



# International Journal of Orthopaedics Sciences

ISSN: 2395-1958  
IJOS 2019; 5(3): 655-658  
© 2019 IJOS  
www.orthopaper.com  
Received: 05-05-2019  
Accepted: 07-06-2019

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## Clinical profile of patients on DVT prophylaxis undergoing major lower limb orthopedic surgeries

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DOI: <https://doi.org/10.22271/ortho.2019.v5.i3l.1608>

#### Abstract

It has been known for a long time that clinical symptoms and signs are of little help in the diagnosis of venous thrombosis of the legs because they lack both sensitivity and specificity. This applies to calf tenderness, pain on dorsiflexion of the foot (the Homan's sign), increased skin temperature, ankle and calf edema, and superficial venous dilatation. Contrast venography, the first objective test and still the gold standard in the diagnosis of venous thrombosis. This clinical prospective study on Efficacy of Enoxaparin as a Thromboprophylactic agent in major lower limb orthopedic surgeries was conducted in department of Orthopedics. During the study period, 180 patients undergoing Surgeries for fracture around hip, femur fracture surgery, patients undergoing Hip and Knee Arthroplasty were given prophylaxis for DVT. A prior consent was obtained from all the patients and the study was approved by the Ethical Committee of the Hospital. The Youngest patient in this study was 20 years and oldest 85 years of age. The average age being 54 years. 43.3% of patients were 60 and above, 21.11% between 50-59, 16.11% between 40-49, 9.44% between 30-39 and 10% between 20-29 years of age. Indications for Hemiarthroplasties were fracture neck of femur in forty two cases. Total Hip Replacement was done in six cases, three of them had avascular necrosis of head of femur and three of them had secondary arthritis of hip. Total Knee Replacement for primary osteoarthritis was done in twenty four cases.

**Keywords:** DVT prophylaxis, major lower limb orthopedic surgeries, hip and knee arthroplasty

#### Introduction

It is now well established that venous thrombosis is caused by a contribution of three factors, i.e. damage to the vein, blood stasis and hypercoagulability. It is also known that thrombosis is more frequent in association with circumstantial risk factors such as pregnancy and delivery, surgery, cancer and other medical illnesses, and with inherited and acquired factors that cause hypercoagulability. The development of our current knowledge on the pathogenesis of venous thrombosis took place over several centuries. The first detailed description of venous thrombosis after delivery was made in England by Richard Wiseman (1676), Sergeant-Chirurgion to King Charles II. In a chapter of 'Several Chirurgicall Treatizes' he wrote about the wife of a pharmacist who, after a difficult labour, developed swelling and pain of the right leg, extending from the knee to the hip, with no inflammation and discoloring of the skin. The description by Wiseman of this case is notable not only because the concept of the proximal propagation of a leg venous thrombus is put forward, but also because Wiseman surmised that thrombus formation was caused by a systemic alteration in circulating blood, thereby pioneering the concept of hypercoagulability [1]. Until the end of the 18<sup>th</sup> century, it was held that venous thrombosis associated with pregnancy and delivery was caused by retention in the legs of 'evil humors', which determined a reflux of blood. For instance, the famous French surgeon Ambroise Pare  $\hat{A}$ , who lived in the 16<sup>th</sup> century, believed that swelling of the legs during pregnancy was caused by the retention and concentration of menstrual blood (Johnson, 1678). Incidentally, Ambroise Pare  $\hat{A}$  was probably the first to describe superficial thrombophlebitis as a complication of varicose veins, as he wrote 'They often swell with concealed and dried blood and cause pain which is increased by going and compression' (Johnson, 1678). Another widely held view was that post-partum thrombosis was caused by the retention of unconsumed milk in the legs (engorgements laiteaux') (Levret, 1766) [2].

The short but well-documented and detailed publication of Findley (1912) should be read by those who are interested in one of the earlier modern reviews on venous thrombosis associated with pregnancy and puerperium. With the exception of the putative first case of venous thrombosis in the apparently healthy young man described by de Saint Pathus (1932), the early descriptions of this condition were mostly related to childbirth. We have to wait until the 19th century and the seminal work of Armand Trousseau (1866) for the first documented case of the association of venous thrombosis with cancer, known to be one of the most frequent predisposing conditions. His observation had to wait nearly 70 years to be confirmed and extended by Sproul (1938), who reported a high frequency of venous thrombosis during the post-mortem examination of patients who died of various malignancies, most notably pancreas carcinoma. According to De Bakey (1954), a pioneer in cardiovascular surgery who reviewed the early literature, the well-known association between venous thrombosis and surgery was first recognized by Spencer Wells in 1866<sup>[3]</sup>. More modern, seminal studies are those of Gunnar Bauer (1942), who called attention to the frequency of venous thrombosis especially after fractures of the legs, and Byrne (1955), who investigated as many as 748 cases and demonstrated that the post-operative state was the second most common predisposing factor (pregnancy and puerperium ranking first), particularly in cancer surgery, in operations involving the pelvis and with fracture of the legs. That medical illnesses, particularly if long-lasting and associated with prolonged immobilization in bed, are a risk factors for venous thrombosis was first established by Ferrier (1810), who noted that the condition occurred not only post partum but also during debilitating infectious diseases such as typhus. According to Lockwood (1951), however, it was as early as at the beginning of the 15th century that Ugo Benzi of Siena described venous thrombosis occurring during a long illness accompanied by fever in a man from Novara named Jacobus Manni. Swelling involved both legs, it is not known whether conditions other than venous thrombosis may have caused it<sup>[4]</sup>.

It has been known for a long time that clinical symptoms and signs are of little help in the diagnosis of venous thrombosis of the legs because they lack both sensitivity and specificity. This applies to calf tenderness, pain on dorsiflexion of the foot (the Homan's sign), increased skin temperature, ankle and calf edema, and superficial venous dilatation. Contrast venography, the first objective test and still the gold standard in the diagnosis of venous thrombosis.

Lack of specificity and sensitivity of clinical diagnosis was definitely demonstrated by Haeger (1969), taking phlebography as the reference method<sup>[5]</sup>.

Haeger concluded that clinical signs could not be used for diagnosis, nor could thrombosis be excluded by their absence. The fallacy of clinical diagnosis, the need for an accurate diagnosis before starting a treatment not free of serious side-effects such as anticoagulants, and the difficulties associated with the widespread use of contrast phlebography as a diagnostic method (invasiveness, pain, superficial thrombophlebitis, difficult interpretation of the results) gave the impetus in the 1970s to the development and validation of a number of objective and non-invasive diagnostic methods, using phlebography as a reference. Those better validated and more used in clinical practice are impedance plethysmography and compression ultrasonography, the latter alone or combined with pulsed Doppler (Duplex) scanning. After a period of popularity that followed the original

independent development of the  $125\text{I} \pm$  fibrinogen uptake test (Browse, 1972; Kakkar, 1972), this method, mainly used for the diagnosis of asymptomatic venous thrombosis in individuals at risk in the post-operative period or during medical conditions such as stroke and myocardial infarction, fell into disrepute because it was shown that it was not as sensitive as originally predicted (Lensing & Hirsh, 1993). In addition, the fear that the infusion of plasma derived fibrinogen might transmit blood-borne infections led to its abandonment during the acquired immune deficiency syndrome (AIDS) epidemics<sup>[6]</sup>.

Several studies have shown that plethysmography and ultrasonography are sensitive to the presence of occlusive venous thrombi involving the veins of the knee and thigh, but are poorly sensitive to non-occlusive thrombi of the upper leg or to thrombi confined to the calf vein, and that withholding anticoagulant treatment on the basis of a negative diagnosis is safe in terms of the occurrence of venous thrombo embolic complications (Hull *et al*, 1985; Lensing *et al*, 1989; see also the review of Prandoni & Mannucci, 1999). At this time, compression ultrasonography with or without the associated use of pulsed Doppler scanning is the most widely used test in Europe to diagnose patients with symptoms and signs that suggest the presence of venous thrombosis.

### Methodology

This clinical prospective study on Efficacy of Enoxaparin as a Thromboprophylactic agent in major lower limb orthopedic surgeries was conducted in department of Orthopedics. During the study period, 180 patients undergoing Surgeries for fracture around hip, femur fracture surgery, patients undergoing Hip and Knee Arthroplasty were given prophylaxis for DVT. A prior consent was obtained from all the patients and the study was approved by the Ethical Committee of the Hospital.

Required data was collected from patients admitted in PES hospital. All patients included in study were assessed pre-operatively with structured questionnaire and physical examination and screened for DVT radio logically by Doppler Ultra sound, Blood investigations like PT and aPTT, with other routine investigations.

### Inclusion Criteria

- Arthroplasty-(Hip and Knee).
- Major Trauma-(Surgeries for fractures around Hip, Femur fracture surgeries.)

### Exclusion Criteria

- Proved cases of DVT
- Pathological fractures.
- Pregnancy
- Hypersensitivity to heparin
- Patient at risk for bleeding complications

### Results

The average age of patients undergoing surgeries for proximal, middle and distal femur fracture was 48.5 years. The average age of patients undergoing Hemi Arthroplasty was 59.8 years. The average age of patients undergoing Total Knee Replacement was 62.9 years. The average age of patients undergoing Total Hip Replacement was 52.2 years. Indications for Hemiarthroplasties were fracture neck of femur in forty two cases. Total Hip Replacement was done in six cases, three of them had avascular necrosis of head of femur and three of them had secondary arthritis of hip. Total

Knee Replacement for primary osteoarthritis was done in twenty four cases.

**Table 1:** Age Incidence

Age Group	Frequency	Percent
20-29	18	10%
30-39	17	9.44%
40-49	29	16.11%
50-59	38	21.11%
60 and Above	78	43.33%
Total	180	

The Youngest patient in this study was 20 years and oldest 85 years of age. The average age being 54 years.43.3% of patients were 60 and above, 21.11% between 50-59, 16.11% between 40-49, 9.44% between 30-39 and 10% between 20-29 years of age. Significant association of age group found in 60 and above.

**Table 4:** Indications for THR

THR						
No of Patients	No of Hips	AVN	Secondary Arthritis	Others	Males	Females
6	6	3	3	0	1	5

Study includes 6 patients with 6 THR. The indications of THR were – 3 AVN, 3 Secondary Arthritis.

**Table 5:** Indications for TKR

TKR					
No of Patients	No of Knees	OA Knee	Others	Males	Females
24	26	26	0	8	16

Study includes 24 patients with 26 TKR. The indications for all cases were Osteoarthritis knee.

**Table 6:** Indications for Hemi Arthroplasty

Hemi Arthroplasty					
No of Patients	No of Hips	Fracture Neck of Femur	Others	Males	females
42	42	42	0	15	27

Study included 42 patients with 42 Hemi arthroplasties. The indications for hemi arthroplasties was fracture neck of femur.

**Table 7:** Indications for Trauma surgeries

Fracture Surgery					
No of patients	Intertrochanteric fracture	Femur shaft Fracture	Distal Femur Fracture	Males	Females
108	42	46	20	52	56

Study includes 108 patients who underwent surgeries for fractures around hip and femur fracture surgery.

**Discussion**

Traditionally the incidence of VTE is thought to be lower in Asians. But emerging evidence from thorough literature search by Liew N C *et al.* [11] of 12 orthopedic publications show the incidence to be 10-83%.

In the western population, the prevalence of DVT after Total Joint Arthroplasty has been reported to be 46-86% as reported by PL Chin *et al.* [7]. In the Asian population it is lower, but recently has been increasing. This lower incidence may be due to lack of prothrombotic clotting factor polymorphysism (factor v Leiden and prothrombin G20210A).

It is known that prevalence of thrombophilia (hereditary / acquired) which predisposes individuals to thromboembolic events like DVT, PE, Myocardial infarction etc. is much less in Indian population than the western countries. Resistance to APC (Activated Protein-C) is the most common inherited risk factor for Venous thrombosis. Most common cause for APC Resistance is Factor V Leiden Mutation. This mutation is the most common genetic predisposition for thromphilia and DVT and has a carrier rate of 5% in west and 1.3% in India [8]. Alexander T Cohen *et al* [9] has shown that perception of ethnic difference is gradually changing & that some Asian studies show the risk of VTE to be equal to that in Caucasian population. A growing elderly population & western life style, including diet could be important contributing factors for this increase.

According to Ramesh K Sen *et al.* [10] there is lack of prospective multicentric trials of VTE in orthopedic trauma patients. A thorough search of Pub Med & Google Scholar revealed 10 selected articles that were reviewed. The incidence of VTE was reported to be 14% after Hip or proximal fractures without prophylaxis & only 8% with prophylaxis. Major Orthopedic Surgery is a compelling risk factor for VTE & its complications. Therefore VTE – Prophylaxis is justified in Indians and Asians.

An exhaustive literature search of published papers on incidence of VTE in Asian population was performed by Leizorowicz *et al.* [11]. After THR surgery the incidence was 16%, after TKR surgery 50% and after HFS 18% [12]. This 18% incidence is similar to the incidence reported by RK Sen. SMART study (Surgical Multi National Asian Registry in Thrombosis) done by A Leizorowicz *et al.* [11] and GG Turpie *et al.* [13] which is a prospective multicenter observational study of Asian patients undergoing major orthopedic surgery, assessed the incidence of symptomatic VTE or sudden deaths in 2420 patients after THR, TKR or HFS without prophylaxis in 11 Asian countries including India and found it to be 2.3% & 1.2% respectively [13]

The SMART Venography study was a prospective observational cohort study was conducted By Alain Leizorovicz [11] in 8 centers in 3 Asian countries (Bangladesh, Korea and Chinese Taiwan). The primary end point was the

composite of venographically detected asymptomatic VTE, confirmed symptomatic VTE or sudden death at hospital discharge. A total of 326 patients undergoing TKR or THR had evaluable venograms. The primary outcome occurred in 36.5% of patients. The rate of symptomatic VTE was 0.9%. In Asians incidence of VTE is high after major orthopedic surgery. Thromboprophylaxis should be considered in Asians. Piovella *et al.* [14] performed a multicenter multinational epidemiological study (AIDA Study-Assesment of Incidence of DVT in Asia) to determine the incidence of DVT in Asian patients undergoing Major Lower Limb orthopedic Surgeries (MLLOS) across 19 centers in Asian countries including India. DVT was diagnosed in 41% of patients. Proximal DVT was found in 10%. Total & proximal DVT rates were highest in TKR patients (58% & 17%), followed by HFS (42% & 7%), then THR (25% & 5%) respectively. DVT was more frequent in females aged at least 65 years

Seung yeol Lee *et al.* [15] in 2015 evaluated the nationwide incidence and risk factors for symptomatic DVT after Major Lower limb Orthopedic Surgeries using the Korean Health Insurance Database from 2011-2015. Their results showed that the incidence of DVT and post-operative DVT after Major Lower limb Orthopedic Surgeries have increased annually. Old age, female gender and Knee replacement surgery were associated with highest risk of developing post-operative DVT.

PS Ko *et al.* [16] performed a prospective study on 80 so called -low risk Chinese patients undergoing THA or TKA without prophylaxis and performed duplex ultrasonography on both lower limbs 6 to 8 days after surgery. A total of 22 patients (27.5%) showed ultrasonographic evidence of DVT. This study showed that patients who are labeled -low risk for DVT actually had significant risk and therefore current practice of providing prophylaxis to only patients deemed at -high risk should be revised.

## Conclusion

- Our study includes 180 patients for VTE prophylaxis with Inj Enoxaparin in major lower limb orthopedic surgeries. (Hip Arthroplasty-48 Patients, Knee Arthroplasty-24 patients, Hip and Femur Fracture surgery-108 patients).
- Males-75(41.66%) Females-105(58.33%)
- Age of the patients ranged from 20 to 85 years.
- Pre-op color Doppler was done to rule out pre-op DVT.

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