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A Comparitive Study between Physiotherapeutic Alone and Combined Physiotherapeutic and Pharmacological Measures in DVT Prophylaxis in Replacement and Spinal Surgeries

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Abstract: *BACKGROUND: Deep Vein Thrombosis is one of the common and dreaded complication of joint replacements and spine surgeries. The incidence of DVT among these cases is significant in spite of the various prophylactic measure such as physiotherapy and pharmacological measures.*

Materials and methods:

110 cases of arthroplasty and spine cases are divided randomly into two groups, in one group only physical measures(group A) are employed while in the second group physical and pharmacological measures(group B) and evaluated by Doppler ultrasonography on 5th and 12th post-operative day and the results are analysed.

Results:

Positive thrombus as revealed by Doppler ultrasonography is seen in 28 cases, asymptomatic DVT is seen in 13 cases (7/51 in group A and in 6/59 in group B), whereas symptomatic DVT is seen in 15 cases(11/51 in the group A and in 4/59 cases in group B) which is statistically significant. Mortality occurred in four cases in group A compared to one case in group B which is not statistically significant.

Conclusion*:*

In patients who underwent arthroplasty or spine surgery, prophylactic use of pharmacological plus mechanical mode of prophylaxis is better than using any of these methods alone as prophylaxis even though the incidence of hematoma formation, wound gaping and the need for evacuation of hematoma was little higher in group B which are not statistically significant.

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I. Introduction

Thromboprophylaxis is a controversial and changing topic. Some have questioned its very need (1).Various objections have been raised as to its use including the relatively low incidence of symptomatic thromboembolic events, the risk of bleeding, and the possibility of late infection. Total hip and knee arthroplasty are extremely successful orthopaedic procedures that relieve pain, improve function, andenhance the quality of patients' lives. However, these proceduresare also associated with a risk of morbidity and mortality from the development of venous thromboembolic disease(2).Prophylaxisagainst deep vein thrombosis is necessary after total joint arthroplasty or spine surgeries, but the ideal prophylactic regimen has not been identified.

The selection of a prophylactic regimen involves a balance between efficacy and safety. Surgeons are particularly concerned about bleeding because it can lead to hematoma formation, infection, a possible reoperation, and a prolonged hospital stay. The selection of a prophylactic agent is also influenced by the more frequent use of regional anaesthesia;however, in our current environment of risk management, it would be wise to remember that the weight ofevidence supports the view that thromboembolism is a potentially serious complication and that on the balance of probability the riskcan be diminished. There is no evidence that careful pharmacological prophylaxis causes major wound bleeding, infection, loosening of the implant ordeath.

Patients suffer symptomatic venous thromboembolism (VTE) after arthroplasty and spine surgeries. Current prophylactic methods include pharmacological regimes such as aspirin, warfarin, and low molecularweight heparin (LMWH) and mechanical techniques such as intermittent pneumatic compression

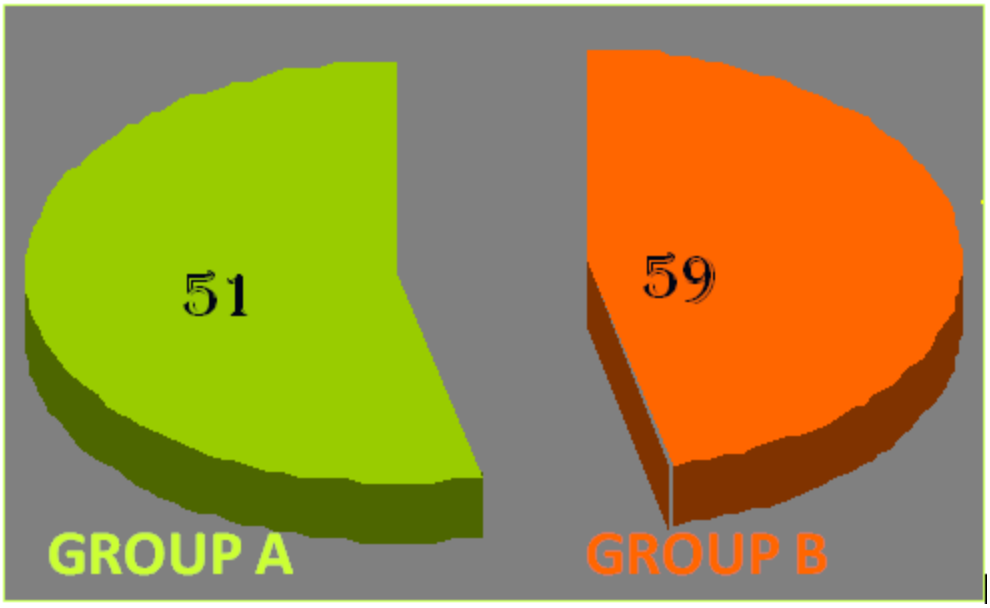
devices(3).While pharmacological prophylaxis may be useful for the prevention ofthromboembolic disease, associated morbidity such as haemorrhagic complications, routine phlebotomy, excessive cost, and dosing by injection after discharge may limit its use(4).

Pneumatic compression devices offer prophylaxis without such associated morbidity, but compliance by patients and nurses is essential. In addition, the type and duration of prophylaxis after hospital discharge are controversial.

The purpose of our study was to compare the efficacy of physical measures alone with combined physical and pharmacological measures in preventing venous thrombosis in knee and hip arthroplasties and spinal surgeries.

II. Materials And Methods:

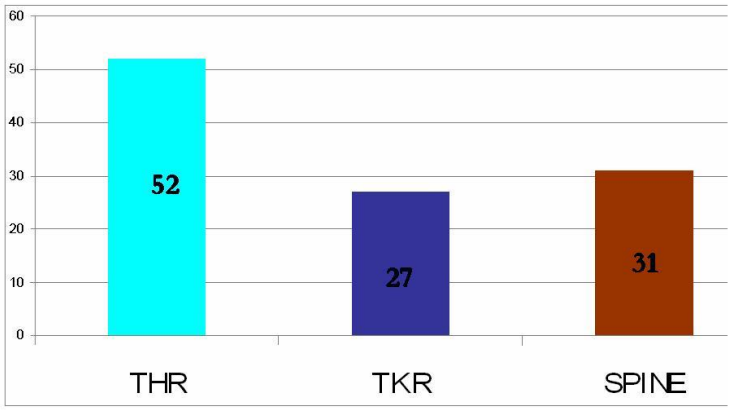
The institutional review board of our hospital approved the study, and all patients are informed about the study. From January 2008 to December 2009,110 patients(57 men and 53 women) who were operated for arthroplasties and spine were recruited and divided randomly into two groups, group A and group B. The average age of the patients was 56 years(range 16-88 years). Group A(n=51) include the group where physical measures are employed and group B (n=59) include the group where the physical and pharmacological measures are employed to prevent the thromboembolism.



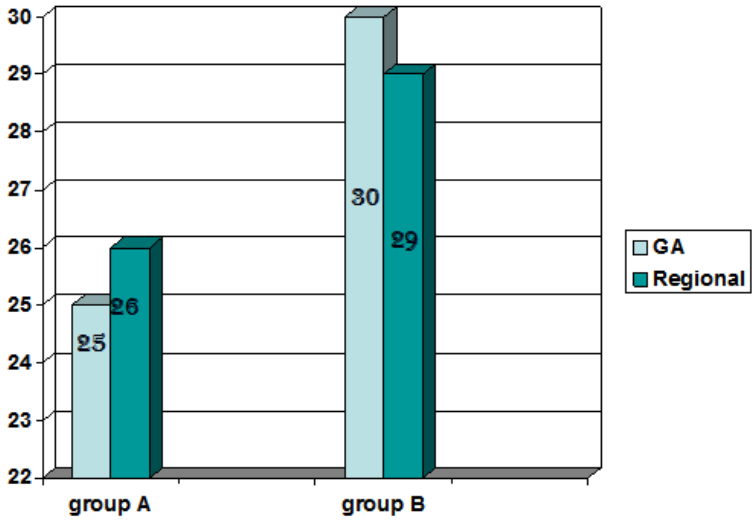
Inour study, patients who underwent total hip, total knee replacements and spinal surgeries for various indications are included.

Patients with a previous history of DVT, chronic venous insufficiency, stroke, varicose veins, malignancy, renal insufficiency, recent myocardial infarction, paraplegic patients, heart failure, who were taking oral contraceptives, or on steroidal/hormonal/ anticoagulant drugs for any medical condition,wereexcluded from the study.

The total cases include 52 cases of hip arthroplasties, 27 cases of knee arthroplasties and 31 cases of spine surgeries. The preoperative workup included a complete blood-cell count, coagulation and chemistry profiles, electrocardiography, chest radiographs , radiographs of the affected joints or spine and echocardiography.



Two orthopaedic surgeons (A.D. and S.D.) performed all the surgeries and the radiologist who performed the Doppler was blinded of the study. In group A there are 25 cases of general anaesthesia and 26 cases of regional anaesthesia, whereas in group B 30 cases of general anaesthesia and 29 cases of regional anaesthesia are present.



All patients were managed postoperatively with the same protocol, foot pumps was started in the immediate post-operative period, for 2 hrs daily and continued for 5 days up to 4th POD. Compressive stockings were given from 1st post op day. Passive mobilization started from 5th post op day. Calf squeezing,quadriceps and hamstrings exercises, deep breathing exercises ,mobilization of the patient around 7th POD once the pain is under control.

For group B patients, along with the above physical measures LMWH was given after 12 hrs after the epidural catheter is removed which is usually done 2nd post operative day.

Patients were daily assessed for any signs of DVT.Patients were assessed for pain and swelling of the limb, calf tenderness, skin discoloration , venous engorgement, enlargement of the girth of the calf or thigh, the Homans sign, temperature elevation , and was looked for local hemorrhage and hematoma at the operative site daily.

Assessment for postoperative DVT was done by color Doppler ultrasonography on postoperative days 5 and 12 (at the time of discharge). Assessment included examination of bilateral common femoral, superficial femoral, popliteal, anterior tibial, and posterior tibial veins. They were assessed for flow, visualised thrombus, compressibility, and augmentation. A deep- vein thrombosis was defined as symptomatic when symptoms that required treatment developed in a patient with a positive sonographic study and a deep-vein thrombosis was defined as asymptomatic when there are no symptoms but the sonography showed a positive result.

III. Results

A positive thrombosis was noted in twenty eight patients (25%) of the 110 cases [eighteen patients (16%) of the group A patients and in ten patients (9%) of the group B patients]. Out of these, 15 patients are associated with symptoms ,11 in group A and 4 patients in group B patients either in the form of calf pain, increase in calf girth or Homans sign positive, while in the rest of the patients, the ultrasonography showed a thrombus but is not associated with symptoms. We performed statistical analysis using the relative risk to determine if the differences between the types of prophylaxis were statistically significant with the p value set at 0.05. There is statistically significant difference between the two groups in the incidence of thrombus formation is very much reduced in group B with a p value of 0.03 which is statistically significant with two sided p-value of 0.0309 with relative risk of 0.7791 with 95% confidence interval ranging from 0.6170 – 0.9838. p value is calculated using Fischer's-exact test.

Ninety five percent of the deep vein thromboses was in the calf veins, 5% in the popliteal vein, and none were in the femoral or iliac vein.

Out of the five deaths(4.5%) that occurred in 110 patients, eighty percent (four cases)of the deaths occurred in the group A patients and all the mortalities occurred before 10^{th} post-operative day whereas the remaining mortalities are seen in group B patients and it happened at the end of third week. One case in group B patient which had pulmonary embolism at the end of tenth post-operative treatment discontinued the treatment was not included in the study. There was no statistically significant difference between the two groups in relation to the mortalities (p value is 0.2780 using chi square test). All these cases showed features suggestive of pulmonary embolism in ECG and confirmed by CT-angiography.

There are no case reports bleeding complications onto death but the need for evacuation of blood or haematoma occurred in eight cases of group B patients out of these two patients required blood transfusion . Wound gaping andechymosis occurred in one case of each in group B patients.

Even though the complications are more in the group B patients but the incidence of mortality and prevention of symptomatic deep-vein thrombosis is significantly reduced.

IV. Discussion

The triad of venous stasis, damage to the vein wall and hypercoagulability that leads to the formation of thrombus is an essentially a peri-operative event.Venous stasis may occur secondary to the positioning of the limb during the procedure, localized postoperative swelling, and a decreased activity level after the operation (5). A dramatic reduction in the venous capacitance of the lower extremity and in venous outflow has been demonstrated during hip arthroplasty, and this may be exacerbated during dislocation of the hip and insertion of the femoral prosthesis. In addition, total knee arthroplasty is usually performed with a tourniquet on the thigh and with the knee in a flexed and subluxated position, which can increase the propensity for clot formation. The endothelium may be injured during positioning and manipulation of the extremity, and it may sustain a thermal injury from bone cement (6). Tissue thromboplastin and other clotting factors are released during the course of the operative procedure, and they can aggregate in regions of venous stasis. A relative hypercoagulable state can develop during the procedure because the blood loss can result in reduction in antithrombin III and inhibition of the endogenous fibrinolytic system, which further promote thrombus propagation.

Sharrock et al. studied circulating markers of thrombingeneration and fibrinolysis during different aspects of a total hip arthroplasty to define exactly when the thrombogenic stimulus reached its peak(7).All of the procedures were performedwith the patient under hypotensive epidural anesthesia.. The levels of multiple markers of thrombin generation, including prothrombin F1.2, thrombin-antithrombin, fibrinopeptide A, and D-dimer, were markedly increased during preparation of the femoral canal and insertion of the femoral component. The levels of these thrombogenic markers wereminimally influenced by preparation of the acetabulum. It has been hypothesized that manipulation of the femoral canal leads to release of thromboplastin in the bone marrow or fat, which causes a thrombogenic stimulus(8).

Sharrock et al. also studied circulatory indices of thrombosis and fibrinolysis following knee arthroplasty(9). Increases in levels of D-dimer, fibrinopeptide, and thrombin-antithrombincomplexes were noted following tourniquet deflation. Manipulationof the femoral canal with placement of an intramedullary device to prepare for the insertion of the femoral or tibial component may also be a thrombogenic stimulus, but this has not yet been studied to our knowledge. Maynard et al. used serial contrast venography to evaluate the development of venous thrombi after unilateral total knee arthroplasty. Twenty-four hours after the procedure, they found a distal deep vein thrombus in 45% (nineteen) of forty-two legs and a popliteal thrombus in 5% (two) of forty-one lower extremities. The findings of these three studies suggest that venous thromboembolic disease begins during the perioperative period, which means that thegoal of prophylaxis is not to prevent clot formation but to preventthrombus propagation (10).

In spine surgeries, venous stasis occurs during surgical positioning and retraction of venous structures. The condition is created by the absence of active muscle contraction, vessel occlusion from both external and

internal (surgical retraction) sources, and postoperative bed rest and immobilization. Venous intimal energy during surgery can initiate both the intrinsic and extrinsic coagulation cascades. With the exception of the anterior lumbar interbody fusion procedures, during which the vena cava and common iliac veins are subject to injury, this mechanism of thrombosis initiation is not highly germane to the spine surgery population.

The other factor that significantly influences the formation of venous thrombus is the type of anesthesia , general or neuraxial anaesthesia.It is well documented in the literature that, when patients are not treated with any prophylaxis after total hip arthroplasty,those who have received spinal or epidural anesthesia have a decreased rate of thrombosis compared with those who have received general anesthesia. Blood loss has been reported to be decreased with the use of epidural anesthesia alone or in combination with general anesthesia as compared with general anesthesia alone. It has been hypothesized that, if loss of blood and transfusion requirements could be minimized, the formation of clots might be decreased.(11).Sharrock et al.(12) have assessed both deep venous thrombosis rates and coagulation parameters in patients who received hypotensive epidural anesthesia during total hip or knee arthroplasty.

Neuraxial (i.e. spinal or epidural) anaesthesia conveys many benefits to orthopaedic patients. The mortality after surgery is reduced by 30%, post-operative analgesia is enhanced and it is weakly thromboprophylactic. However, more recently the AmericanFood and Drug Administration has raised concerns that on occasions a spinal haematoma may develop. Neuraxial anaesthesia (spinal or epidural) reducesthe frequency of DVT after hip replacement. The mechanisms include reduced sympathetic tone, increased blood flow(13), altered blood viscosity and fibrinolysis(14).

V. Mechanical Prophylaxis :

Mechanical prophylaxis is attractive because it carries norisk of bleeding. Various modalities we employed are:

1. Earlymobilisation:

Early mobilisationis likely to reduce the rate of VTE both by stimulating venous flow in the legs through the calf muscle pumps and by enhancing venous return through improved ventilation. Delayed mobilisation will be inevitable for some patients with intercurrent illness, confusion or surgical complications.

2. Neuraxial anaesthesia

Neuraxial anaesthesia (spinal or epidural) reduces the frequency of DVT after hip replacement.The risk reductions are not adequate to recommend the use of regional anaesthesia as the only thromboprophylactic method.

3.Graduated compression stockings:

Graduated stockings work by increasing venous flow(15) the stockings must be well-fitted and remain properlyapplied. Caution should be observed when stockings areused in patients with peripheral arterial disease or peripheralneuropathy. Hui et al.(16) showed that GCS were ineffective in preventing DVT after hip replacements. In a further study by the samedepartment Best(17)showed that 98% of GCS failed to produce the ideal gradient of 18, 14 and 8mmHg from the ankle to the knee. Samama et al. demonstrated that in patients undergoing THR there was a 50% reduction in the prevalence of DVT using GCS and LMWH over LMWH alone.

4. Sequential pneumatic compression devices.:

These devices work by sequential inflation of chambersalong the calf and thigh, thus ‘milking’ venous bloodproximally. Endothelial fibrinolysis is also activated. Compliance is a drawback withthese devices, because they can be uncomfortable forthe patient and because they must be put on and takenoff each time the patient leaves the bed.

VI. Pharmacological Prophylaxis

The drug we employed in our study is **Low-Molecular-Weight Heparin**. The antithrombotic activity of low-molecular-weight heparin isprimarily mediated through the inhibition of factor Xa. A fixed dose of low-molecular weight heparin can be used, and there is no need for laboratory monitoring. Prophylactic doses of low-molecular-weight heparin do not increase the activated partial thromboplastin time. The low-molecular-weight heparins are metabolized in the kidney and therefore should be used with caution in patients with renal insufficiency. The low-molecular-weight heparins, as a class of drugs, have been shown to reduce the risk of proximal and distal deep-vein thrombosis by at least 70% compared with the risk in patients treated with a placebo.

Low molecular weight heparin is used in all the cases of group B 12hrs after the removal of epidural catheter at the dose of 3800IU or 0.4ml subcutaneously once daily till the sutures are removed which is usually done on the 12th post-operative day. LMWH is used in all the cases because of easy availability, minimal side effects and due to its cost-effectiveness compared to other drugs.

To our knowledge, till to date there is no comparative study between the efficacy of the physical and combined measures for the prevention of deep venous thrombosis. There are a lot of comparative studies in between the efficacy of the drugs of various groups. The only drawback in our study is small sample size. Even though venography is specific and sensitive but being an invasive procedure , the patient compliance and acceptance is poor, so Doppler ultrasonography non-invasive study is selected for our study. There is only one meta-analysis done by westrich et al.,to assess the efficacy of four common regimes for thromboembolic prophylaxis after total knee arthroplasty: aspirin, warfarin, low-molecular-weight heparin (LMWH) and pneumatic compression and found that the incidence of DVT was 53% in the aspirin group, 45% (541/1203) in the warfarin group, 29% (311/1075) in the LMWH group, and 17% (86/509) in the pneumatic compression device group(18). Several recent studies have demonstrated that the prevalence of deep-vein thrombsis after total knee arthroplasty in the Asian populations is similar to that in the western population(19).

However, the locations of the thromboses in Asian patients have differed, with a predominance of distal clots (in the calf) and very few proximal clots (in the thigh or pelvis) or pulmonary emboli.

In contrast to the situation in Western countries, where routine prophylaxis against deep-vein thrombosis is standard practice after total joint replacement or spine surgeries, pharmaceutical prophylaxis against deep-vein thrombosis is not routine in most hospitals in the East. Therefore prophylactic strategies after major orthopaedic procedures remain controversial in the East.

The Art, rather than Science, of clinical medicine is to apply knowledge in a balanced way, tailored to the needs of the individual patient. Thromboprophylaxis has been often regarded as a dichotomy; either chemical or mechanical. The advantages of drugs, namely their ease of use, relative cheapness and efficacy, must be weighed against the potential for bleeding both into the surgical wound and into the spinal cord after neuraxial anaesthesia. The advantages of mechanical prophylaxis such as the foot pump, with no bleeding, no drug interactions and reasonable efficacy must be taken into account against the disadvantages of compliance, refitting when mobilising and the impracticality of extended use. A sensible approach would be to use the foot pump as soon as possible after injury or surgery and then to switch to chemical prophylaxis once the risk of bleeding has subsided and for as long as the risk of thromboembolism pertains.

For patients with a particular risk of thrombosis, thetwo can be combined in the hope of a synergistic effect.

VII. Conclusion:

Thromboembolism is a common and costly complication. Thromboprophylaxis is mandatory but must be safe and effective. Each hospital should have a protocol, ideally incorporated into a care plan based upon a synthesis of best current evidence and pragmatism. The risk of thrombosis starts usually during perioperative period and so prophylaxis should start as soon as possible. Because safety must be balanced against efficacy, a combination of mechanical and pharmacological methods should be considered. Thought must be given,
at least for some, to prolonging pharmacological prophylaxisbeyond hospital discharge.

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