Original Article

Role of calf muscle stimulation in the prevention of DVT in Indian patients undergoing surgeries for fractures around the hip

Aman Goyal, Sumit Arora, Sumit Batra[1], Rohit Sharma[2], Mahesh Kumar Mittal[2], Vinod K Sharma[1]

Abstract

Background: The venous stasis of soleal vein during surgery may be an important factor in the development of deep vein thrombosis (DVT). The stimulation of calf muscle during surgery may help in preventing DVT. The present study is conducted to evaluate the role of peroperative calf muscle electrostimulation in prevention of DVT in patients undergoing surgeries around the hip joint.
Materials and Methods: The study comprised 200 patients undergoing surgeries around the hip joint. The patients having risk factors (such as previous myocardial infarction, malignancies, paraplegia or lower limb monoplegia, previous history of DVT or varicose veins, etc.) for the development of DVT were excluded. They were randomized into two groups: 100 cases were given peroperative calf muscle electrostimulation for DVT prophylaxis (Group A) and the remaining 100 patients were taken as controls without any prophylaxis (Group B). The color Doppler ultrasound was performed to exclude pre-existing DVT and on 7th day postoperative to find out the incidence of DVT in both the groups.
Results: Two patients among Group A and six patients among Group B demonstrated DVT on ultrasonography, but the difference was not found to be statistically significant (P=0.279). None of the patients had any clinical evidence of DVT.
Conclusion: The role of peroperative calf muscle electrostimulation for DVT prophylaxis remains controversial. The risk of developing DVT in patients undergoing surgeries around the hip joint is very less in patients analysed in our series.

Key words: Deep vein thrombosis, electrostimulation, hip surgeries, thromboprophylaxis

Introduction

Deep vein thrombosis (DVT) and pulmonary embolism is a serious yet preventable cause of postoperative morbidity and mortality. It is estimated that 20 million cases of lower extremity DVT occur in the USA alone and account for the vast majority of pulmonary embolism each year.[1] Major orthopedic surgeries of the lower limbs are a high risk for the development of DVT and its incidence has been reported to range from 6 to 75%.[2-4] Various measures available for DVT prophylaxis, include early mobilization and physiotherapy, pharmacological means [unfractionated heparin, low molecular weight heparin (LMWH), Dextran 40 and 70, warfarin, aspirin], and mechanical means (mechanical calf muscle stimulation, thigh-high anti-embolic stockings, pneumatic calf muscle compression, electrical stimulation of calf muscle). It has been reported that venous return may be reduced to half after administration of anesthesia, which may even reduce to one-seventh of its preoperative rate.[5] This venous stasis, especially of the soleal veins, during the surgery may be an important factor in the development of DVT. The role of peroperative electrostimulation of calf muscles with modern-day handheld electrostimulation device in the prevention of DVT remain sparse in literature.[5-7]

We prospectively sought to determine the efficacy of prophylaxis against DVT with peroperative electrostimulation of calf muscles in a consecutive case–control series.

Materials and Methods

This was a prospective randomized study, which was carried

Department of Orthopaedic Surgery, Maulana Azad Medical College and Associated LokNayak Hospital, New Delhi, [1]Central Institute of Orthopaedics, [2]Department of Radiodiagnosis, Vardhman Mahavir Medical College and Associated Safdarjang Hospital, New Delhi, India

Address for correspondence: Dr. Aman Goyal,
Department of Orthopaedic Surgery, Maulana Azad Medical College and Associated LokNayak Hospital, New Delhi – 110002, India.
E-mail: amangoyalaries@gmail.com

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out between November 2008 and February 2011. An approval from the Institutional Review Board was obtained. The present study included 200 consecutive patients who sustained trauma around the hip joint and underwent surgeries under spinal anesthesia.

Patients >25 years requiring surgeries around the hip joint who underwent surgery within 2 weeks of sustaining trauma, and were operated under spinal anesthesia were enrolled. Established cases of DVT, or patients taking antithrombotic medication, patients who sustained open fractures, and patients on pacemakers were excluded from the study. Patients with other serious life-threatening conditions, pathological fractures, and associated vascular injuries were also excluded from the study. The patients were randomized into two groups of 100 patients each by odd–even number, with even numbered patients considered as cases for peroperative calf muscle electrostimulation (Group A) and odd numbered ones considered as controls (Group B). All of them received standard primary care and underwent adequate orthogonal radiographs. The patients were encouraged to perform active and passive physiotherapy as tolerated. Preoperative Doppler ultrasound was done on HDI 4000 (Philips Medical Systems Inc., Boston, MA, USA) for all the patients on both the lower limbs using linear probe (5.38–12 MHz) a day prior to the surgery to rule out pre-existing DVT, thereby excluding any patient with clinical or subclinical DVT as a result of trauma. First group of patients received thromboprophylaxis using the VenioPlus™ (Ad Rem Technology, France) stimulator device for electrostimulation of the calf muscles during surgery was stimulated given to both calf muscles whereas the other group of patients (Group B) did not receive any sort of thromboprophylaxis. The stimulator device delivered the low voltage (peak value being usually around 15–25 V) and small energy impulses (below 25 μC per impulse) to calf muscles. A record was maintained about the involved side, the type of surgery, and the position during surgery for both the groups.

All the patients were mobilized in bed as tolerated postoperatively, and static and dynamic exercises were started on the next day after the surgery. It was ensured that none of the patients was immobilized in bed for more than 3 days after the surgery. All the patients were examined daily for clinical signs of DVT like diffuse swelling of the leg and foot, calf tenderness (Moses sign) and Homan's sign (pain on passive dorsiflexion of foot). Another Doppler ultrasound was performed on the 7th postoperative day on the same machine for all the patients on bilateral lower limbs to look for DVT. The radiologist was blinded about the study and group of the patients. The Doppler assessment included examination of bilateral common femoral, superficial femoral, popliteal, anterior tibial, and posterior tibial veins. They were assessed for flow, visualized thrombus, compressibility, and augmentation. A diagnosis of DVT was made when there was visualization of thrombosis, absence of flow, and lack of compressibility or augmentation. The thrombi were classified to be proximal if they were found in popliteal vein or more proximal locations, and distal if they involved tibial or calf muscle veins. Patients who had both proximal and distal thrombus were classified as having proximal thrombosis. The patients having evidence of DVT on Doppler examination were treated according to the American College of Chest Physicians guidelines.[8]

Statistical analysis

All the statistical analyses were performed on Statistical Package for Social Sciences (SPSS Inc., version 16.0, Chicago, IL, USA) for Windows. Fisher's exact test was used to examine the significance of association (contingency) between the two kinds of interventions. It was referenced for two-tailed *P* value and 95% confidence interval was constructed around sensitivity proportions using normal approximation method. A value of <0.05 was assumed to attain sufficient statistical significance.

Results

The mean age of the patients was 54.3 years (19-82 years), whereas it was 55.3 (19-82 years and 53.3 years (22-80 years), respectively, in case and control groups,and the difference was found to be statistically insignificant ($P>0.05$). One hundred and fifty six patients were males and 44 were females. Right lower limb was operated upon in 56% (n-112) of the patients. The various traumatic conditions for which the patients were operated upon and surgeries are summarized in Table 1. Majority of the surgeries (66% cases) were conducted in supine position, whereas 34% (n=68) patients were operated in lateral position.

Eight patients (two among Group A and six among Group B) were diagnosed to have DVT on color Doppler ultrasound study on the 7th postoperative day, but the difference was not found to be statistically significant ($P=0.279$). None of these patients had any clinical signs or symptoms of DVT or pulmonary embolism. Among them, four patients were males (two each among Group A and B) and another four were females (both in the Group B). Six patients (four among Group B and two among Group A) were above 50 years ($P<0.05$), while two patients (both in Group B) were below 50 years of age. Four patients were operated in supine position with traction (two each among Group A and B), while another four were operated in lateral position (all among Group B). Four of them (two each among Group A and B) were operated with dynamic hip

Table 1: Various surgical procedures done along with patients' diagnoses

Diagnoses of the patients (n=200)	Cases	Controls	Surgical procedure done (n=200)	Cases	Controls
Fracture acetabulum (n=7)	4	3	Open reduction and internal fixation (n=7)	4	3
Fractures of the neck of femur (n=75)	40	35	Closed reduction, cannulated lag screws fixation (n=12)	7	5
			Hemi-replacement hip arthroplasty (n=63)	34	29
Fracture intertrochanteric femur (n=103)	49	54	Dynamic hip screw/dynamic condylar screw(n=110)	53	57
Fracture subtrochanteric femur (n=15)	7	8	Proximal femoral nailing(n=8)	2	6
Total	100	100	Total	100	100

screw; two underwent hemi-replacement hip arthroplasty, one closed reduction and internal fixation of neck of femur fracture, and another open reduction and internal fixation of acetabulum. All the patients had distal venous thrombus formation involving only the intermuscular (soleal) veins without any proximal migration, which resolved with anticoagulant therapy given in form of low molecular weight heparin (dalteparin) 5000 U subcutaneously twice a day for 7 days along with oral warfarin 5 mg daily for 6 weeks. Doppler ultrasonography was done at the end of 6 weeks to confirm resolution of the thrombus.

Discussion

The incidence of DVT in patients undergoing various surgeries around the hip joint are reported to have wide variation, especially in Indian scenario.[4,9-12] The distribution of lower limb DVT in Indian patients is not exactly known and any specific approach to its prevention remains a dilemma. As a consequence, thromboprophylaxis is not practiced routinely in this subcontinent. Most of the thrombi in this population have been reported to be distal, which resolve spontaneously without any long-term consequences.[3,4,12,13]

Contrast venography has usually been considered as a diagnostic modality of choice for detection of DVT and concerns have been raised on duplex ultrasonography yielding indeterminate studies.[14] Though nonfilling of contrast in deep veins on venography has been accepted as an indirect sign of DVT, Björgell *et al*. (2000) showed that isolated nonfilling of posterior tibial and deep muscle veins of the calf seen on venography can equally be caused by other pathological conditions like edema, bleeding, ligaments and muscle rupture, Baker's cyst, and superficial thrombophlebitis, or arises without any detectable explanation, thereby leading to an exaggerated number of patients with thrombosis in these studies.[15] Nowadays, duplex ultrasonography has become the diagnostic standard in most of the hospitals in the United States, making it more representative of real-time medical management.[16] The compression ultrasonic technique had an accuracy of 97%, a sensitivity of 100%, and a specificity of 97%. It appears to be an effective technique for diagnosing venous thrombosis, and is safe, well accepted by both patients and staff, can be performed quickly, and carries no inherent risks of the procedure itself owing to its non-invasive nature. It can also be easily repeated, thus making it suitable for monitoring high-risk patients.[17]

Dhillon *et al*.[3] and Piovella *et al*.[18] reported high incidence of DVT by venography in Asian patients undergoing lower limb surgeries without prophylaxis.On the other hand, Jain *et al.*,[10] Bagaria*etal.*,[11] Mavalankar *et al.*,[12] Atichartakarn *et al.*,[19] and Mitra*et al*.[20] reported a low incidence of DVT by venography in Asian patients undergoing hip surgeries. The results of our study seem to be in tune with the observations of manystudies demonstrating lower incidences of DVTin these patients [Tables 2 and 3].[10-12,19,20]

We did not find any correlation between the presence of clinical signs of DVT and Doppler ultrasound findings in our study as all the eight patients, who demonstrated DVT on ultra sound, did not show any clinical feature of the same. This further confirms the unreliability of physical signs in the diagnosis of DVT, as shown by Stulberg *et al*.[2] All the patients included in our study had surgery performed under spinal anesthesia. It has been suggested that patients undergoing surgery in general anesthesia are 50% more likely to develop DVT than those under spinal anesthesia as vasodilatation that accompanies spinal anesthesia increases the blood flow to lower limbs, thus inhibiting stasis and hypercoagulability.[12] Effect of limb position and manipulation during surgery causing femoral vein occlusion is well studied in total hip replacement.[21] It has been suggested that surgeries in lateral position with hip in flexion, adduction, and internal rotation may lead to femoral vein kinking which may further reduce the venous flow return from the lower limb. However, our study did not show any significant relation between the position during surgery and the occurrence of DVT.

LMWH is currently recommended as the preferred agent for thromboprophylaxis,[8] but it increases the treatment cost and has risk of bleeding complications and in turn, lead to infection, re-operation[10,16] To obviate these potential complications, non-pharmacological methods have been considered. Since stasis is considered as a major factor in the development of DVT, efforts have been made to increase the venous blood flow in the deep veins during

Table 2: Studies valuating DVT during major orthopedic surgeries of lower limbs involving patients of Indian subcontinent

Study	This study (2011)	Dhillon *et al.*[3] (1996)	Agarwala *et al.*[4] (2003)	Jain *et al.*[10] (2004)	Bagaria *et al.*[11](2006)	Mavalankar *et al.*[12](2007)
No. of patients	200	88	104	40 (50 hips)	147	125
Cases + controls	100 + 100	-	51 + 53	25 + 25	-	-
Average age (years)	54.27	64	62	47	64.2	61.5
Male + female	156 + 44	27 + 61	39 + 65	27 + 13	71 + 67	45 + 80
Procedure	Hip fracture surgery and hip hemiarthroplasty	Hip fracture surgery (40) + THR (14) +TKR (34)	THR (37) + TKR (48) + hip fracture surgery (19)	THR	THR (23) + TKR (22) + hip fracture surgery (102)	THR (11) + TKR (59) + lower limb surgery (55)
Prophylaxis	Calf muscle electrostimulation	None	Dalteparin	Enoxaparin	None	None
Radiological method	Doppler ultrasound (pre-op and post-op 7th day)	Venography (post-op 6th to10th day)	Contrast venography (post-op 6th day)	Doppler ultrasound (pre-op and post-op 4thand 13th day)	Doppler ultrasound (post-op 6th–10th day)	Doppler ultrasound (post-op 7th–14th day)
Anesthesia	All spinal	GA – 40 Spinal – 48	-	Spinal – 40 GA – 10	-	All spinal
Effect of position	Not significant	Not significant	-	-	-	-
Clinical DVT	0	19	29	10	-	2
Proximal DVT	0	11	1	0	3 (2.04%)	3 (2.4%)
Distal DVT	6(controls) + 2 (cases)	44	19 + 29	0	5 (3.4%)	6 (4.8%)
Pulmonary embolism	0	1	0	0	1 (0.68%)	0
Total DVT	8 (4%)	55 (62.5%)	19 (43.2%) + 30 (60%)	0	9 (6.12%)	9 (7.2%)
Conclusion	Low incidence	High incidence	High incidence	Low incidence	Low incidence	Low incidence

Pre op = Preoperative, post op = Postoperative, THR = Total hip replacement, TKR = Total knee replacement

Table 3: Various studies conducted worldwide on the evaluation of DVT during major orthopedic surgeries of lower limbs

Study	Froehlich *et al.*[17] (1989)	DiGiovanni *et al.*[23] (2000)	Ryan *et al.*[25] (2002)	Kim *et al.*[13] (2003)	Colwell *et al.*[16](2010)
No. of patients	40	989 (1021 hips)	100	200 (300 hips)	410 (414 hips)
Cases + controls	-	-	50 + 50	-	204 + 207
Average age (years)	81.6	65	69	56.6	62.5
Male + female	-	469 + 520	62 + 38	106 + 94	218 + 196
Procedure	Hip fracture surgeries	THR	THR	THR	THR
Prophylaxis	Compression device and warfarin	Unfractionated heparin	Compression device vs. stockings	None	Compression device vs. LMWH
Method of assessment	Doppler ultrasound (every 4th day) and venography (11th day)	Doppler ultrasound (198) + clinical exam (823)	Magnetic resonance venography	Venography and lung perfusion scan (7th day)	Doppler ultrasound
Nature of study	Postoperative	Peroperative	Postoperative	Postoperative	Postoperative
Anesthesia	-	All spinal	All spinal	-	GA – 167 Spinal – 176 Combined – 52
Effect of position	-	Considered significant	-	-	-
Proximal DVT	5	USG – 7(3.5%) Clinical – 4(0.5%)	15 (4 + 11)	-	5 (3 + 2)
Distal DVT	3 (considered insignificant)	USG – 7(3.5%) Clinical – 3(0.35%)	-	-	11 (5 + 6)
Pulmonary embolism	-	USG – 0 Clinical – 5(0.48%)	0	0	4 (2 +2)
Total DVT	5 (12.5%)	USG-14(7.1%) Clinical-7(0.85%)	15 (15%)	72	20 (5%)

THR = Total hip replacement, TKR = Total knee replacement, LMWH = Low molecular weight heparin

and after surgical interventions. Mechanical compression devices have been considered to prevent clot formation by increasing the venous blood flow from the legs and causing the release of endothelial-derived relaxing factors and urokinase,[22,23] though these devices may have poor patient compliance, incompatibility in patients with lower limb

injuries, and ineffectiveness in preventing pelvic thrombi.[24]

Doran *et al*. demonstrated that out of the three factors involved in causation of DVT – venous stasis, hypercoagulability, and endothelial damage (Virchow's triad) – peroperative venous stasis appears to be the most important factor in causing DVT postoperatively, and thus calf muscle stimulation during the operation prevented the reduction in venous flow velocity in legs and reduced the risk of postoperative DVT. Also, the biochemical stresses in the form of metabolites produced during the surgery in the operated limb add to the risk of DVT in the limb undergoing the procedure as compared to the opposite nonoperated limb.[5] Lindstrom *et al*. studied the effects of peroperative calf muscle stimulation in patients undergoing major abdominal surgeries with groups of impulses producing a short lasting tetany of calf muscles. It had similar effects on the incidence of postoperative thrombosis as compared with that of Dextran 40.[6]

Doran *et al*. also demonstrated that during lower limb surgery, the velocity of venous return reduces to a level that DVT can develop in 50% of patients and it can be effectively counteracted by calf muscle electrostimulation whilst the operation is in progress.[5]

We have used hand held VeinoPlus stimulator device which delivers electrical impulses into a vicinity of motor points on the muscle via skin patch electrodes in order to squeeze the blood from deep veins of calf. The electrical impulses are characterized by low energy and low voltage within safe limits. It produces a train of impulses with rectangular voltage waveform when connected to the electrodes. The waveform of current of every impulse is symmetrical and exponential biphasic during the treatment, thus causing powerful and almost symmetrical calf muscle contractions on each side.[7]

Considering the small sample size of our study, it may not be very prudent to draw firm conclusions on the usefulness of calf muscle electrostimulation device (VenioPlus) in the prevention of DVT following orthopedic surgeries around the hip joint in patients having no additional risk factors. Multicentric studies with larger sample size may evaluate therapeutic benefits of this device in lower limb surgeries.

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