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Original Research Article

Study the incidence of postoperative deep vein thrombosis in high and moderate risk patients' in general surgical ward in a tertiary care teaching hospital, Bihar

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Abstract

Background: Deep vein thrombosis by definition is formation of blood clot within the deep veins. These are a major cause of morbidity and mortality in patients undergoing major abdominal and orthopedic surgery 18 months of study was done. High or moderate risk of deep vein thrombosis admitted in General Surgery ward.

Methods & Patients: About 75 patients among the 82 screened, completed the study protocol. Patients fulfilling the selection criteria and having DVT on the screening (within 7days of admission) Duplex ultrasonography (DUS), and those diagnosed with chronic DVT are excluded from the study population. Patient already on anticoagulation or on antiplatelet medications are also excluded. Duplex USG of both the lower limb deep venous system –including bilateral external iliac, common femoral, superficial femoral, popliteal and anterior and posterior tibial veins, calf veins and to look for the followings: inability to compress the vein, lack of spontaneous flow, loss of respiratory flow variation, venous distention, absence of colour filling of lumen by Color Doppler, patient being examined in supine posture. Presence of these features was taken as positive for presence of DVT. First one being was done preoperatively (7 days of admission), and the next one at discharge (as soon as the patient is mobilized).

Results: There were 5 deaths and 2 dropouts. In a total 47 patients [developed malignancies for different reasons] colorectal carcinoma was 23 [48.94%], followed by metastatic disease 10 [21.27%] and periampullary carcinoma and carcinoma gallbladder 4 [8.51%]. Average overall (preoperative postoperative) immobility was 5.31 days. Majority of the study subjects were

immobile for 1-5 days 58 (77.33%) in postoperative phase. About 57 (76%) of the subjects were immobile in preoperative phase. None of the cases were reported to be immobile during pre or post operative phase. Four of the deaths were documented as due to sepsis and MODS, one due to acute myocardial infarction. None of the patients who died had any clinical features of pulmonary emboli or DVT.

Conclusion: Complications must be anticipated, and preventive actions must be taken in every surgical case. Early recognition with prompt appropriate intervention is the best way to prevent progression to a potentially disastrous situation. We opine that the employment of thrombo-prophylaxis may be advocated for patients with cancers undergoing prolonged surgical procedures or patients being immobilized for prolonged duration after the procedure. In other patients the cost-effective alternatives of early ambulation as well as mechanical prophylaxis might be employed to reduce the development of VTE.

Keywords: Venous thromboembolic events, deep vein thrombosis, pulmonary embolism, postoperative, thrombo-prophylaxis, Surgery Ward.

Introduction

Venous thromboembolic events that occur after surgery include deep vein thrombosis (DVT) and pulmonary embolism. These are a major cause of morbidity and mortality in patients undergoing major abdominal and orthopedic surgery.¹ In western countries, DVT occurs in 45% to 84% of patients after hip the absence and knee surgery in of prophylaxis.² Studies from the west as well as from Asia indicate lower predilection for DVT and pulmonary embolism among Asians.^{3, 4} Unfortunately few studies related to DVT have been published from India. Of these, two studies conducted in orthopedic patients, reported a high⁵ and other a very low^6 incidence of DVT. Although a third study reported a high incidence of DVT, the incidence of associated pulmonary embolism very low (1.9%).⁷ A prospective was randomized control trial conducted in Tata Memorial Hospital Mumbai, between March 2002 to January 2004, among colorectal carcinoma patients, showed no incidence of DVT in both the arms of the study population. one receiving pharmacoprophylaxis and the other without it. This trial was prematurely terminated due to unexpectedly low incidence of DVT in these high risk patients.⁸ Further studies are needed to confirm this apparently low risk of DVT among high risk surgical patients in India,

and therefore the actual need for pharmacoprophylaxis.

Most venous thrombi occur in the superficial or deep veins of the leg. Deep venous thrombosis (DVT) in the larger leg veins—at or above the knee (e.g., popliteal, femoral, and iliac veins)—is more serious because such thrombi more often embolize to the lungs and give rise to pulmonary infarction.⁸ Although they can cause local pain and edema, venous obstructions from DVTs can be rapidly offset by collateral channels. Consequently, DVTs are asymptomatic in approximately 50% of affected individuals and are recognized only in retrospect after embolization.⁹ The high incidence of DVT in postoperative patients is due to the multiple risk factors that exist in patients admitted to hospitals, the most important being malignancies, vascular disease, trauma, and surgery, as well as other conditions that lead to prolonged hospitalization. In the process leading to thrombosis, the damage to vascular endothelial cells caused by abdominal surgery and tissue injury, and underlying coagulation disorders are all interrelated.^{10, 11}

This study conducted in KM Medical College & Hospital included 75 high and moderate risk general surgical patients, with the aim to find out the incidence of DVT in them. None received chemoprophylaxis for DVT but all received mechanical prophylactic measures.

Material and Methods

The study was a prospective observational study, conducted during the month of October 2016 to March 2018, for a period of 18 months in the Department of General Surgery in patients having high or moderate risk of deep vein thrombosis admitted in General Surgery ward, Mata Gujri Memorial Medical College & Lions Seva Kendra Hospital, Kishanganj, Bihar.

- High risk general surgical patients being defined as- minor surgery (duration <2hrs) with risk factors and age>60 years; major surgery and age>40 years and/or risk factors
- Moderate risk general surgical patient being defined as- minor surgery with risk factors; major surgery with age>40 years but no additional risk factors

Patients fulfilling the aforesaid selection criteria and having DVT on the screening admission) 7days Duplex (within of ultrasonography (DUS), and those diagnosed with chronic DVT are excluded from the study population. Patient already on anticoagulation or on antiplatelet medications are also excluded. Patients who fulfilled the aforesaid selection criteria and consented to the study after proper understanding are included in the study and subjected to the following procedures as study technique-

- Detailed history and clinical examination (as per proforma)
- 2) Duplex USG of both the lower limb deep venous system -including bilateral external iliac, common femoral, superficial femoral, popliteal and anterior and posterior tibial veins, calf veins and to look for the followings: inability to compress the vein, lack of spontaneous flow, loss of respiratory flow variation. venous distention, absence of colour filling of lumen by Color Doppler, patient being examined in supine posture. Presence of

these features was taken as positive for presence of DVT. First one being done preoperatively (7 days of admission), and the next one at discharge (as soon as the patient is mobilized).

- 3) ECG in all leads in patients complaining of chest pain breathlessness and tachypnoea, and if it shows strain pattern, then the patient would be investigated and treated according to, the standard practice for investigating and treating pulmonary embolism and DVT.
- Serological and other special tests for hypercoagulability in select group of patients
- 5) d-dimer assay in select group of patients, values less than 1000ng/ml was taken as negative for presence of VTE (venous thromboembolism)

Study tools that were used

Detailed history and clinical examination proforma

- Xario (Toshiba make) Colour Doppler machine with transducer frequency 7-14MHz
- ECG machine in selectcases
- Serological and other special tests analyzers for hypercoagulability in select group of patients
- d-dimer assayer
- Intermittent Pneumatic compression device (VENAFLOW 30 AE)
- Graduated compression stockinet

All patients have had DVT prophylaxis in the form of mechanical prophylaxis like intermittent pneumatic compression, graduated compression stockinet, and early mobilization/calf exercise, either alone or in suitable combination according to feasibility, and conventional measures like adequate hydration. None received any form of pharmacoprophylaxis and none had received antiplatelet drugs. Interventions are taken only in the cases those are diagnosed as cases of pulmonary embolism or DVT, which are

dealt with as per the prevalent standard of care. All the patients were studied up to date of the discharge; follow up for DVT thereafter was not done.

Results

The study was a prospective observational study, conducted during the month of October 2016 to March 2018, for a period of 18 months in the Department of General Surgery in patients having high or moderate risk of deep vein thrombosis admitted in General Surgery ward, Mata Gujri Memorial Medical College & L.S.K. Hospital, Kishanganj (Bihar). Seventy five patients among the 82 screened, completed the study protocol. There were 5 deaths and 2 dropouts. Four of the deaths were documented as due to sepsis and MODS, and one due to acute myocardial infarction. None of the patients who died had any clinical features of PE or DVT. Most of the patients were in the age group of >40-60yrs (45.33%), followed by >20-40 yes considerable amount were above age of 60 yrs (17.33%).

| Table | 1: | Analysis | of | malignancies | in | the |
|---------|------|----------|----|--------------|----|-----|
| populat | tion | (n=47) | | | | |

| Malignancy | No of patients | Percentage |
|-------------------------|----------------|------------|
| Colorectal | 23 | 48.94 |
| Periampullary carcinoma | 4 | 8.51 |
| Carcinoma stomach | 3 | 6.38 |
| Carcinoma gallbladder | 4 | 8.51 |
| Cholangiocarcinoma | 1 | 2.13 |
| Carcinoma Breast | 2 | 4.26 |
| Metastatic disease | 10 | 21.27 |
| Total | 47 | 100.00 |

In a total 47 patients [developed malignancies for different reasons] colorectal carcinoma was 23 [48.94%], followed by metastatic disease 10 [21.27%] and periampullary carcinoma and carcinoma gallbladder 4 [8.51%] [Table 1].

Table 2: Days of immobility (bed ridden state) (n=75)

| No of days | No of patients | | | |
|------------|----------------|---------------|--|--|
| | Preoperative | Postoperative | | |
| <1 | 57 (76%) | 2 (2.67%) | | |
| 1-5 | 15 (20%) | 58 (77.33%) | | |
| >5-10 | 3 (4%) | 15 (20%) | | |
| >10 | 0 (0%) | 0(0%) | | |
| Total | 75 | 75 | | |

Average overall (preoperative postoperative) immobility was 5.31 days. Majority of the study subjects were immobile for 1-5 days 58 (77.33%) in postoperative phase. About 57 (76%) of the subjects were immobile in preoperative phase. None of the cases were reported to be immobile during pre or post operative phase [Table 2].

| Age, Sex | Primary diagnosis | Complication leading to | Documented cause | Prophylaxis used | Result of preoperative |
|---------------|----------------------------|-------------------------|------------------|------------------------|------------------------|
| | | death | of death | | screening duplex |
| | | | | | scan |
| 5yrs, male | Pancreatic head carcinoma | Anastomotic leak | sepsis | Intermittent pneumatic | Negative |
| | | | | compression | |
| 56yrs, female | Obstructive jaundice, | cholangitis | sepsis | Intermittent pneumatic | Negative |
| | cholangitic liver abscess, | | | compression | |
| | due to | | | | |
| | choledocholithiasis | | | | |

| Table 3: Analysis of death among the screened population | (n=5) |
|--|-------|
|--|-------|

| 49 yrs, male | Carcinoma head of the pancreas | Anastomotic leak following palliative bypass | sepsis | Intermittent pneumatic compression | negative |
|-----------------|---|---|---|---|----------|
| 57 yrs, male | Carcinoma stomach, diabetic, no h/o heart disease | Palliative operation, post- op chest pain, ECG, troponin (+) | Inferior wall Acute myocard ial infarctio n | Intermittent pneumatic compression | Negative |
| 55yrs, m ale | Carcinaoma left colon | Left hemicolectomy, anastomotic leak> sepsis >proximal ileostomy and mucous fistula> persistent sepsis> MODS | sepsis | Intermittent pneumatic compression and graduated compression stockinet | Negative |

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| Study | Study Design | Study population | No. of patients studied | Incidence of DVT (%) |
|---------------------------------|---|----------------------------|-------------------------|----------------------|
| Shead et al ¹² | Prospective | Surgical | 50 | 28 |
| Sharma etal ¹³ | Prospective | Orthopedic | 112 | 19.6 |
| Agarwala et al ¹⁴ | Prospective | Orthopedic | 104 | 60 |
| Jain et al ¹⁵ | Prospective | Orthopedic | 72 | 2.7 |
| Bhan et al ¹⁶ | Prospective | Orthopedic | 30 | 23.3 |
| | International, multicentre Retrospective | Orthopedic | 271 | 9.9 |
| Leizorovicz et al ¹⁷ | Prospective, International, multicentre | Orthopedic | 2420* | 2.3 |
| Maini et al ¹⁸ | 1 | 1 | | |
| Saraf et al ¹⁹ | Prospective | Orthopedic | 70 | 10 |
| Mavalankar et al ²⁰ | Prospective | Orthopedic | 125 | 7.2 |
| Kakkar et al ²¹ | Autopsy based | Medical inpatients | 1000 autopsies | 15.9 [*] |
| Sharma et al ²² | Prospective | Medical indoor patients | 163 | 3 |
| Present Study | Prospective observational study | Colorectal carcinoma | 75 | 92 |

Table 4: Studies from India on incidence of DVT among hospitalized patients

[DVT, deep venous thrombosis;* conducted in 39 centers in 11 Asian countries including 403 patients from nine center in India pulmonary embolism diagnosed at autopsy, not DVT,RCT-randomized controlled trial]

Discussion

The Eman Saleh M Shahin et al study²³ revealed that prevalence of deep vein thrombosis was 46.6% while the incidence was 25%. On the other hand 84.5% of study patient were at risk for deep vein thrombosis. The study results found that 58.8% of patients included in the study were male. Additionally 65.4% of patients theirs age ranged from 41 to 60 years old and 23.7% their age 40 years younger however only 10.8% were more than 60 years old. Otherwise 69.1% of the sample was illiterate and 74.1% were married. On the other hand 32.5% of the study sample their body mass index ranged from 20 to 25 and 35.6% ranged from 26 to 30 however 20.6% their body mass index over 30 and only 11.3% was lower than 20. Moreover, 78.9% of the studied patients have a job or working. Additionally, a significant relationship between risk level and both incidence and prevalence of deep vein thrombosis was founded with P-Value of 0.001 and 0.000 respectively.²³

Our study result can be interpreted by the actual low risk of DVT in this population, or the adequacy of mechanical measures to tide over whatever risk there is. One factor in the absence of DVT in the study may be the short preoperative immobility, but then the impact of genetic factors in the low prevalence of DVT in the Asians cannot be ruled out. There is a low

prevalence of the thrombophilic trait known as factor V Leiden mutation and possible lower level of fibrinogen, factor VIIc and factor VIIIc.⁴ Another thrombophilic trait thrombin gene G20210A associated with increased plasma prothombin may be less prevalent in Asians.²⁴ Also the fact that the current study didn't have a single patients with, recent cardiac morbidity, nephrotic syndrome, exogenous oestrogen intake, previous history of PE/ DVT, pregnancy, puerperium paraproteinemia or limb paresis might have influenced the incidence.^{25, 26} At the same time it must be impressed that we were successful to make patients ambulatory, early in the the postoperative period, and compliance to the compression device and the stockinet used in prophylaxis were good. However this finding cannot be projected to the huge population of general surgical patients in India. Large studies from India are required to confirm our findings.

Jain and his study group reported a very low incidence of DVT following TKA and THA in Indian patients.28 Only two patients in their series of 106 patients from North India undergoing THA and TKA showed duplex sonographic evidence of proximal DVT.¹⁵ Agarwala and his associates by using contrast venography as a diagnostic tool for DVT, however, reported a very high incidence of

DVT both in patients not receiving chemoprophylaxis (60%) and in patients receiving prophylaxis(43.2%) in their study of patients underwent major limb surgeries.¹⁴

An apparent shortcoming of this study is the descriptive nature, which might necessitate caution, especially while interpreting the findings with respect to determination of risk factors. The diagnosis of DVT is often not suspected clinically, and there is a possibility of underdiagnosis. Therefore, venous compression ultrasonography was performed for all patients irrespective of the clinical suspicion. Doppler analysis has emerged as a sensitive and accurate non-invasive test for confirming the presence of acute DVT. Its sensitivity and specificity for the diagnosis of symptomatic proximal DVT are 97 and 94 per cent, respectively.²⁷

Conclusion

The current prospective observational study among the 75 high and moderate risk general surgical patients in absence of pharmacoprophylaxis showed nil incidence of DVT in the study population, all of whom received mechanical prophylactic measures. This is a small study, with its limitations, done in a short period of time, in a single hospital. The findings cannot be projected into the large population of general surgery patients at risk of DVT in India; however it may indicate the need for a larger study. The current standard of care of pharmacoprophylaxis with the low molecular weight heparin is safe, requires less monitoring and have very little contraindications. Still considering the huge population of general surgical patients likely to be in the high and moderate risk category for DVT, the cost of pharmacoprophylaxis with LMWHs will be a huge economic burden for a country like India. Therefore it is wise to suggest a large multicentere prospective trial concentrating on general surgical patients in India is the need of the day. And if simple mechanical measure is good enough to alleviate the DVT risk then, that will save a lot of healthcare expenditure, and the hazards are associated with the anticoagulants.

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