

Venous Thromboembolism following Major Abdominal Surgery in Indian Population: A Single Center Experience

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ABSTRACT

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Background: Postoperative venous thromboembolism is a proven major health problem in western countries. Hence there are specific guidelines advocating thromboprophylaxis in most cases. The few studies available regarding incidence in Indian patients provide conflicting data regarding the incidence of thromboembolism and need for thromboprophylaxis in our patients. In our study, we analysed the incidence of deep venous thrombosis in patients who underwent major abdominal surgeries over 5 years.

Materials & Methods: This was a retrospective descriptive study among 757 patients admitted in the surgical wards of Government Medical College, Trivandrum from January 2005 to December 2009 and underwent major abdominal surgeries. From the data, the incidence of postoperative deep venous thrombosis was detected.

Results: Of the 757 patients studied, 0.92% developed deep venous thrombosis in the post-operative setting. No form of prophylaxis was found to be used in any of these patients.

Conclusion: It has been found in this study that the rate of postoperative DVT is negligible after major abdominal surgeries. This prompts us to say that routine chemical prophylaxis is an unnecessary intervention in Indian patients who undergo major abdominal operations and may be administered only in very high risk patients.

Keywords: Anticoagulant, Deep Vein Thrombosis, Laparotomy, Postoperative, Thromboprophylaxis

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INTRODUCTION

Deep venous thrombosis (DVT) or Venous Thromboembolism (VTE) is one of the common complications observed among western population in the postoperative period. Many studies have described the risk of DVT during major surgeries and the need for routine prophylaxis. The incidence of venous thromboembolism in Western populations undergoing major surgery without any thromboprophylaxis has been reported to range from 32% to 88%.¹ During the acute phase of DVT, 10 to 40% of patients will develop Pulmonary Embolism (PE), which has an estimated mortality rate of 10 to 20%.² However, the mortality rate for PE has been stated to be as high as 30% in studies that included autopsy-based PE diagnosis. In fact, autopsy studies document that 50% of all patients dying in hospital have some form of DVT, pointing out that many episodes of PE may not be recognized clinically before death.³ Death occurs within one month of an episode in around 6% of those with DVT and 10% of those with PE.⁴ The major outcomes of venous thrombosis are death, recurrence, anticoagulation-induced major

bleeding and post-thrombotic syndrome. Mortality rates are lower among patients with idiopathic venous thrombosis and highest among those with cancer. In cancer patients undergoing abdominal surgeries, DVT and PE are more common postoperative complications, making the outcome much worse.⁵ Since surgery and malignancy are independent risk factors, postoperative cancer patients are at a particularly high risk of developing DVT. The mechanism of acute lower-limb DVT after surgical treatment of abdominal malignancies comprises several factors, including coagulation disorders, which are present in most tumour patients, damage to vascular endothelial cells caused by abdominal surgery and tissue injury, coagulation disorders and venous stasis.⁶ Sites of cancer with the highest rates of VTE include the pancreas (8.1%), kidneys (5.6%), ovaries (5.6%), lungs (5.1%), and stomach (4.9%). Among the hematologic malignancies, myeloma (5%), non-Hodgkin's lymphoma (4.8%), and Hodgkin's disease (4.6%) are supposed to have the highest rates of VTE.⁷ VTE is also feared by most surgeons performing weight loss surgery because of the perception of greater risk for the severely obese

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patient. VTE is one of the major causes of mortality for patients undergoing bariatric surgery.

DVT commonly affects the leg veins or the deep veins of the pelvis. In high-risk hospitalized patients, most deep vein thrombi occur in the small calf veins, are asymptomatic, and are rarely detected, even if asymptomatic. Although many thrombi are initially asymptomatic, in many cases, the affected extremity may be painful, swollen, red, and warm, with engorged superficial veins. Vague aching pain, tenderness along the distribution of the veins, edema, and erythema are some nonspecific signs and vary in frequency and severity. Tenderness, swelling of the whole leg, >3 cm difference in circumference between calves, pitting edema, and collateral superficial veins are the most specific signs. A combination of ≥ 3 signs, with the absence of another likely diagnosis makes DVT more probable. To identify clinically important thrombi in patients, Wells' score for DVT have been developed, which combines many clinical parameters to increase the sensitivity.⁸ Recently, the revised Geneva score has been introduced for determination of probability of pulmonary embolism.⁹ Along with these scoring systems, D-dimer assay is validated as a diagnostic tool to safely exclude the presence of venous thromboembolism (VTE) due to its high negative predictive value.¹⁰ For the purpose of risk stratification for thromboprophylaxis, Geerts et al. stratified patients into 3 groups: (a) Very high risk (Age >60 years with malignancy, obesity or any other risk factor), (b) High risk (Age 40–60 years with malignancy or obesity), (c) Moderate risk (Age >40 years with no risk factors).¹¹

As per the ASCO (American Society of Clinical Oncology) recommendations, patients undergoing major surgery should receive prophylaxis starting before surgery and continuing for at least 7 to 10 days. Extended prophylaxis for up to 4 weeks should be considered in those undergoing major abdominal or pelvic surgery with high-risk features. Several randomised trials have shown that both unfractionated heparin (UHF) and low molecular weight heparins (LMWH's) are effective in the prevention of DVT.¹² LMWH is recommended for the initial 5 to 10 days of treatment for deep vein thrombosis and pulmonary embolism as well as for long-term secondary prophylaxis (at least 6 months).¹³ The UK national guidance, published by the National Institute for Health and Clinical Excellence (NICE), first in 2007 (for surgical inpatients) and more recently in 2010 (for all hospitalised patients), provides guidance for all hospital specialities about assessing patients for any risk of VTE, and

about pharmacological or mechanical prophylaxis.¹⁴ An important issue for consideration when producing local policies for VTE prophylaxis is risk stratification, or in other words whether some patients at risk for VTE are at greater risk than others and therefore should receive different doses of anticoagulant drugs or different mechanical methods.

Though the true incidence of DVT with routine screening is controversial, the incidence of clinically detectable DVT is thought to be small. Despite this low incidence of clinically detectable DVT and pulmonary embolism (PE) in many large review studies, majority of surgeons select some form of DVT prophylaxis for abdominal surgeries. The thrombosis risk factors considered most important by surgeons when deciding about prophylaxis are previous history of venous thromboembolism, hypercoagulability, and malignancy. In a postal survey conducted on general surgeons in Wales, all those who responded routinely used prophylaxis, the most frequent modalities used being heparin (100%) and graded compression stockings (79%). In the same study, all surgeons continued prophylaxis after surgery, 53% until patients were mobile, 45% until they were discharged, and one surgeon continued prophylaxis for seven days after discharge.¹⁵

The chemoprophylactic agents employed include Unfractionated Heparin (UFH), Low-molecular-weight heparins (LMWHs), Warfarin and Fondaparinux. LMWHs have replaced regular heparin in many hospitals because of their many advantages over the latter, as they have superior or comparable efficacy and safety, they have very less risk of bleeding because of low immunogenicity, they have decreased frequency of thrombocytopenia and osteopenia, they prevent early recurrence of thrombus in the treatment of DVT because they achieve higher quality of anticoagulation in the first hours, they can be taken as single daily dose and they do not require activated partial thromboplastin time monitoring.¹⁶ A number of mechanical thromboprophylactic modalities are also available. They include electrical calf stimulation, intermittent pneumatic compression devices, graduated compression stockings (GCS), and venous foot pump devices. Although studies state that these devices have lesser efficacy in preventing post-operative VTE, the most important advantage of mechanical thromboprophylaxis is the lack of bleeding complications. The incidence of VTE in Asian patients is traditionally considered to be lower than the Western population.¹⁷ This fact becomes all the more important in a country like India where a large majority of the general popu-

lation may not be able to afford such a bill unless the public health system is able to provide it free of cost. If the incidence of DVT is truly negligible, prophylaxis may not be indicated. The purpose of this review was to determine the incidence of clinically detectable DVT in patients undergoing major abdominal surgeries over a 5 year period at a large volume, tertiary care center. Since the general recommendations regarding routine thromboprophylaxis were established after the study period, it was thought unlikely that any patient would have received prophylactic antithrombosis. An accurate assessment of the incidence and the risk factors in this ethnic group will probably help clinicians in making important decisions about post-operative thromboprophylaxis. The objective of this study was to find the incidence of deep venous thrombosis after major abdominal surgeries.

MATERIALS AND METHODS

The study was done as a retrospective descriptive study based on hospital records, at the General Surgery department of Government Medical College, Trivandrum. Clinical and radiological data about all the patients who underwent elective major abdominal surgeries from January 2005 to December 2009 was obtained from the Medical Records Library. A total of 757 patients were included in this study, as they matched the inclusion criteria. Major abdominal surgery was defined as any surgical procedure done under general anaesthesia where the duration of operation lasted more than 1 hour. Excluded patients included those already on anti-coagulants, those with diagnosed bleeding or clotting disorders, as well as pregnant and lactating patients. Patients were identified from a computerised database of all in-patient diagnoses, classified based on the International Classification of Diseases (ICD) code. The in-patient records were used to collect data, while the out-patient records were used to determine follow-up and outcomes.

Data was obtained regarding the patients demographic profile, the disease at presentation and the surgical procedure carried out. Deep vein thrombosis (DVT) was suspected based on the clinical criteria of limb pain and swelling. Also, it was noted whether any form of thromboprophylaxis - mechanical or chemical was used. In suspected cases, sonography was done by the radiologist using 7.5 or 10 MHz linear transducer probes performed duplex ultrasonography. DVT was confirmed by the presence of a thrombus seen on B-mode imaging, compressibility of the veins, respiratory phasicity and augmentation response. The

confirmed cases of VTE were treated with intravenous infusion of heparin followed by a course of oral warfarin for a period of three months. The therapeutic level monitoring for heparin was done using activated partial thromboplastin time and of warfarin by international normalised ratio.

Institutional Ethical Committee clearance was obtained before data collection. The resultant data was entered into a prefixed proforma. All statistical analyses were performed using SPSS ver. 12.0 (SPSS Inc., USA).

RESULTS

Among these 757 patients who have undergone different major surgical procedures during the study period; 430 patients were males and 327 were females. Out of this; 146 (19%) patients underwent surgery for duodenal-perforation-peritonitis (**Table 1**).

The average duration of surgery underwent among the study group was 2 hours and 10 minutes. The longest time recorded was for pancreaticoduodenectomy (mean of 4 hours and 07 minutes) and the shortest time recorded was for duodenal perforation peritonitis (mean of 1 hour and 21 minutes). Male to female ratio in duration of surgery was 1.31, and the average duration of stay in hospital was 12 days. The average weight of patients was 57.7 kg and the height was 162.5 cm. 27 patients had a BMI more than 30. No form of venous thromboprophylaxis was found employed in any of the obese patients.

Table 1. Gender wise distribution of type of surgery

Type of Surgery	Male	Female	Total
Abdomino-Perineal Resection	43	34	77
Anterior Resection	31	30	61
Cholecystectomy			
+ / - Choledocotomy	20	27	47
Duodenal Perforation Peritonitis	91	55	146
Gastrectomy	31	21	52
Gastric Perforation Peritonitis	29	14	43
Gastrojejunostomy	12	10	22
Ileal & Jejunal Perforation Peritonitis	14	9	23
Laparoscopic Cholecystectomy	11	24	35
Left Hemicolectomy	20	18	38
Mesenteric Ischemia	12	6	18
Pancreaticoduodenectomy	19	6	25
Right Hemicolectomy	39	36	75
Small bowel Obstruction	29	29	58
Splenectomy	29	8	37
Total	430	327	757

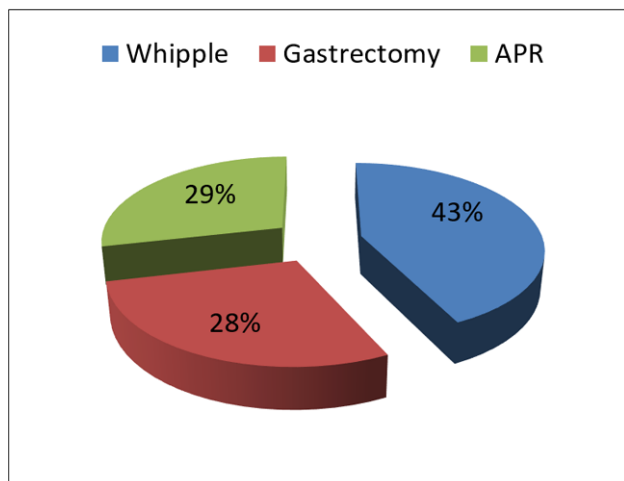


Figure 1. Distribution of patient with DVT

During the study period, 7 patients developed deep venous thrombosis (0.92%). Of these, 3 were following pancreaticoduodenectomy, 2 after gastrectomy and 2 after abdomino-perineal resection. For all of these patients, the common factors were malignancy, prolonged surgical duration (more than 3 hours) and prolonged immobilisation (more than 72 hours). After doppler confirmation all 7 of these had treatment with heparin and no mortality was recorded (Figure 1).

There was a mortality of 37 in the population of 757(4.9%). Of these, ten patients died on the operative table due to cardiovascular arrest, while 20 patients died within the first postoperative week due to sepsis or cardiovascular events. 7 patients died within the hospital stay period due to sepsis and related events. None of these patients had a documented event of DVT. The post-operative complications included wound infections (15.7%), pulmonary complications (10.5%), sepsis (5.1%), burst abdomen (2.9%), anastomotic dehiscence (2.7%) and enterocutaneous fistula (2.1%) (Figure 2).

DISCUSSION

This study provides information on incidence and risk factors for VTE in Indian population undergoing major abdominal surgery. As per this study, the incidence of postoperative thrombosis in patients undergoing major abdominal procedures is very minimal, to the level of 0.92% only. The fact that no form of prophylaxis was found to be used might be explained by the fact that the thromboprophylaxis guidelines were not established and accepted until after 2007. The differential occurrence of a particular disease in various ethnic groups is often attributed to the influence of multiple

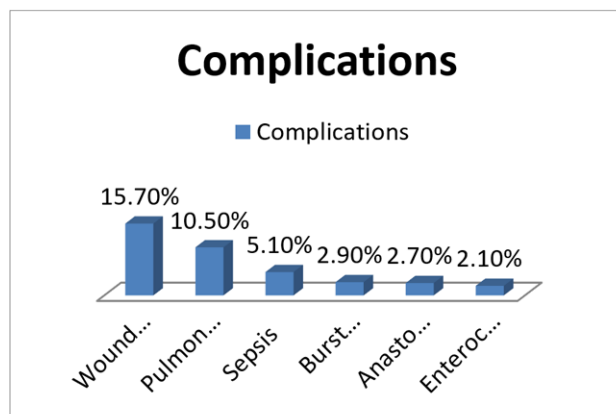


Figure 2. Complications other than mortality

acquired and genetic traits. The genetic traits that may be possible explanations for the reduced incidence of VTE in Asian population include activated protein C resistance, decreased prevalence of homocystinaemia, and a lesser prevalence of factor V Leiden mutation.¹⁸ Acquired traits that are thought to be risk factors for development of VTE and have been found to be less prevalent in Asian patients include obesity and heart failure.

Epidemiological data on the incidence of VTE in Asian populations is highly confusing and ambiguous. While most studies have shown that the incidence of DVT is lower in Asian patients than their western counterparts.¹⁹ Some of the recent studies from this region has shown significant incidence of DVT in high risk surgical patients.²⁰ The results of our study are consistent with most of the previously published results and reconfirm that the incidence of VTE in Indian patients is significantly lower than in the Western population. Being an important cause of postoperative morbidity; comprehensive data on the incidence of VTE will probably help in formulating guidelines for patients of Indian origin.

An apparent shortcoming of this study is the descriptive nature, which may warrant caution, especially while interpreting the findings with respect to determination of risk factors. These numbers although statistically small, are clinically not insignificant, particularly in view of obtaining this large a group of patients who got no prophylaxis. There is an increasing trend towards use of routine thromboprophylaxis in surgery in India based on the data obtained from Western populations. The findings of this study may thus emphasise the need of a multicentre prospective randomised trial to validate the use of thromboprophylaxis before it is adopted and approved for the Indian population.

CONCLUSION

In conclusion, we find that in this large descriptive study of an Indian population undergoing major abdominal surgery, the incidence of deep venous thrombosis is significantly lower than in Western population. As a corollary, it may be prudent not to apply the Western criteria of universal thromboprophylaxis in this ethnic group and limit its use to those with very high risk factors only. We opine that the employment of thromboprophylaxis may be advocated for patients with cancers undergoing prolonged surgical procedures or patients being immobilised for prolonged duration after the procedure.

END NOTE

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Conflict of Interest: None declared

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