertain, and there have not been randomized clinical trials demonstrating effectiveness of any particular form of VTE prophylaxis. These include vascular surgery, laparoscopic surgery, knee arthroscopy in the absence of more complicated surgery, elective spine surgery, and isolated lower extremity fractures [19].

**Moderate risk patients** — Moderate risk surgical patients include those undergoing minor surgery who have additional risk factors, or those age 40 to 60 who will require general anaesthesia for more than 30 minutes and have no additional adverse patient- or surgery-related risk factors. Without prophylaxis their risk of proximal vein thrombosis is 2 to 4 percent and their risk of fatal pulmonary embolism is 0.1 to 0.4 percent. Patients undergoing general gynecologic, urologic, thoracic, or neurosurgical procedures usually fall into the moderate risk category.

**High risk patients** — The high risk surgical group includes those >60 years of age undergoing major surgical procedures as well as those aged 40 to 60 with additional patient- or surgery-related risk factors [24]. Without prophylaxis the risk of proximal vein thrombosis and fatal pulmonary embolism in this group has been estimated to be 4 to 8 percent and 0.4 to 1.0 percent, respectively. Examples of patients in the high risk group are those undergoing hip or knee arthroplasty, pelvic or hip fracture surgery, major trauma, spinal cord injury, or cancer surgery

A number of factors increase the risk of VTE during orthopedic surgery, including the supine position on the operating table, the anatomic position of the extremity in a patient undergoing knee arthroplasty, and the use of a thigh tourniquet. As examples, internal injury may result from positioning of the extremity, and compression of the femoral vein may occur due to flexion and adduction of the hip during surgery on this joint.

## PREVENTION OF VTE/PE :

**Primary prophylaxis** — Primary prophylaxis is carried out using either drugs or physical methods that are effective for preventing DVT. Prophylaxis is ideally started either before or shortly after surgery and continued at least until the patient is fully ambulatory.

The measures currently available for VTE prophylaxis in surgical patients include low dose unfractionated heparin, low molecular weight (LMW) heparin, fondaparinux, warfarin, intermittent pneumatic compression (IPC) and/or graduated compression stockings (GCS).

**Secondary prevention** — Secondary prevention involves the early detection and treatment of subclinical venous thrombosis by screening postoperative patients with objective tests that are sensitive for the presence of DVT.

A Cochrane review of the use of LMW heparin to prevent VTE in patients with lower leg immobilization concluded that LMW heparin in outpatients significantly reduced the incidence of VTE (20). A further meta-analysis reviewed the use of intermittent pneumatic compression (IPC) with or without pharmacologic prophylaxis used in the form of LMW heparin. It was shown that, compared with IPC alone, combined prophylactic modalities decreased the incidence of VTE (21).

## PHARMACOLOGIC AGENTS FOR VTE PREVENTION

**Low dose unfractionated heparin** — Low dose subcutaneous unfractionated heparin (UFH) for prophylaxis of VTE is usually given in a dose of 5000 units two hours preoperatively and then every 8 to 12 hours postoperatively (ie, either twice or three times daily).

Low dose UFH has the advantage that it is relatively inexpensive, easily administered, and anticoagulant monitoring is not required. However, the platelet count should be monitored regularly in all patients receiving low dose UFH to detect the development of heparin-induced thrombocytopenia.

**Low molecular weight heparin** — A number of low molecular weight heparin (LMW Heparin) preparations are available. These drugs have the advantage that they can be given subcutaneously once or twice daily at a constant dose without laboratory monitoring. In addition, there is a lower incidence of heparin-induced thrombocytopenia than with UFH

A meta-analysis of all studies comparing prophylaxis with UFH versus LMW Heparin confirmed that the incidence of heparin-induced thrombocytopenia is significantly less with LMW Heparin (22)

**Aspirin** — Aspirin, with or without other anti-platelet drugs, is highly effective in reducing major arterial thrombotic events in patients who are at risk or who have established atherosclerotic disease. On the other hand, there is little evidence that aspirin has a significant effect on the prevention of venous thrombo-embolic events in surgi-

cal patients. However, other studies have shown either no significant benefit or inferiority when compared with other modalities such as LMW heparin. (23)

2012 ACCP Guidelines recommend against the use of aspirin alone as thrombo-prophylaxis against VTE for any medical or surgical patient group.(15)

**MECHANICALMETHODSOFTHROMBOPROPHYLAXIS** : Mechanical methods for the prevention of VTE are primarily indicated in patients at high risk of bleeding. Mechanical methods of thrombo-prophylaxis are placed on the patient just prior to the start of surgery and used continuously until hospital discharge.

**Intermittent pneumatic compression (IPC)** prevents venous thrombosis by enhancing blood flow in the deep veins of the legs, thereby preventing venous stasis. IPC also reduces plasminogen activator inhibitor-1 (PAI-1), thereby increasing endogenous fibrinolytic activity .IPC is virtually free of clinically important side effects and therefore offers an alternative for VTE prevention in patients with a high risk of bleeding should anticoagulants be employed. However, IPC is contraindicated in patients with evidence of leg ischemia due to peripheral vascular disease.

In the 2008 ACCP guidelines, the uses of IPC, graduated compression stockings (GCS), and the venous foot pump (VFP) were critically reviewed .The best evidence for efficacy is with IPC devices. The combined use of IPC and a pharmacologic agent was found to be superior to IPC alone in reducing the overall incidence of VTE, particularly the incidence of DVT.(24)

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