Research Project

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An Overview of Clinical Studies Assessing the Effectiveness of a Multi-Modal Regime for Prevention of Deep Vein Thrombosis Following Total Joint Replacement of the Hip or Knee with a Focus on Mechanical Pneumatic Device Effectiveness

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Proposal Objectives: To evaluate a minimum of thirty clinical trials in the evaluation of prophylaxis of deep vein thrombosis utilizing mechanical pneumatic compression, oral anticoagulation, and regional anesthesia to answer the following questions. Is a **comprehensive program** encompassing regional anesthesia, mechanical pneumatic compression, and oral anticoagulation effective in the prevention of deep vein thrombosis following total joint replacement of the hip or knee?

1. **Which mechanical pneumatic device** for the prevention of deep vein thrombosis following total joint replacement of the hip or knee is more effective?
2. What are the **ideal parameters** for the delivery of pneumatic compression?
3. What are some of the **patient compliance issues** which affect the effectiveness of mechanical pneumatic compression devices in the prevention of deep vein thrombosis following total joint replacement of the hip or knee?
4. What **educational programs** would be beneficial in improving patient and staff compliance in the continuous use of mechanical pneumatic compression devices such as sequential compression and foot-pump devices in postoperative total hip or knee joint replacement patients?
5. What **new mechanical pneumatic compression devices** are under clinical trial for deep vein thrombosis prophylaxis in patients undergoing total joint replacement of the hip or knee and what compliance issues do they address?

Data Sources: A review of greater than four referenced study conclusions will be reviewed to answer each of the following questions. A literature search was done on greater than thirty related clinical trials done within the last five to ten years on the subject of multimodal prophylaxis of deep vein thrombosis in total joint replacement of the hip or knee post operative patients.

Review Methods: The trials identified as relevant to each question were reviewed and summarized with the results presented and each question addressed.

Results: It was found that mechanical pneumatic compression devices of both sequential compression devices and foot-pumps reduced the risk of deep vein thrombosis by two-thirds when used alone and by about half when used in combination with pharmacologic

therapy. Mechanical methods reduced the risk of proximal vein thrombosis (femoral artery) and pulmonary embolism by two-fifths. Oral anticoagulation when used alone reduced the risk of deep vein thrombosis and proximal vein thrombosis by half. Oral anticoagulation therapy nearly doubled the risk of major bleeding and appeared less effective than heparin in preventing deep vein thrombosis. Compared with general anesthesia, regional (epidural) anesthesia reduced the risk of deep vein thrombosis by about half. New pneumatic mechanical devices with automatic sensing feedback systems are being developed with alarms with sounds which when the optimum pressures are interrupted signal staff to correct the problem, or reapply the devices when interrupted by the patient for care activities.

Conclusions: Unless contraindicated such as in severe peripheral arterial disease, patients undergoing total joint replacement of the hip or knee would benefit from mechanical pneumatic compression therapy for prevention of deep vein thrombosis. Patients who are at high risk of developing deep vein thrombosis such as previous history of DVT, cancer, congestive heart failure, stroke, may also benefit from pharmacologic thrombo-prophylactic medication. Education of patients and staff in the rationale and benefits of compliance compression devices following joint replacement surgery improved compliance. New improved pneumatic compression devices are being tested in clinical trials to address the issues of comfort and continues uninterrupted delivery of optimal pressure desired. Compliance by the patient in wearing the pneumatic compression device affects the incidence of DVT. Where there was high patient compliance there was a lower incidence of DVT. Nursing and staff education on an ongoing basis also improves patient compliance with use of compression devices and also reduces the incidence of DVT.

Introduction

All patients undergoing total joint replacement of the hip or knee are at risk of deep vein thrombosis (DVT), and pulmonary embolus (PE) [1]. The risk of DVT following joint replacement ranges from 45% to 70% [2]. Kakkar and colleagues found that without prophylaxis, the overall incidence of DVT is 40% to 84% with proximal thrombosis occurring in 8% to 34% of patients. Propagation of calf thrombosis to more proximal thrombi was shown to occur at a rate of 24% [29]. Pulmonary embolus which may present as anxiety, shortness of breath, chest pain, or positive V/Q scan or pulmonary angiogram has been documented to occur in up to 20% of patients undergoing joint surgery. Of the 20 % of the patients who develop pulmonary embolus, one will be fatal[14]. Prophylaxis against DVT and PE includes pharmacologic and mechanical measures. A large number of studies have ben done showing the efficacy of all these measures. The National Institutes of Health Consensus Development Conference on the Prevention of Venous Thrombosis and Pulmonary Embolism suggested that mechanical devices may be effective when used alone and also when used as adjunctive therapy with pharmacologic prophylaxis. A major concern has been identified as to patient compliance with the use of mechanical DVT prophylaxis [14].

Background and Physiology of Deep Vein Thrombosis

Prolonged anesthesia or any period of limited mobility may result in thrombus formation in a deep vein of the lower extremities. The components of Virchow's triad of risk factors which precipitate such thrombus are:

- Damage to the venous wall
- Change in blood flow
- Hyper-coagulability

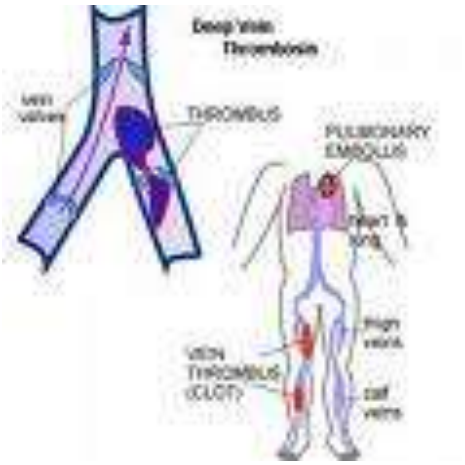
During orthopedic surgery to the lower limb direct venous wall damage may occur as a consequence of this procedure such as kinking of the femoral artery during total hip arthroplasty. Venous stasis of the lower limb is a consequence of immobility and hyper-coagulability may be secondary to tissue damage, inflammation, or malignant disease.

DVT occurrence may also produce long term vascular damage leading to chronic venous insufficiency. The 1993 National Confidential Inquiry into peri-operative disease report indicated that pulmonary embolism (PE) was the most common cause of post-operative death after hysterectomy and elective hip operations.

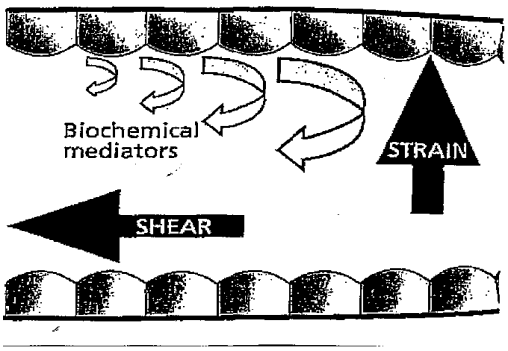
What is a Deep Vein Thrombosis?

A thrombosis is a blood clot formation composed of red blood corpuscles, platelets, and fibrin fibers which forms in the deep veins of the thigh and or the calf. The blood clot or thrombus is a soft round jelly like formation which may partially or totally fill the vein. It can be only a few millimeters in size or it may be several centimeters long. The two serious consequences can be:

1. The clot blocks the blood flow through the vein causing blood in the vein below the clot to pool. Swelling and pain develops in the area affected exhibiting signs of a deep vein thrombosis or DVT.
2. A large clot (thrombus) can break free and travel through the venous system and reach the arteries of the lung and plug the artery causing a life threatening situation. This potentially fatal condition is called a Pulmonary Embolus or PE.



The blood in healthy individuals is propelled through the deep veins of the leg through the contraction of the leg muscles. The rhythmic contractions of calf and thigh muscles massage the blood through these deep veins. This circulating blood is protected against formation of blood clots by a system of anti clot substances that can mix with the blood only when the blood circulates. If the muscles are at rest for longer periods such as sitting on an airplane or lying motionless after an operation, the blood flow in the deep veins ceases. The anti clot substances cannot mix with the blood and prevent the formation of blood clots. Blood platelets accumulate or clump together, then the fibrinogen in the blood begins to form fast fibers that bind the platelets and red blood cells together in a soft lump and forms a blood clot. The thrombus can destroy the valves in the deep veins.The blood clot may form in any vein of both lower limbs, not only the veins of the operated leg.



How often do the Thrombi Occur?

Most DVT's do not cause any inconvenience and may not be detected. The following table lists the frequency of the four types of DVT. Symptomatic DVT accounts for about 5% of all the DVT's which cause symptoms. Large thrombi may form and break free in the calf or thigh vein and travel to the lungs and result in Pulmonary Embolus.

Frequency of Different Forms of DVT

Type of DVT	Frequency of DVT
Deep Vein Thrombosis (DVT)	40-80%
Symptomatic DVT	2-5 %
Diagnosed Pulmonary Embolus	1-6 %
Lethal Pulmonary Embolus	0.1 – 0.2 %

[34]

Rarely, the clot may be so large as to occlude blood flow to the entire pulmonary artery and cease blood flow to the heart. The rate of lethal Pulmonary Embolus after total hip and total knee replacement is about one per thousand [35].

The majority of blood clots everywhere during the 6 weeks period after the surgery are taken care of by the body. They are either dissolved or new veins grow through large clots [36].

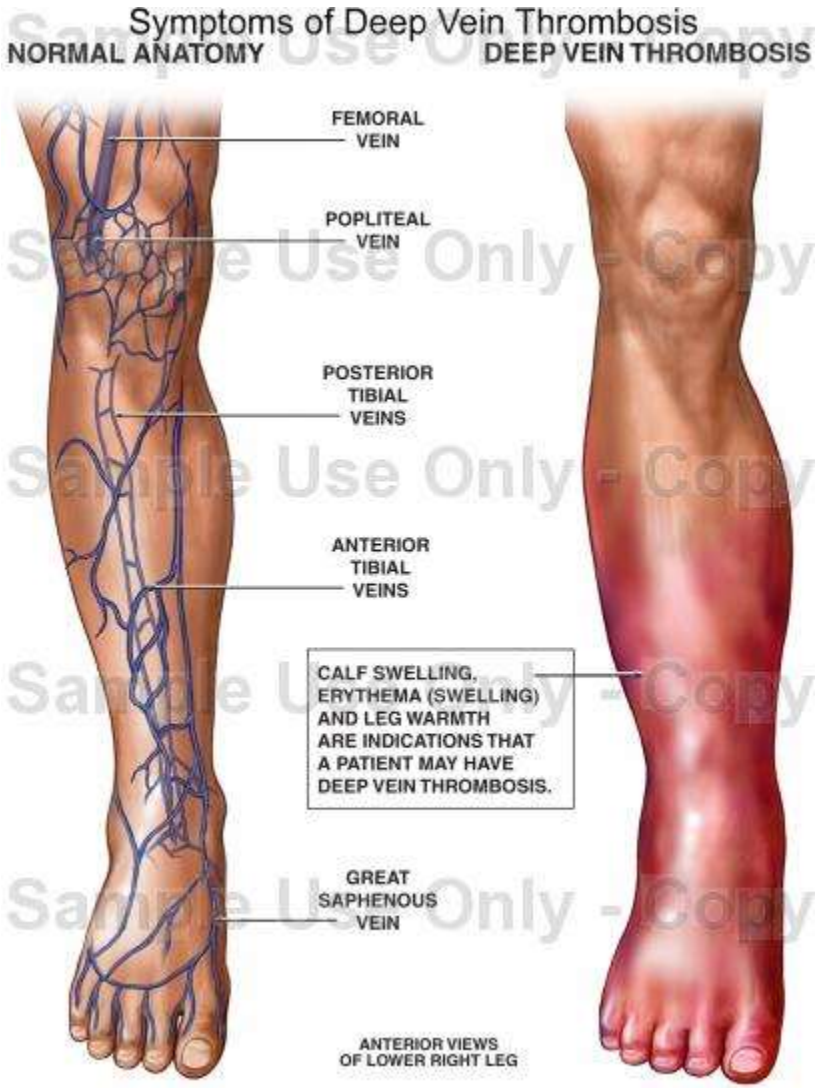
There are reports saying that blood clots cause more deaths than cancers and injuries together (Aventis Pharmaceuticals).

What are the Signs of a DVT?

Most commonly, the DVT occurs in just one leg and may include any or all of the following symptoms:

- Pain in the calf or in the thigh
- Swelling of the lower leg and foot
- The calf and thigh muscles above the clotted veins are painful upon palpation
- Passive stretching of the calf muscles by pushing the foot cranially (towards the head) provokes severe pain in calf muscles
- Discoloration or redness of the calf or thigh area

The patient should immediately seek medical care.



What are the Signs of a Pulmonary Embolus?

- Dizziness
- Shortness of breath
- Coughing
- Chest pain

These symptoms require emergency care.

When are the majority of the thrombi formed?

The majority of the thrombi are formed during the operation. The risk period for development of deep vein thrombosis and pulmonary embolus after total knee and total hip replacement continues for up to three months after the operation.

When are most DVT's detected?

The majority of deep vein thrombi are detected two to five days post operatively during the patient's hospitalization period.

There is additionally a second risk period of risk for DVT for 10-14 days post-operatively when the patient is already discharged home from the hospital. Approximately 3% of all patients with total hip operations have returned to the hospital due to the development of more extensive thrombi in the lower extremities.

How is a DVT diagnosed?

One of two diagnostic methods is utilized to diagnose DVT

1. Venography: The radiologist injects contrast material into a vein on top of the foot. The thrombi will appear as a defect in contrast material on the X-ray picture of the veins. This is a costly as well as painful procedure and the contrast agent may cause irritation of the vein and could itself contribute to the development of new thrombi.
2. Duplex Ultrasonography : This method uses sound-waves to diagnose DVTs. It is painless, requires no injection of contrast material, is painless, and no radiation is given to the patient. This test is cheaper than

What are the risk factors for DVT?

Total hip or knee joint replacement surgery is the most important risk factor for the development of DVT. The four mechanisms that contribute to the formation of the thrombi during and after surgery are:

1. Prolonged immobilization of the lower extremity muscles during and after the surgery.
2. The blood clotting cascade system is activated during the surgery which releases substances that produce a blood clot in the severed vessels. This is a life saving protective mechanism.
3. Damage to the veins may occur during the total hip or knee replacement as the surgeon retracts, folds, twists and manipulates soft tissues involving veins which leads to the formation of a thrombus.
4. During the total joint replacement, especially during insertion of cemented shafts of total hip prosthesis, the surgeon pushes contents of bone marrow which enter the circulation. This bone marrow in the circulating bloodstream activates the clotting cascade system which encourages clotting.

Additional Risk Factors which contribute to DVT

1. Increasing age
2. Previous history of deep vein thrombosis
3. heart disease, concomitant malignant disease (cancer)
4. Use of Estrogens
5. Smoking and Obesity

Prevention of DVT

The prevention of DVT is focused on preventing stagnation of blood in the veins and to diminish the coagulation tendency of the blood. This is prevented by:

- early mobilization of the patient post operatively
- simple leg exercises
- mechanical compression through elastic support stockings (TEDS) and
- mechanical pneumatic compression sleeve stockings
- In most hospitals the surgeons also use pharmacological prophylaxis for DVT with anticoagulants. The anticoagulants decrease the clotting of the blood.
- This anticoagulant is often given during the operation which increase bleeding during and after surgery.

Patients on pharmacological therapy may still develop a DVT or Pulmonary Embolus and must watch for these signs and symptoms. Some of these pharmacological agents are as follows:

- **Dextran** is given intravenously during and up to two weeks after the operation.
- **Aspirin** is taken orally which is not tolerated by many patients.
- **Warfarin (Coumadin)** which acts by blocking the formation of clotting factors I the liver, requires about two to four days to become effective. It is taken orally and must be dosed by frequent blood tests. Dangerous bleeding may occur, it is effective and has many other side effects.
- **Heparin** inhibits the clotting of platelets and erythrocytes and is given by subcutaneous injection.
- **Low Molecular Weight Heparin such as Lovenox** is used more recently due to fewer bleeding complications and is administered by subcutaneous injection.

It is recommended that activation of the fibrinolytic system is recommended for at least 7-10 days following elective total hip or total knee replacement [3]. The following diagram gives a visual description of how active blood flow in a vessel promotes release of these biochemical mediators which decrease the formation of blood clots through activation of the fibrinolytic system.

How is a DVT Treated?

The patient may be hospitalized for a thigh DVT or Pulmonary Embolism and treated with intravenous Heparin. A DVT located in the calf vein is usually treated on an outpatient basis on oral or subcutaneous medication [34].

Foot pumps and mechanical pneumatic sequential compression devices are two of the currently used types of deep vein thrombosis prevention compression devices on the market.

Foot pumps

Foot pumps are a form of pneumatic compression device with one inflatable chamber which intermittently compresses the plantar venous plexus of the foot according to a programmed pressure amount. This compression increases the venous return while also activating the fibrinolytic system [3]. These systems operate with the use of a control pump which is electrical, with some new models under development which are portable.

Mechanical Sequential Compression Device

Mechanical sequential compression devices are stockings with one or more inflatable chambers which are applied to the lower extremities which inflate and deflate intermittently according to a programmed pressure value and cycle. The device is powered by an electrical pump which is not portable. The multiple chambers inflate in a distal to proximal sequence with a normal pressure gradient from higher at the distal chambers (furthest from the heart) to a lower pressure at the proximal chambers (closest to the heart). While mechanical prophylaxis avoids the increased hemorrhagic risks associated with pharmacologic agents, these mechanical pneumatic devices have been associated with complications as a result of device malfunction as well as inappropriate use [5].

Overview

The aim of this overview will include a minimum of greater than or equal to thirty two study reviews and one meta-analysis of 56 trials which focus on answering a series of questions related to mechanical pneumatic compression devices and prevention of DVT.

Introduction

Since Gardner and Fox described a physiological pumping mechanism of the human foot and introduced the venous foot pump for prevention of deep vein thrombosis, there have been numerous global studies. These studies have documented the safety and efficacy of intermittent pneumatic compression devices for preventing deep vein thrombosis after hip and knee arthroplasty [2]. The compliance with use of mechanical DVT prophylaxis has been found to affect DVT reduction as compared to pharmacological prophylaxis. The development of deep vein thrombosis in post operative total joint replacement patients of the hip and knee may lead to pulmonary embolus a potentially life threatening event. It is associated with a 30% mortality rate. Research has shown that DVT of the lower extremity is primarily responsible. Mechanical prophylaxis consists of elastic stockings and mechanical pneumatic compression devices. Thrombemboloic prophylaxis after total hip arthroplasty remains controversial. Pharmacological thromboembolic prophylaxis agents are widely used but have their own risk such as excessive bleeding. Pharmacologic methods continue to be considered as the standard for prophylaxis with pneumatic compression also is an alternative or adjunctive treatment [5] Pneumatic compression has been shown to be effective for prophylaxis of thromboembolism after major surgery [5].

Question #1
Is a comprehensive program encompassing regional anesthesia, mechanical pneumatic compression, and oral anticoagulation effective in the prevention of deep vein thrombosis following total joint replacement of the hip or knee?

A investigation was performed at the Department of Orthopedics, University of North Carolina Chapel Hill to evaluate the efficacy of intermittent pneumatic compression in a prospective study of 425 consecutive patients [9]. Three hundred and twenty four patients were primary total hip replacement and 178 patients were revisions. The patients received intra-operative and postoperative thigh high elastic stockings and thigh high intermittent pneumatic compression stocking sleeves. Vascular technologists performed venous duplex ultra-sonography on both lower extremities of all patients at a mean of six days (range 2-15 days) postoperatively. All patients were followed for at least one year to detect late thromboembolism.

Fourty-five to seventy-five percent of patients who received no prophylaxis after total hip arthroplasty develop a deep vein thrombosis and one to three percent had a fatal pulmonary embolism [9]. These events pose the greatest potentially lethal complications in the early postoperative period. Proximal thrombi (closest to the heart) in the lower limbs are believed to be the precipitating factoring the development of most of the pulmonary emboli. Effective prophylaxis against DVT is essential in the management of all patients undergoing total hip arthroplasty.

In a meta-analysis of fifty-six trials involving various methods to prevent venous thromboembolism after total hip arthroplasty in 8,000 patients, Imperale and Speroff reported a rate of proximal DVT of 5% in 10 studies. It included 864 patients managed with Warfarin (Coumadin), a rate of 6 % in 20 studies that included 2,065 patients managed with either intermittent pneumatic compression or graded stockings [10]. A study by Woolsen [11] showed that intra-operative initiation of intermittent pneumatic compression reduced the risk of proximal DVT to 6 %. However, in this study, patient's who had a risk factor for developing thrombosis such as having a prior history of thromboembolism or varicose veins, were managed with intermittent pneumatic compression, as well as low dose Warfarin (Coumadin) [11].

The major advantage of prophylaxis with intermittent pneumatic compression are the presumed decrease in the prevalence of bleeding complications and the lack of necessity of the monitoring required with oral anti-coagulation therapy. Warfarin (Coumadin) and low molecular weight heparin have been associated with bleeding complications.

Methods
The study was conducted on 515 primary or revision total hip arthroplasty patients at one institution between 1991 and 1997. All of the patients except those who were receiving Warfarin (Coumadin) for cardiovascular reasons and those patients with a known risk for thromboembolism were considered for the prospective study. Fourteen patients had a bilateral total hip arthroplasy during one hospitalization and counted as separate events as none were done in one surgical session. Thirteen hips were excluded, 5 because the

patients were on chronic Warfarin therapy. Seven hips in 4 patients who were managed with intermittent pneumatic compression were excluded due to being discharged from the hospital without a venous duplex scan being performed. One pneumatic compression hip was excluded because the post operative scan showed chronic thrombotic changes.

All patients were instructed to discontinue ASA (aspirin) and NSAID's (non-steroidal anti-inflammatory drugs) one to two weeks prior to the surgery. The 425 patients included in the study were managed both intra-operatively and post-operatively with pneumatic compression devices. All patients wore bilateral thigh high anti-thromboembolic stockings as well as intermittent pneumatic compression devices (manufactured by Kendall, Boston, Mass.) from the time of the operation until venous duplex scan was done at a mean of 6 days post-surgery. The patients were allowed to remove the intermittent compression devices while bathing or participating I physical therapy.

The device design was a sleeve with four transverse calf chambers and 2 transverse thigh chambers. These chambers inflated sequentially for eleven seconds each, from distal (ankle) to proximal (thigh).The deflation period between cycles was 60 seconds before the patient arrived in the operating room with thigh high elastic stockins and intermittent pneumatic device sleeves in place on the uninvolved limb. After anesthesia and sterile draping of the involved limb, a sterile thigh high intermittent pneumatic compression sleeve was applied and compression was begun before the incision. Two hundred and ninety-nine of the total hip arthroplasties were done in women, and 203 in men. The mean age was 61.5 years, the mean weight was 75 kgs or 160 pounds. The pre-op diagnosis was osteoarthritis in 179 hips, (55%), avascular necrosis in 61 hips (19%), rheumatoid arthritis in 39 hips A(12 %), arthritis secondary to a pediatric or adolescent hip disorder in 13 hips (4%), fracture in 10 hips (3%), post-traumatic arthritis in 7 hips and miscellaneous in 15 hips (15%). The remaining 178 procedures were total hip revisions.

The patients were encouraged to have regional anesthesia if possible because previous studies demonstrated a lower incidence of DVT. Regional anesthesia was used alone or in combination with general anesthesia in 440 procedures or 88%. General anesthesia was used alone in 62 hips (12%).

Three hundred and twelve (62%) of the procedures were done in patients who had at least one of the following risk factors:

- Obesity BMI > 30
- Diabetes Mellitus
- Thromboemboloic event
- Cancer

In the beginning of the study the patient's began routine ambulation and physical therapy on the first and second post-operative day. Duplex scans were performed on the 4th post operative day. All patients were instructed to begin exercises in bed immediately after the

operation. The ultrasonography machine was Acuson XP-5 Color Flow Duplex Scanner (Mountain View, Calif.) accuracy 94%. Real time imaging was obtained from the external iliac vein through the proximal portions of the calf vessels {9}.

The following table summarizes the study *Efficacy of Prophylaxis Against Thromboembolism with Intermittent Pneumatic Compression [9].*

Comparison of Data for Hips in Patients with and without Deep Vein Thrombosis Total 502 Hips				
	No Deep Vein Thrombosis N=479	**Deep Vein Thrombosis N= 23**	**P Value**	**Power * (1-B)**
Mean age (yrs.)	61.4	62.4	0.76	0.06
Age of > 75 yrs.	98 (20)	2 (9)	0.28	0.37
Gender M F	 190 (40) 289 (60)	 13 (57) 10 (43)		
Body Mass Index of > 30	97 (20)	8 (35)	0.12	0.33
Approach Anterior Posterior Transtrochanteric	 72 (15) 357 (75) 50 (10)	 6 (26) 15 (65) 2 (9)	0.37	0.24
Duration of the Operation <120 mins. 120-180 mins. 181-240 mins. > 240 mins.	 12 (3) 205 (43) 143 (30) 119 (25)	 2 (9) 7 (30) 7 (30) 7 (30)	0.21	
Type of anesthesia General Regional	 58 (12) 421 (88)	 4 (17) 19 (83)	0.51	0.12

* The power to detect the observed difference at p= 0.05

The data are given as the number of hipsk, with the percentage in parentheses [9]

In this study patients found to have an asymptomatic proximal or distal DVT on a duplex scan were managed for 3 months with low dose Warfarin (Coumadin) alone. All the other patients were recommended to take 650 mg of Aspirin once daily after discharge. There was no method of verifying compliance. All the patients were clinically evaluated for signs and symptoms of DVT and PE for one year after discharge.

Results

The compliance of the patients and the nursing staffs administration of the intermittent pneumatic compression prophylaxis was observed as excellent. No patient developed a symptomatic DVT while in the hospital. An asymptomatic DVT was found on the duplex scan (4.6%). There were 19 DVT (18 ipsililateral and 1 contralateral)., proximal DVT (3.8%) and 4 (one ipsilateral and 3 contralateral), distal DVT (0.8%). There were no differences detected between patients with and without DVT as to age ($p = 0.76$), and gender ($p = 0.13$), BMI ($p = 0.12$), duration of the operation ($p = 0.21$), type of anesthesia (general or regional ($p = 0.51$), or presence of a classic risk factor ($p = 0.22$). Patients 75 years and older had a lower incidence of DVT than those patients younger than 75.

A symptomatic PE occurred in 3 patients (0.06%). All were women diagnosed V-Q Scan. One PE patient had an ipsilateral femoral vein thrombosis. Three symptomatic ipsilateral DVT's developed after the patients were discharged from the hospital, 2 of which had a proximal DVT. No patient developed an asymptomatic PE and there were no fatal PE's.

Discussion

This prospective study demonstrated that DVT was detected by postoperative duplex ultrasonography of 4.6 % of 502 total hip arthroplasty patients managed with thigh high anti-thromboembolism stockings and thigh high intermittent pneumatic compression devices. Proximal DVT (femoral vein) occurred in 3.8% of the 502 patients. The mechanical pneumatic compression was begun on both lower extremities prior to the surgical incision. All the patients were tested for DVT at a mean of 6 days post operatively. Symptomatic PE occurred in 0.6% of the hospitalized patients. No fatal PE's occurred. The 0.6% of symptomatic non-fatal PE is a decrease over the rate of 0.7% for patients managed with low molecular weight heparin and 2.7% for those managed with Warfarin (Coumadin) [10].

The prevalence of thromboembolism with mechanical pneumatic prophylaxis used in this study compared to those reported for pharmacologic prophylaxis with either low molecular weight heparin or Warfarin (Coumadin). The 3.8% rate of proximal DVT in this study is comparable with the 4% rate of proximal DVT reported by Woolson in his similar prophylactic study Protocol which was carried out with regional anesthesia [11].

This study also included higher risk patients for development of DVT, those with a classic risk factor history such as cancer, thromboembolism, diabetes, atherocsclerotic hypertensive cardiovascular disease, obesity and congestive heart failure. The low

prevalence of DVT in this study suggests that intermittent thigh high pneumatic compression devices with duplex ultrasonography surveillance may be sufficient prophylaxis in high risk patients. The advantage of intermittent pneumatic compression is that it is not associated with a high rate of bleeding complications after primary total hip arthroplasty.

In one randomized study by Imperiale, T. F. and Speroff, T.,*A meta-analysis of methods to prevent venous thrombo-embolism following total hip replacement [12]*, major bleeding was a complication in 1.5% of 397 patients managed with Warfarin (Coumadin), and 2.8% of 398 patients managed with low molecular weight heparin [12]. In the Hull study, the Warfarin (Coumadin) group 2.5% of 397 patients developed a wound hematoma, and the low molecular weight heparin group 5.8% of 398 patients developed wound hematomas (0.9%). In this study 5 patients in 502 total hip arthroplasties developed a post-op wound hematoma, one hematoma required surgical evacuation. No patient developed any other bleeding complication.

One study by Hooker, Jennifer, BS, Lachiewicz, F. ZMD, and Kelley S. Scott, MD, *Efficacy of prophylaxis against thromboembolism with intermittent pneumatic compression after primary and revision total hip arthroplast y[11*],suggested that a longer delay in testing after THA might increase the incidence of positive duplex scan as a result of the propagation of smaller thrombi. However, in this study there was no difference found in the patients who had duplex ultrasonography done 2-5 days post-op versus those who had the duplex test 6 days post-op. DVT thrombosis developed at a mean of 3 days post-op. Several studies have demonstrated kinking and subsequent occlusion of the common femoral vein during THA [5]. Wuh et al. showed that intra-operative intermittent pneumatic compression can help maintain blood flow through the kinked vein, thereby decreasing the prevalence of DVT. This study initiated intra-operative mechanical pneumatic compression inititation before the incision was made.

Several studies have demonstrated a decreased prevalence of DVT after spinal or epidural anesthesia (regional). In this study a significant difference between general and regional anesthesia could not be detected with development of DVT ($p = 0.51$)[9].As 88% of 440 of 502 surgeries were performed with regional anesthesia, the study did not have sufficient power to detect small variations as 8100 procedures would have needed to be studied.

Three patients (0.6%) developed a DVT after initial negative duplex after discharge from the hospital. The possible etiology is propagation from small calf thrombi not detectable at the time of the original scan. This emphasizes the need for educating patients on the signs and symptoms of DVT at discharge and the need to instruct the patient to seek prompt medical treatment.

The present study showed the efficacy of prophylaxis against thromboembolism utilizing pneumatic compression devices after either primary or revision THA. Intermittent pneumatic compression devices used intra-operatively and post-operatively reduced the rates of both DVT and PE. The overall incidence of thromboembolism was similar to the prophylaxis using wither Warfarin(Coumadin) or low molecular weight heparin. The advantage is that there were fewer serious bleeding complications. This

prospective study of 502 THA patients utilizing intermittent pneumatic compression devices combined with duplex ultra-sonography was found to be a safe and effective method of preventing both DVT and PE even with the inclusion of patients with risk factors for these complications {9}.

Meta-Analysis

The Meta-analysis of 17 trials (2412 patients) assessed graduated compression stockings, 22 trials (2779) patients) assessed intermittent pneumatic compression devices, and 3 trials (176 patients) assessed foot-pumps. This meta-analysis was done by Roderick, P. et al, *Towards evidence-based guidelines for the prevention of venous thromboembolism: systematic reviews of mechanical methods, oral anticoagulation, dextran, and regional anesthesia as thromboprophylaxis[23]*.

Objectives

The objectives of this meta-analysis using the Cochrane method of analysis was to assess the benefits of reductions in the risks of deep vein thrombosis and pulmonary embolism and the hazards of major bleeding associated with:

1. Mechanical compression (graduated compression stockings), intermittent pneumatic compression devices, and foot-pumps
2. Dextran
3. Oral anti-coagulation
4. Regional anesthesia (an alternative to general anesthesia) in surgical and medical patients

There is significant variation in surgical practice both between and within the surgical specialties as to preventive measures for DVT. Some thrombo-prophylactic methods have not been reviewed at all whereas others have been reviewed more than once but with conflicting findings.

Review Methods

All trials identified were identified utilizing the criteria of primary outcomes of DVT, PE, major bleeding, proximal vein thrombosis, and fatal PE. The trials were assessed as monotherapy and as adjunctive therapy(additional form of thrombo-prophylaxis).

Results

Mechanical compression methods reduced the risk of DVT by about two thirds (2/3) when used as monotherapy and about half (1/2) when added to adjunct therapy. These benefits were similar regardless of the particular method used, graduated compression stockings, intermittent pneumatic compression devices, or foot-pumps. The results were similar in each of the surgical group studies. Mechanical method reduced the risk of PVT by about half (1/2) and the risk of PE by two fifths (2/5). Oral anticoagulants when used as monotherapy, reduced the risk of DVT and PVT by about half (1/2), and the protection was similar in each of the surgical groups{23].

PE was reduced by four fifths (4/5) but the reduction was statically uncertain as it was reported only in a minority of trials, thus may have been subject to selection bias. Oral anti-coagulant regimen approximately doubled the risk of major bleeding and appeared less effective at preventing DVT than heparin. Heparin was associated with less jmajor bleeding events. Dextran decreased the risk of DVT and PVT by about half regardless of the type of surgery. Again, too few studies reported PE for reliable effects of this outcome. Dextran appeared to be less effective in preventing DVT than heparin therapy. Dextran was linked to an increased risk of bleeding but the results were unreliable. Regional anesthesia reduced the risk of DVT by about one half (1/2) compared with general anesthesia.

Conclusions

Patients undergoing a surgical procedure would be expected from these study results to benefit from a mechanical compression method of thrombo-prophylaxis such as pneumatic compression or graduated compression stockings. Patients who are considered to be at particularly high risk of venous throm0-embolism may also benefit from a pharmacological thrombo-prophylactic agent. Oral anticoagulants and dextran therapy appears less effective at preventing DVT than standard low dose unfractionated heparin or low meolcular weight heparin therapies even though they are associated with less bleeding. If possible, the use of regional anesthesia in place of general anesthesia may additionally protect against DVT [23].

Executive Summary of the Meta-analysis

Towards evidence based guidelines for the prevention of venous thromboembolism: systematic reviews of mechanical methods, oral ant-coagulation, dextran, and regional anesthesia as thromboprophlyaxis [23].

Objectives

The study objectives were to asses the benefits in reductions in the risks of DVT and PE, and major hazards of bleeding events of

1. Mechanical compression (graduated compression stockings), intermittent pneumatic compression devices, foot-pumps
2. Oral anti-coagulants
3. Dextran
4. Regional anesthesia (as an alternative to general anesthesia) in surgical and medical patients

Search Strategy

A systematic search of electronic data bases was done (Medline, Embase, Biosis, Derwent).

- Search of anti-thrombotic trialists collaboration database
- Contact of trailists and manufacturers

- Searching of bibliographies of identified papers and reviews of thrombo-prophylaxis

Selection Criteria

Properly randomized studies were selected. Non-English language trials were also included. The comparisons were of the effect of one of the methods under review versus a control group. Also included were direct comparison between different versions of a method, or direct comparison between a pharmacological agent (dextran or oral anti-coagulant) and low molecular weight or unfractionated heparin. Only trials with assessment of DVT by radiological methods were included.

Data Collection and Analysis

The trials were evaluated by at least two review authors for methodological quality. The trial patients with primary and secondary outcomes were recorded. The primary outcomes were DVT, PE, and major bleeding events. The secondary outcomes were proximal vein thrombosis and fatal PE. Trials were separated into monotherapy, ones that evaluated a method as the only means of thrombo-prophylaxis and adjunctive therapy, the trials that evaluated the effects of adding another form of thrombo-prophylaxis.

Main Results

Mechanical compression and mechanical pneumatic intermittent compression methods reduced the risk of DVT by about two thirds (2/3) when used alone (mono-therapy). When a pharmacological method was added (adjunct), the risk of DVT was reduced by about half (1/2).

The reduction of risk of DVT was similar irrespective of the particular method used, graduated compression stockings, intermittent pneumatic compression or foot-pumps and similar in each surgical group.

Mechanical methods reduced the risk of proximal vein thrombosis (PVT) by about half and risk of pulmonary embolus (PE) by two-fifths (2/5).

Oral anti-coagulants when used as alone (mono-therapy), reduced the risk of DVT and PVT by about half. This reduction appeared to be the same in each of the surgical groups studied. There was a large four-fifths decrease in PE but the magnitude of this reduction is statistically uncertain as PE was reported only by a minority of trials which may reflect selection bias. While the addition of oral anti-coagulation was found to be approximately double the risk of a major bleeding episode. Oral anti-coagulant regimens appeared less effective in preventing DVT than heparin regimens (64% greater risk of DVT) and were 35% less likely to be associated with a major bleeding episode.

Dextran was found to reduce the risk of DVT and PVT by about half (1/2) irrespective of the type of surgery, although too few trials had reported PE to give reliable results of effect on this outcome. Dextran appeared less effective in decreasing DVT than Heparin regimens that were studied. Dextran was also found to increase the risk of major bleeding but too few major bleeding episodes were reported for the size of this risk to be a reliable result.

Regional anesthesia compared with general anesthesia reduced the risk of DVT by about half. This reduced risk of DVT appeared similar in each of the surgical settings studied. Regional anesthesia was also associated with less major bleeding than general anesthesia.

Conclusion

Excluding a clear contra-indication (such as sever peripheral artery disease), patients undergoing a surgical procedure would expect to benefit from a mechanical compression method of thrombo-prophylaxis (such as graduated compression stockings, intermittent pneumatic mechanical compression stockings, or foot-pumps) irrespective of their absoloute risk of venous thrombo-embolism. Patients who are at high risk of DVT may also benefit from a pharmacological thrombo-prophylactic agent. Oral anti-coagulant and dextran regimens appear less effective at preventing DVT than standard low dose unfractionated heparin or low molecular weight heparin regimens which may be less appropriate for patients at high risk of venous thrombo-embolism even though they are associated with fewer bleeding events.

When possible, regional anesthesia as an alternative to general anesthesia may also provide additional protection against venous thrombo-embolism. Further randomized trials are needed in the area of preventionh of DVT among high risk medical patients (such as stroke) as there is little information regarding prevention of DVT among this high risk population [23].

Tables

Health Technology Assessment 2005; Vo DVT
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Category	No. of Trials With data	DVT Compression	DVT Control	Odds ratio & Confidence interval Compression: Control
(a)Graduated Compression Monotherapy				
Graduated Compression Stockings	9	8.6%	21.2%	
Intermittent Pneumatic Compression	19	10.1 %	23.4%	
Footpump	2	18.0%	52.3%	
(a) Subtotal	30	9.8%	23.7%	
(b) Compression (adjunctive therapy)				
Graduated Compression Stockings	8	9.6	19.4%	
Intermittent Pneumatic Comrpession	3	11.8%	15.3%	
Footpump	1	0.096%	20.0%	
(b) Subtotal	12	10.0%	18.1%	

0.0 0.5 1.0 1.5

■ 99% Confidence intervals
♦ 95% Confidence intervals

Category	No. of Trials With data	DVT Compression	DVT Control	Odds ratio & Confidence interval Compression: Control		
(c) All Patients (Mono-or adjunctive therapy)						
Graduated Comression Stockings	17	9.0%	20.4%	■		
Intermittent Pneumatic Compression	22	10.4%	21.9%	■		
Footpump	3	12.8%	43.3 %	■		
All Trials	42	9.9%	21.99%	♦		
				0.0	0.5	1.0

1.5

■ 99% Confidence intervals

♦ 95% Confidence intervals

Compression better Compression worse

Study Fukaska University School of Medicine, Japan

Another study by Fujisawa, et al [1], from the department of Orthopedic Surgery, Fukaska University School of Medicine, Japan, *Effect of calf=thigh intermittent pneumatic compression device after total hip arthropolasty comparative analysis with plantar compression on the effectiveness of reducing thrombogenesis and leg swelling was reviewed.* In this study 121 total patients undergoing total hip arthroplasty were randomized into the two groups 59 patients in the calf-thigh pneumatic compression group and 63 patients into the plantar compression group or foot=pump.

The two pneumatic compression devices were compared to evaluate which was more effective for reducing thrombogenesis.

D-Dimer Levels

Seven days post-op THA the mean D-Dimer levels of calf-thigh compression group and the plantar compression group (foot-pump) were 8.86 and 9.26 ug/ml respectively. No significant difference was found p=0.697 between the two groups.

Thigh Circumference Differences

However increased ratio of the circumference of the thigh averaged 1.22 % in the calf-thigh compression group and 3.19% in the plantar compression (footpump) group which was significantly different p =0.01.

Result

Result of the calf-thigh pneumatic compression was found to be more effective than plantar compression (foot-pump) for reducing thigh swelling post-operatively.

Device	Chambers	Pressure	Cycle Time (secs)	Inflation Time (secs)
Calf-thigh pneumatic compression	2	20-80 mmHg	14	3.1
Foot0pump A-V impulse system	1	120-160 mmhg	20	0.4

[1]

Patients with a history of DVT, PE, CHF, venous insufficiency or presence of a malignant tumor were excluded.

Study by Ragucci MV et. Al. Comprehensive deep venous thrombosis prevention strategy after total-knee arthroplasty consists of the use of epidural anesthesia versus general anesthesia, aspirin, venous foot pumps and early mobilization [4]. The prevalence of DVT is as high as 35% in patients receiving pharmaocological prevention alone. The study conducted by New York University School of Medicine of 100 total knee arthroplasty patients enrolled into a prospective trial [4]. All patients performed full weight bearing on post-op day #1 and ambulation as tolerated. Venous foot compression foot pumps and aspirin were used immediately post op. Bilateral venous duplex scans were performed in all the patients to assess the presence of DVT during the first post-op week.

Results

Three (3%) of the patients, demonstrated evidence of DVT.

Conclusion

The combination of epidural anesthesia aspirin, immediately post operative venous foot-pumps, and early ambulation together seem to be a more effective approach to prevent the occurrence of thrombo-embolic events after total knee replacements than pharmacological alone [4].

Question #2

Which mechanical pneumatic device for the prevention of DVT following total joint replacement of the hip or knee is more effective, and what are the ideal parameters for the delivery of pneumatic compression.

Studies have been conducted to identify the ideal parameters or delivered compression pressures for delivery of pneumatic compression to the lower extremities.

Bioengineering studies on a simulated leg have been idealized to investigate the effects of external compression on three hemodynamic criteria:

1. Degree of vessel collapse
2. Level of fluid velocity
3. Level of shear stress

These studies were conducted by Olsen, Kamin, and Shapiro. Bioengineering studies of periodic external compression as prophlylaxis against deep vein thrombosis part II: experimental studies on a simulated leg in the Journal of Biomechanical Engineering [6]. The report describes how the wave speed gradient of applied external pressure alters hemodynamic parameters. The authors conclusions were that a combination of sequential and graded compression may be the most effective means of mechanical prophylaxis DVT.

In vivo studies have been conducted. In 10 volunteers, Nicolaides and associates analyzed mean and peak blood flow velocities measured by doppler ultrasound in the femoral vein during sequential compression{7}.
They recommended pressures of:

Ankle 45 mmhg
Calf 40 mmhg
Thigh 25 mmhg

They also recommended a decompression time of one minute. This was based on the required time of 45 seconds for the veins to refill. The rationale for 1 minute decompression was that the fuller the veins were, the better activating clotting factors would be circulated from the soleal veins and axial valve pockets. Kam and co-authors studied blood flow with radioactive labeling in 23 volunteers[23]. They suggested a faster rate of pressure rise and a sequence time of 0.5 seconds, compared with Nicolaides group's of 1 second.

This data was analyzed by manufacturers for the key pressure waveform parameters generated by pneumatic compression devices to optimize the hemodynamic factors important in decreasing clot formation and propagation [8]. It was also shown that in the thigh chamber that both the correct maximum pressure and correct rate of pressure use was reached. This may explain why some studies have shown a decrease in distal DVT but an increase in proximal DVT with pneumatic compression as compared with Warfarin (Coumadin) [6]. The pneumatic compression devices must be tested to ensure they actually deliver the pressures and therapy they are designed to do.

Study by Lachiewicz, Kelly, and Haden of: Two Mechanical Devices for Prophylaxis of Thromboembolism after total knee arthroplasty

The optimal type of pneumatic compression for mechanical prophylaxis of thromboembolism after total knee arthroplasty, are not known. This study compared two types of calf compression, with the hypothesis the device which delivered a larger increase in peak venous velocity would result in a lower rate of thromboembolism. The study was a prospective, randomized study of 423 patients (472 knees). Duplex ultrasonography was performed post operatively. A rapid inflation asymmetrical compression (RIAC) device was used on 206 patients (232 knees) and a sequential circumferential compression device (SCD) was used on 217 patients (240 knees).

The rapid inflation asymmetrical compression device (RIAC) rate of deep vein thromboembolism was 6.9k% as compared to the sequential compression device (SCD) which was 15% (p= 0.007). In the 47 patients who underwent bilateral total knee replacement 4% developed thrombi using the RIAC compared with 22.7% for the patients who wore the sequential compression deviceSCD (p= 0.05 per knee). This study found that the use of rapid inflation, asymmetrical calf compression resulted in a significantly lower rate of thromboembolism[37].

Background

A common complication of total knee arthroplasty (TKA) is deep vein thrombosis or DVT. There are a variety of prophylactic regimens recommended. Studies have suggested that pneumatic compression devices are an important prophylaxis. Thigh high sequential compression, aspirin, footpumps and aspirin comparisons have been studied and also shown to be an effective prophylaxis. New methods of calf compression which deliver higher venous flow have been studied in a smaller group of patients. The optimal characteristics for pneumatic compression devices are not known. Also, there have been no prospective randomized studies that compare the efficacy of the different devices on the market today. The aim of this study was to determine which of two pneumatic calf-compression devices together with adjunctive aspirin decreased the rate of DVT.

The rapid inflation asymmetrical compression (RIAC) device (Venaflow; Air-cast, Summit, New Jersey) is a knee high applied sleeve with two longitudinal posterior chambers. The RIAC inflates rapidly once time every minute, with a length of

compression of six seconds and at a programmed pressure of 45-52 mmHg. The other device called the sequential compression device (SCD, Kendall, Mansfield, Massachusetts). The SCD also is a knee high sleeve with three transverse calf chambers. The compression cycle is followed by a 60 second venting cycle achieving a pressure of 45 mmHg.

The study hypothesis was that the RIAC device would produce a lower rate of thromboembolism. The rationale for the decrease in DVT was that the RIAC delivered a larger peak venous velocity above and below the junction of the greater saphenous and common femoral veins.

Pneumatic compression Device	Rate of Inflation per minute	Chambers	Duration of compression	Pressure in mmHg
RIAC	1 X per minute	2 longitudinal Posterior chambers	6 seconds	456-52 mmHg
SCD	1X every 60 seconds	3 transverse calf chambers		45 mmHg

[37]

Patients and Methods

The study took place between April 1999 and March 2003. All patients undergoing TKA primary or revision in one institution under two surgeons, were screened for the study. The study included those patients with a past history of DVT, pulmonary embolism, heart disease, and varicose veins. The study was IRB approved. The patients were consented and randomized to either the RIAC or the SCD arm utilizing sealed envelopes. The patients discontinued aspirin, non-steroidal and anti-inflammatory medications prior to the surgery. The patients were instructed to take 325 mg of Aspirin the night prior to the surgery. The compression device was applied to the contralateral limb in the operating room before the surgery and then on the operated limb at the end of the surgical procedure. All patients wore elastic compression hose beneath the pneumatic compression devices. The compression devices were only removed for bathing once daily And for physical therapy sessions twice daily. A timing device was not in place to determine the exact length of time the devices were in place but estimated between 12 to 16 hours per day. Aspirin 650 mg twice daily was given post-operatively. There was no method of measuring compliance of home use of the Aspirin or wearing of the elastic compression stockings.

Bilateral duplex ultrasonography was performed three to five days after the operation which is an institutionally validated method of detection of deep vein thrombosis.

Events during the study were:

- 442 patients were entered
- 19 patients were excluded
- 12 had surgery cancelled
- 2 did not have ultrasonography
- 2 did not have TKA, one had a resection arthroplasty and one an arthrodesis
- 3 suffered an acute myocardial infarction post-operatively
- 423 patients completed the study

Statistical Analysis

Chi square analysis of categorical variables was done. Fisher's exact test was used for the chi-squared test because of the small frequency counts for several cells. The level of significance was set at $p < 0.05$.

The power of the study analysis was determined to be 230 knees needed for each group for a power of 0.8 at the level of significance of 0.05.

Result

There were 206 patients (232 knees) were randomized to the RIAC device group and 217 patients (240 knees) to the SCD group. The in hospital mortality was 0.2%. The patient was a 78 year old man who developed an acute myocardial infarction 12 hours after the surgery and died on the second post-operative day after angioplasty and stent placement. One patient had a sympotomatic non-fatal pulmonary embolism on the 12th post-operative day and also had a large right calf thrombis diagnosed.

The rate of DVT diagnosed was 6.9% with the RIAC device and 15% with the SCD, see table.

The rate of thromboembolism in both groups

	RIAC	**SCD**	**P value**
No. of patients	206	217	
Number of knees	232	240	
In-hospital mortality (%)	0	1 (0.46)	
Pulmonary embolism (%)	0	1(0.46)	
Number of thrombi (%)	16 (6.9)	36 (15)	0.007
Proximal (popliteal or femoral)	1	6	

The difference was found to be statistically high (p= 0.007).

In the group of 47 bilateral TKA patients, one patient developed bilateral calf thrombi (4%) with the RIAC device and five with seven thrombi (three calf, one bilateral calrf, one calf and popliteal thromus, 15.9%, seven of 44 limbs at risk) with the SCD device.

There were no complications from either pneumatic compression device. No patient developed a symptomatic DVT during the six months post discharge.

Discussion

Therapeutic doses of Warfarin (Coumadim) or low molecular weight heparin cannot be used intra-operatively or even early post-operatively in patients who have received regional anaesthesia with an epidural or continuous spinal catheter due to the risk of intra-thecal hemorrhage. Thus, mechanical prophylactic devices which can be utilized intra-operatively on the contra-lateral limb (non-operative limb), and immediately post-operatively on the operated limb are desireable.

Several different mechanical devices such as foot-pumps, foot-calf pumps, calf-thigh pumps and calf compression devices are available for choosing for prophylaxis. They differ in length and location of the compression sleeve, frequency and duration of activation, and rate of rise of pressure as well as differences in the maximum pressure delivered. Again, the optimal characteristics of these devices for the prevention of DVT after TKA are not known. Westrich et al investigated ten patients who had unilateral TKA. A cross over study was done to establish the hemodynamic effect of several pneumatic compression devices. Duplex ultrasonography was used to determine the mean peak venous velocity augmentation above and below the junction of the saphenous and common femoral veins in addition to the increase in venous volume at the site. The study established that one type of posterior calf sleeve (RIAC) increased mean peak venous velocity augmentation by 91% compared to the 88% for the conventionally used calf-thigh SCD. They did not find any statistically significant difference in the mean venous volum augmentqation between any of the seven devices studied.

The hypothesis in this study was that the device which provided a greater rise in peak venous velocity (RIAC) would have a decreased rate of DVT.

There was only one death from a fatal myocardial infarction and only one symptomatic pulmonary embolus.

There was a significant statistically difference in the rate of DVT between the patients who had the RIAC device and the patients who had the SCD.

Ultrasonography for use in the diagnosis of DVT has been validated for 25 years.

The rationale for the decreased incidence of DVT for the patients in the RIAC group may be due to decreased venous stasis, increased local fibrinolysis, inhibition of the coagulation cascade, or the increased peak venous velocity as measured in the proximal deep venous system.

As a result of the study data the RIAC device and aspirin is used for all patients undergoin unilateral, primary or revision TKA at the Unversity of North Carolina at Chapel Hill [37].

Foot-sole pump device study

A study of another mechanical pneumatic intermittent DVT prophylaxis device called the intermittent foot sole pump system a commonly used device was done by Giannoni, et. al. called Total knee replacement prevention of deep vein thrombosis using pharmacological (low-molecular weight heparin) and mechanical (intermittent foot sole pump system) combined prophylaxis.

The objective of this study was to determine the role of combined mechanical and pharmacological prophylaxis in the prevention of DVT after total knee replacement. This was a prospective study[38].

Methods

This study took place between October 2002 and June 2003 and included 38 total knee procedures were carried out on 34 patients (4 patients had bilateral TKR). Patients were screened for concomitant DVT's prior to their surgery with echo-color-flow of the legs. The patients received one daily dose of subcutaneous nadroparin calcium. The intermittent foot sole pump (IFSP) was applied in the recovery room post-operatively on both feet for about 5 hours a day and all night. The foot pump was continued at home until day 15 post-op.

Results

There were no major pre-op or post-op complications. The incidence of DVT was 7.9% (3cases). In one case it was found to be a re-thrombosis. All patients were treated with low molecular weight heparin. There were no pulmonary embolsms.

Conclusion

In this experience, the combined prophylaxis with nandroparin calcium (low molecular weight heparin) and IRSP the incidence of DVT was significantly reduced.

Long term it has been found that about 50% of patients who develop symptomatic proximal DVT and 30% of patients with calf vein thrombosis will go on to develop a chronic venous insufficiency.

Clinical studies again have reported that the incidence of DVT is up to 70-84% without prophylaxis.

To prevent this complication different prophylactic methods have been used such as aspirin, warfarin (coumadin), and more currently low molecular weight heparins. To date the optimal regime of antithrombotic prophylaxis with no risk of hemorrhagic complications has not yet been established.

Low-molecular weight heparin carries a possible risk of bleeding thus some authors have suggested that the use of mechanical devices such as graduated elastic compression stockings, or a foot sole pumping system.

Studies have been done on the use of the intermittent foot sole pump after TKA but as reported by Warwick et al, no statistically significant differences in the incidence of DVT have been determined between a group of patients treated with enoxaparin (low molecular weight heparin) alone and a group of patients treated with IFSP alone. This

study objective was to determine the DVT incidence after TKA when two different prophylactic methods were used.

Materials and Methods

This study took place between October 2002 and June 2003 and included 38 elective TKA patients in 34 patients. The primary diagnosis was osteoarthrosis in 31 knees, osteonecrosis in 5 knees, and post-traumatic arthritis in 2 knees.

All patients had ultrasound exams to screen for DVT. Echo color flow scans were done 1-2 weeks prior to the surgery to exclude concomitant DVT of both lower extremities, post-operatively prior to discharge and 30 days after the surgery. The thrombi were classified as proximal if located in the popliteal, iliac or femoral vein, and distal if only calf veins ere involved. All patients received epidural anesthesia. All patients received the same type of prosthesis (Smith and Nephew Profix implant) except for 2 patients who received a Zimmer prosthesis for post traumatic arthritis.

Surgical Procedure

The same surgical procedure was performed for all patients. Antibiotic prophylaxis was given. The patients received one daily subcutaneous injection of nadroparin calcium dosed according to body weight. The low molecular weight heparin was started the day of the surgery post operatively and continued at home until weight bearing of the operated leg was complete (15-30 days).

Elastic compression stockings were applied after surgery. The IFSP (A-V Impulse system, Novamedix, Andover, UK) was applied to both feet postoperatively in the recovery room.

This foot pump has a single inflatable chamber for each foot that rapidly inflates in 0.4 seconds with a pressure of 130mmHg and deflates after 1 second. This cycle repeats every 20 seconds.

The foot-pump was removed only for walking, daily hygiene, and physical therapy. They were continued until the 15^{th} post operative day. The foot pump impulse system was worn for an average of 14 hours per day (range 8-18 hours).

If DVT was suspected D-dimer blood tests were done, x-rays and perfusional and ventilatory pulmonary scintigraphy were performed. DVT evaluation was done at 15 and 30 days post op. All patients were followed for a minimum of 6 months.

Results

The mean hospital length of stay was 7 days with a range of 7-12 days. There were no LMWH or IFSP related deaths. The following table shows:

Thromboembolic events in 34 patients submitted to TKA and treated with LMWH and IFSP in 6 months follow-up.

Thromboembolic	Percentage Events	No. of Patients %
Distal DVT	7.9	3
Proximal DVT	0	0
PE	0	0

Thromboembolic Events

The incidence of DVT was 7.9% and 3 were distal DVT's diagnosed by ultrasonography. There was no proximal vein thrombus, and no evidence of PE.

General and local adverse reactions

There were two patients who developed delayed wound healing with superficial serous drainage. One patient with a history of multi-infarctual dementia developed narcolexia into the 4th postoperative day. A CT scan was done and excluded recent hemorrhagic or ischemic changes. After six months no patient had signs or symptoms of DVT and no death occurred.

Discussion and conclusions

TKA surgery carries DVT as the most serious postoperative complication. It also carries the risk of PE and the later development of postphlebitic syndrome. The most common location of the DVT in TKA patients is the calf. However development of thrombus into the popliteal and femoral veins is a cause of fatal PE.

Prophylaxis from Aspirin alone shows an incidence of DVT in the range of 41% to 78%.

Warfarin (Coumadin) alone has shown to be effective in reducing DVT when compared to no prophylaxis but the rates of DVT remain high in the range of 35% to 59%.

The use of low molecular weight heparin (LMWH) has shown a significant improvement in the prevention of DVT. The incidence of DVT in patients treated with LMWH for prophylaxis is about 23% which is still a high incidence. All these pharmacologic drugs may cause side effects such as bleeding, hemarthrothis, and wound hematomas.

To avoid hemorrhagic complications, some authors have suggested that mechanical devices like graduated elastic compression stockings or foot sole pumping systems may be used.

The first foot pneumatic compression device was utilized in 1983 by Gardner et al. to prevent DVT in non-ambulating patients after surgery. This was explained as a pumping mechanism which mimicked weight bearing. These mechanical methods are based on the physiological mechanism of heart pumping blood in the foot sole.

The foot sole pump can expel a larger amount of blood than the active contraction of soleus and gastrocnemius muscles of the calf muscle pump which is a low flow system of blood flow.

The rationale for the use of intermittent pneumatic compression in decreasing DVT occurrence is based on the mechanical action on venous blood, and several studies have shown that IPCD causes venous turbulence in the valve pocket areas where clot formation frequently begins[38].

Several authors also conclude that the IPCD increased fibrinolysis through the stimulation of release of urokinase and tissue plasminogen activator from the endothelium [38].

This IFSP pneumatic device produces a forceful ejection of blood from foot to calf with a pressure of more than **100mmHg as compared to the traditional intermittent pneumatic compression devices where the increase in the venous pressure is only 20-30 mmHg [38].**

In conclusion, mechanical devices which function to reduce venous stasis are effective in reducing the rate of DVT after TKA. The current literature has few studies on the effectiveness of combined prophylaxis with antithrombotic therapy and mechanical compression devices in TKA.

This study resulted in 38 consecutive TKA resulting in 7.9% DVT incidence. IFSP was tolerated well by all 38 patients with a statistical significance of $p< 0.001$. This suggests that LMWH and IFSP after TKA is safe and effective in the prevention of DVT. The use of nadroparin calcium (LMWH) and IFSP after TKA is recommended wherever possible [38].

2. **What factors impact patient compliance with mechanical pneumatic compression devices?**

The study: *Foot pump prophylaxis for deep venous thrombosis-rate of effective usage following knee and hip arthroplasty* by Charalambous et al., evaluated patient compliance and factors impacting usage [5]. For the foot pump to be effective, it is recommended that they are worn continuously when the patient is non-ambulatory. They must be applied

correctly so they exert sufficient pressure to compress the plantar venous system and return blood to the heart.

Foot pumps have been shown to be applied properly and function correctly 59% of the time in trauma patients[5]. Also, there is lack of evidence as to the rate of effective use of these devices in TKA post-operative patients.

This study performed was a prospective cohort study to determine the rate of effective usage in patients undergoing elective TKA or THA and observed the usage rate changes as the patient progressed in mobilization post operatively.

Results

There were 621 observations made in 29 patients. Foot pumps were found to be worn, applied properly, and functioning correctly on both legs only 231 of 621 times (37%). On 390 observations, the foot pumps were either not worn (288) or worn but not turned on or not applying sufficient pressure (102).

It was found that there was a gradual decrease in the rate of effective usage as the post operative days increased [5]/

The correct utilization rate was significantly higher at night compared to daytime. When questions during our first visit, 8 of 29 (28%) of the patients did not know the purpose of wearing foot pumps [5].

Another study was done of patient compliance and satisfaction with mechanical devices for preventing deep venous thrombosis after joint replacement done by Robertson, et at., at Tulane University School of Medicine in the department of Orthopedics.

A consecutive series of 224 patients having total joint arthroplasty at Tulane University included patients who were treated with two types of mechanical pneumatic compression devices for the prevention of DVT[16]. The first 104 patients (named group 1), wore the thigh high sequential compression device or SCD. The next 120 patients (named group 2), wore a foot pump mechanical pneumatic compression device. The patient's compliance with each device was documented daily each hour until discharge.

A patient satisfaction questionnaire was obtained from each patient. The general findings of the study found that patient understanding about the devices aided compliance, 73% in group 1 and 77% in group 2. The satisfaction questionnaire revealed significantly greater satisfaction in group 2 (73%) versus group 1 (55%). A subgroup of 35 patients who used both devices, 24 patients preferred the foot pumps. Seven preferred the SCD and 4 had no preference[16]. This study demonstrated a greater satisfaction and higher degree of compliance with the foot pumps for DCT prophylaxis [16].

Patients who have arthroplasty of the hip or knee are all at risk for DVT and PE. Prophylaxis against DVT/PE has included pharmacologic and mechanical measures. Several studies have shown the efficacy of all these measures. The National Institutes of Health (NIH) Development conference on the prevention of venous thrombosis and PE suggested that mechanical devices may be effective when used alone as well as when used in conjunction with pharmacological prophylaxis. However, concerns have been expressed about patient compliance with the use of mechanical DVT prophylaxis [7].

This study by Robertson et. al, evaluated patient compliance and satisfaction comparing two types of mechanical compression devices , sequential compression devices (SCD) versus foot pump devices. All patients undergoing joint arthroplasty were monitored throughout their hospitalization with accurate documentation of their hospitalization with accurate documentation of their compliance. Demographic and operative variables were documented on all patient including risk factors for DVT/PE. A patient satisfaction questionnaire was completed prior to discharge regarding patient satisfaction with the devices[16].

Methods and Materials

The study consisted of two consecutive groups of patients who were undergoing a primary or revision total joint arthroplasty at Tulane University Hospital in New Orleans. Each group received treatment with one of two types of mechanical compression devices for DVT. The patients were not randomized but automatically assigned to group1 at the beginning of the study and patients in group 2 had arthroplasty surgery in the second half of the study.

Group 1 (104 patients) were managed with elastic stockings (ted hose) plus sequential compression device (Kendall, Mansfield, Mass.). The routine use of elasticf stockings was not monitored.

The SCD consisted of a six chamber device applied to the entire leg from calf to groin, producing the sequential compression of the lower extremity and milking venous blood proximally. The 120 patients in group 2 were treated with the foot pump (Plexi-pulse, NuTech, San Antonia, Tex.). The foot pump is applied to the foot only and provides pulsatile compression of the planter venous plexus, as well as peripheral veins of the foot.

Both groups received patient education on the function and purpose of their device. Pharmacologic prophylaxis added per surgeon discretion using Enoxaparin (Lovenox) or Warfarin (Coumadin).

Risk factors for each patient were assessed. These risk factors included sex, age > 40, obesity, use of oral contraceptives, history of venous insufficiency, previous DVT/PE, malignancy, or congestive heart failure (CHF).

Each patient ‘s chart contained a flow chart to document patient compliance placed with the vital sign chart. All staff physicians, nurses, and physical therapists were required to

document patient compliance every time they entered a study patient's room. The patient's charts were labeled to alert medical personnel that the patient was enrolled in the study. The foot pump device has a meter which accurately records the amount of time a patient has been properly wearing the device. This electronic record was compared with the manual flow chart to assess accuracy.

A patient satisfaction questionnaire was completed by each study patient prior to discharge. This questionnaire included questions regarding their knowledge of the purpose of the device, how it functioned and why the patient was not compliant. Both groups were surveyed on comfort or discomfort experienced while wearing the devices. The subgroup (exposure to both devices) was asked an additional question as to their preference between the two devices.

Statistical analysis included a chi-square test and students t test. P valus of less than 0.05 was considered significant [16].

Results

The average hospital stay was 6 days with patients ambulatory by post op day 4 and discharges occurred between 3-7 days. Compliance data for all patients was available through day 3.

The total compliance difference of 3.2 hours was noted between group 1 and group 2. Patients in group 1 (SCD) were compliant 72.5% of the time. Group 2 (foot pumps) were compliant 76.3% of the time. This difference in compliance between the two groups showed a statistical significance test $p = 0.05$. In group 2 (foot pumps), 35 patients undergoing revision surgery and had used the SCD during the previous surgery, 24 preferred the foot pump, 7 preferred the SCD, and 4 had no preference. The preference for the foot pump was statistically significant ($p < .005$).

Patient education was determined by both groups as the primary reason the prevention of blood clots was why they were compliant, 75% group 1 and 80% group 2. The primary reason for non-compliance by patients in group 1 was stated to be that the devices were "too hot" and the accompanying elastic stockings were bothersome. Group 2 patients stated their main reason for non-compliance was that the foot pump was painful on the foot and heel and that the forceful pulsations were bothersome. Three patients reported skin blisters related to the wearing of the device one in group 1 (SCD) and 2 in group 2 (foot pumps).

Reasons for Non-Compliance with Foot Pumps

Painful to foot and heel	**5**
Forceful pulsation	**4**
Tight	**3**
Blisters	**1**

Reasons for Non-Compliance with Sequential Compression Devices

Hot/Sweaty	**14**
Elastic Stockings bothersome	**9**
Tight	**4**
Itchy	**4**
Blisters	**2**

Discussion

DVT and PE are major causes of morbidity and mortality after total joint arthroplasty [16]. The efficacy of intermittent external pneumatic compression may be achieved through three mechanisms.

1. Increased velocity of venous return, reduction stasis.
2. Stimulation of regional fibrinolytic activity reducing hyper-coagulability.
3. Reduction of veno-dilation thereby reducing endothelial damage.

In a study by Camerota et. al the factor of patient compliance with mechanical compression devices are highlighted.[18]. Also, Westrich and Sculo [19], demonstrated the degree of compliance to be significant in the prevalence of DVT after TKA patients who wore foot pumps finding no DVT in patients compliant wearing foot pumps 80% of the time and a significant incidence of DVT in patients with 55% compliance. Thus, throboembolic complications during use of compression devices are associated with compliance. The primary factor contributing to non-compliance by patients with the use of compression devices for DVT prophylaxis has been rejection by patients who find the intermittent inflatable sleeves uncomfortable [18].

Educating patients about the purpose of these devices are of primary importance. TKA patients often use a continuous passive motion device (CPM) and the total hip patient uses and abduction pillow or balanced suspension. The mechanical compression device may be seen as the only piece of equipment they can remove. Nursing staff may be sympathetic and leave them off instead of explaining why they are so important for care. The high degree of compliance observed in this study was attributed to the education of patients and nursing staff. 100% compliance should be the goal.

This study found patient compliance high in both groups. The foot pump group expressed greater satisfaction and greater comfort.

There are other advantages found with the use of foot pumps. They do not require the application of thigh high elastic stockings which have been noted to cause a venous tourniquet effect whey they roll down. Also, thigh high elastic stockings have been associated with the development of peroneal nerve palsy caused by chronic increased pressure on the peroneal nerve [20].

The TKA may require bulky post operative dressings which may hamper the effectiveness of SCD, where the use of the foot pump would seem more advantageous.

The foot pump was also seen more easily used with the CPM machine, continuous passive motion machine. The foot pump was simpler to apply and use so the patient, family, or visitors were able to remove and re-apply the device after the patient walked to the bathroom or returned from a physical therapy session. Thus the results of this study established an advantage of foot pump use over sequential compression devices in patient compliance and satisfaction for use in mechanical prophylaxis after total joint arthroplasty[18].

I have one more study review for question 3 if recommended.

Question 4.

What educational programs would be beneficial in improving patient and staff compliance in the continuous use of mechanical pneumatic compression devices such as sequential compression and foot pump devices in post operative total hip or knee joint replacement patients?

A prospective study from the department of surgery, Santa Barbara Cottage Hospital, by David Stewart et. al, *A Prospective Study of Nurse and Patient Education on Compliance with Sequential Compression Devices* was done to evaluate the effect of patient and nurse education by surgeons on sequential compression device compliance [21].

Compliance was checked twice daily on the study group of patients. The outcomes were compliance rates with SCD use before and after nurse and patient education. The nurses were blinded to the study. The patient received a handout that explained the importance of SCD on surgical units. Prior to the education, surgical units had a compliance rate of 61.5%, whereas non-surgical units had a 48% compliance rate. The difference was significant ($p = 0.014$). After patient and nurse education on the surgical floors, compliance rates increased to 65%, a difference that was not of statistical significance ($p = 0.515$). Thus, a nursing units daily experience is the most important factor in compliance rates. Focused nursing in-services and patient education may have an incremental value [21].

As stated previously, DVT events are events that without any form of prophylaxis are estimated to occur in 40-60% of hospitalized patients. In addition to PE which can result in morbidity and mortality, 20% of patients can incur sub acute chronic complications of DVT that have disabling effects on mobility and quality of life. Sequential compression devices have become the most oommon prophylaxis for DVT in the hospital setting.

SCD's are desireable to use in surgical patients where bleeding complications after surgery or trauma may prevent the additional use of heparin or anti-platelet agents [22]. For this reason, compliance with the use of SCD's in surgical patients is of great importance. In current practice compliance rates of the SCD was only 48% on a unit where a prospective study by Comerota et al and compliance in the ICU was 78%. Also, it was found that patients after transfer from the ICU to the ward, was decreased to 33% [18].

The study observes the rate of compliance with implementation of nurse and patient education as a solution to improve SCD compliance rates.

Methods

The observation period included the time the patient was admitted to the time of discharge. All patients admitted to the surgical service who had SCD's ordered were included in this study from surgical and IZCU units. None of the pat\ients or nurses were aware of the study to avoid influencing the outcome. Resident rounds were mande on all patients in the am and pm where flow sheets were used to document compliance. The data was collected twice daily fro two months. The am and pm data was separated to evaluate the different nursing shifts care of each patient. After the baseline observation period, one surgical resident conducted an educational in service with the nursing staff of the surgical floor for the day and evening shift. This educational program stressed the purpose and benefits on sequential compression devices.

A one page informational flyer was also created by the Investigator and given to each patient. This flyer requested that patients replace their own SCD's after ambulation or ask a nurse to do so.

Please notify your nurse if your compression stockings are not on, they are important for preventing blood clots during your hospital stay.

After the educational inservice and implementation of patient information handouts, a two month observation period was performed where data sheets were collected as previously discussed evaluating the same parameters.

Results

At the end of the first period of observation (pre-education), compliance rates were calculated. The surgical floor had a significantly higher compliance rate of 61.5% than the non-surgical floors 48%, which was statistically significant ($p= 0.014$). After the nursing inservice education and patient education, the surgical floor experienced an even higher compliance rate of 65% compared with the non-surgical units which did not receive education a rate of 48% which was significant ($p = 0.004$). The comparison of compliance rates on the surgical floors before and after nurse and patient education did reveal a small improvement in compliance, but this was not a statistically significant ($p = 0.515$).

Pneumatic compression devices are frequently ordered for general surgical and trauma patients and are currently the safest and least invasive therapy available which may help decrease the incidence of DVT. However, the effectiveness of SCD is impacted by poor compliance rates for the following reasons.

1. One major factor may be that nurses, patients, and physicians may not appreciate their importance. Instituting periodic educational interventions with nurses and house staff might prevent this problem. Having audits of compliance of SCD use by both physicians and nurses is one mechanism to improve compliance. Promoting routine SCD use with 100% compliance as a goal or outcome for standard of care may be the best strategy for improvement.
2. Nurses and health care staff should be required to document the use of SCD in the patient record or log for accountability and for compliance with SCD orders. Physician progress notes should also include a note on SCD use, again increasing the importance and compliance of DVT just as other key care documentations such as medications, vital signs, incisions, wounds, and physical assessments.
3. Also, all nursing unit areas of specialized care with both nursing and bed shortages where surgical patients may be admitted to with limited experience and knowledge on the importance of SCD therapy for surgical patients must receive reinforced education. These nurses may not notice that SC are not ordered, not be functioning properly, or may not be continuously applied to the patient. The data in this study found that compliance rates are more affected by nursing experience than by structured lectures. The unit with the most experience with SCD had the best compliance rates which further improved with education.

Nurses who were more experienced in SCD therapy as their daily responsibility on a regular basis demonstrated better compliance. This was found to be more effective than lectures.

Patient education in this study did not increase compliance rates significantly. The posted sign is a constant reminder of the importance of SCD use showed insignificant increased use of SCD.

Conclusion

Improvement in SCD compliance is primarily driven by physicians and nurses. SCD compliance rates directly impacts their efficacy. The compliance rates were found to be most affected by the total physician and nurse's experience of the nursing unit on a daily basis. Educational interventions were found to be only incremental in value. The compliance with sequential compression devices will be the best for patients admitted to the units most experienced with the importance of the role of SCD in the care of these patients [21].

Due to the possible development of late thrombi through propagation from a small calf thrombi post discharge, emphasis in the need for patient education regarding this is needed. The patient needs education about seeking prompt medical attention if symptoms of a DVT occur prior to and after discharge.

Question 5.

What new mechanical pneumatic compression devices are under clinical trial for deep vein thrombosis prophylaxis in patients undergoing total joint replacement for the hip or knee and what compliance issues do they address?

A study of a miniature mobile intermittent pneumatic compression device for the prevention of deep vein thrombosis after joint replacement was done by Tel Aviv University at Tel Aviv-Soirasky Medical Center titled *A miniature and mobile intermittent pneumatic compression device for the prevention of deep vein thrombosis after joint replacement by Galen and colleagues [24]*.

Background

The device call the WizAir is a miniature, lightweight (690grams), battery operated and mobile intermittent pneumatic compression device (ICD) which enables continuous intra-operative use and immediate patient mobilization post operatively. The efficacy of the WizAir was compared with the Kendall SCD. Peak femoral vein flow velocity was measure in 20 healthy volunteers at rest with each device. No significance between them were found. A second prospective randomized clinical trail was used to compare the efficacy of the device in preventing DVT after joint replacement in 50 patients (N =25 per group). No patients in this group developed a DVT. Doppler ultrasound was done and found no significant differences. The WizAir DVT anti-thrombotic compression device is as safe and effective as the Kendall SCD [24].

Study

Mechanical prophylaxis of DVT following joint replacement includes elastic compression stockings, and intermittent calf compression devices that have almost no side effects. Intermittent pneumatic compression devices (ICD's) have been shown to be as effective in preventing DVT and PE as Warfarin (Coumadin), heparin, and low molecular weight heparin (LMWH) and do not cause side effects of excessive bleeding [23]. ICD's have almost no side effects and are well tolerated by patients. They are safely implemented either during or after surgery. They assure high venous blood flow and emptying of the lower limbs. ICD's also exert a systemic fibrinolytic effect.

The disadvantages of current ICD's include non-compliance due to the limited mobility of the patients who are confined to an immobile device. This confinement interferes with rehabilitation [25].

The WixAir ICD device manufactured by Medical Compression Systems DBN-Ltd, Oragiva, Israel, is easily protable. It is battery operated and weighs only 690 grams (lbs). The sleeves are sterilizable and they are not bulky like the large conventional SCD's. They can be applied intr-operatively without interfering with the field of surgery. They also offer easier post operative patient ambulation with no delay in rehabilitation. The

effect of the lightweight WizAir was compared to the common Kendall SCD device (Kendall, Mansfield, MA, USA).

Patients and Methods

Two trials were conducted to evaluate the effectiveness of the WizAir DVT device in comparison to the Kendall SCD device from 1999 to 2000. In the first trial, 20 healthy volunteers had their peak femoral vein blood flow velocity measure, once at rest, and once with each device. This was measured using a duplex ultrasound (Toshiba). The volunteers rested 10 minutes prior to each measurement. Resting peak flow velocity was recorded, after which either the WizAir DVT device or the Kendall SCD device was randomly chosen for resting peak femoral flow velocity first and then swapped for the other one using the same test protocol. Results were determined by comparing peak pre-compression curves with the peak curves using the compression devices. Results were calculated as percent change in peak pressure velocity (improvement in blood flow) during the use of each ICD as compared to the resting base values.

The trial was prospective and randomized (closed envelopes were randomly drawn for each patient. Fifty patients undergoing elective joint replacement surgery for THA or TKA, were randomly divided into two subgroups, one treated with the WizAir DVT and the other the Kendall SCD.

Inclusion criteria was age> a60 yeasrs and surgery consisting of primary elective THA or TKA. Patients who were on Coumadin were excluded, as well as any patients with conditions affecting coagulation such as varicose veins, coagulopathy, thrombocyte disorders, cancer, or previous DVT. Aspirin was discontinued 14 days prior to surgery. Informed consent was obtained prior to randomization. The Kendall SCD group received routine treatment which included Heparin 5000 units sub-cutaneously twice daily for 6 days postoperatively, as well as pneumatic compression applied to both legs using the Kendall SCD immediately following surgery. The SCD was in operation continuously with a pressure of 35-55 mmHg for 5 consecutive days. Only minimal interruptions were allowed for bathing and physical therapy.

Patients in the WizAir group received identical treatment to that of the Kendall SCD group. Both devices had knee length calf cuffs with three pneumatic cells. The WizAir has a low volume calve sleeve design with sequential compression pressures of 50 mmHg (+ or – 10) for 6 seconds every minute. Each patient received a Doppler Ultrasound on the 6^{th} post operative day to evaluate DVT of the lower limb by a senior ultrasound specialist.

Statistics

The volunteer trail statistical analysis was per formed using the paired t-test. The results comparing the two clinical groups were analyzed statistically using the binomial test confidence interval. The hypothesis testing significance was calculated for the whole group of 50 patients with the power of the test being > 0.70.

Results

Preliminary results of the trial showed a mean increase in femoral vein peak flow of 66% during the application of the WizAir DVT and this increase was 65% with the Kendall SCD ($p = 0.9$). Thus both compression devices reach increased femoral vein peak flow velocity to the same extent. Both groups were similar in age and sex distributions. Anesthesia and surgery were similar for all patients. There were no reports of DVT or PE. There were no DVT's detected in any of the 50 patients.

Sub cutaneous heparin treatment 5,000 units twice daily usually lowers the incidence of DVT to 25%. This demonstrates that the absence of any case of DVT in 50 patients is significantly lower than that expected for treatment with heparin alone ($p < 0.0001$). Th significant added DVT prophylaxis seen in both of these study groups is attributed to the ICD treatment.

Discussion

The side effects associated with DVT prevention are the primary issues which determine the more preferable options for prophylaxis to choose from all that is available. Bleeding has been found to occur in 2-10% of patients who receive pharmacological DVT prophylaxis post operatively. This results in morbidity and rarely mortality [25]. It has been established that the beginning of DVT formation usually occurs during the operation itself [26]. This is the critical time period where ICD's could offer critical prophylactic protection. Pharmacological prophylaxis is seldom if ever used before the first post operative day due to the possibility of profuse bleeding. The additional advantages of ICD's over pharmacological prophylaxis includes post operative pain reduction is that no laboratory monitoring is required. ICD's promote the systematic endogenic fibrinolytic effect as they mechanically improve and enhance femoral vein blood flow [29].

The current ICD models on the market are bulky and there use during the operations, are cumbersome. Also, their post operative use confines the patient to the stationary device and post pones and limits mobilization and rehabilitation of the patient. Patient non-compliance occurs due to this confinement.

The WizAir DVT ICD was designed to overcome these compliance and use problems. The study group patients were able to walk about with the device secured by a strap hanging from the shoulder similar to a lady's handbag. This portable design allows easy ambulation without interruption of compression therapy.

Among the healthy volunteers, measurement of peak flow velocity in the femoral vein showed a similar significant enhancement using either the Kendall SCD or the Wiz Air DVT ICD.

In the clinical trial which involved two similar groups of patients having either THA or TKA, there was no significant difference between the tow devices for prevention of

DVT. In the absence of prophylaxis, these patients would have a 50-70% rate of DVT [30]. The 50 study patients had no incidence of DVT.

In conclusion, the WizAir DVT is as effective in the prevention of DVT as other commercially available devices such as the Kendall SCD comparator in this study. The continuous use of this ICD device at home can contribute to earlier hospital discharge which could lead to significant cost effectiveness [24].

Study of a New Design in a Pneumatic Compression Device

This study done by Bassam and colleagues, Can a new design of pneumatic compression device reduce variations in delivered therapy for the mechanical prophylaxis of thrombo-embolic disease after total hip arthroplasy, evaluated the pressure variables associated with pneumatic compression. A new sequential compression device with feedback to maintain optimal therapy was investigated. Outcomes of improvement in therapy were to be determined [7].

Patients and Methods

A series of 50 patients undergoing elective THA were enrolled prospectively. In addition, to pharmacological prophylaxis for thrombo-embolic disease. All patients received compression from a modified device.

Maximum pressures generated and the rate of pressure rise in each of three compartments within the device sleeves were measured, and the results compared with data from historical controls.

Results

Therapy was considered ideal when in a compression cycle all chambers of both right and left sleeves reach within 10% of their target pressure rise rates. The average patient received this ideal therapy 88% of the time that the new trial sequential compression device was operating. This was an improvement over previous devices.

Conclusion

The purpose of this new device could deliver a more reliable and consistent sequential compression therapy than currently used systems. Increased consistency of delivery should make it easier to evaluate accurately the benefits of mechanical prophylaxis of sequential compression devices.

Patients and Method

After IRB approval was obtained a sample size of 50 patients was determined for this study who were undergoing elective THA surgery approached at random and those who agreed consented and entered into the study.

At the time of this study, the standard department protocol for thrombo- embolic prophylaxis included both Warfarin (Coumadin) and mechanical therapy using a 3-chamber (ankle, calf, and thigh), thigh high sequential compression device applied bilaterally to the lower limbs. Kendall company model 5330, Mansfield, Massachusettes, was used. The initial dose of 7.5mg to 10mg of Warfarin (Coumadin) based on the patient's weight was given 90 minutes before surgery. The subsequent doses were adjusted to achieve a target international normalized ratio (INR) of 1.6 to 2.3 [7] The sequential pneumatic compression device was applied post operatively until the patient was discharged from the hospital.

The new sequential compression device was developed at the study center to correct the variations in pressure waveform delivery found in previous studies. The new device uses a dedicated pressure monitoring line and flow control valve for each individual chamber, providing a feedback loop allowing dynamic control of each chambers pressure and rate of pressure rise during each cycle. This results in accurate and precise delivery of a determined pressure waveform under changing conditions i.e., compression sleeve snugness, or position on the limb encountered during the therapy [7].

The new device was used for the first 48 hours post operative period and then was exchanged for a traditional compression device the Kendall SCD (models 5325 and 6325, Kendall Healthcare, Mainsfield, Mass.).The first 48 hours is the time the patient is least ambulatory.

The following table show the average maximum pressure expected in each of the 3 chambers and the cycle time specified in the manufacturers operations manual. **The new device was programmed to deliver these same wave forms.**

The experimental device was equipped with an internal data recorder capable of monitoring and recording pressure waveform data from each of the 3 sleeve chambers at a rate of 15 Hz(hertz). Accuracy for the pressure recordings had previously been calculated at + or – 0.3 mmHg/sec for rate of pressure rise in each pressure wave form.

Table for Manufacturer's recommended average values for Kendall SCD model 5325 and 6325 pneumatic pressure control device.

Pressure Waveform Parameter	**Value**
Maximum Pressure mmHg	
Ankle chamber	45
Calf chamber	40
Thigh chamber	27
Rate of pressure rise, mmHg/sec	
Ankle chamber	13.6
Calf chamber	9.7
Thigh chamber	4.8
Total duration of 1 cycle in seconds	71
Inflation portion of cycle in seconds	11
Deflation portion of cycle in seconds	60

[7]

After 48 hours of therapy, the data recorded for each patient were downloaded into a computer for analysis. The recorder was recalibrated and rechecked before re-use.

The initial outcome measure among 53 patients enrolled was that no complications occurred. Two patients were withdrawn for staffing shortages, and one data recorder failure. Patients received therapy for 82.7% of the time.

The primary outcome measure of target value pressures achieved in all chambers was 97.7% of cycles recorded. The mean duration of interruption was 2.4 hours. The average of the longest interruptions of therapy was 17.9 hours. The device function was found to function well for long periods as well as after interruptions.

Fifty-one patients completed queswtionnaires assessing their subjective tolerance results. Eight-four percent said they would use the system again. The largest disruption was sleep disturbance caused by the noise of the new device which will be addressed with improved sound insulation in the future.

Most recent decreased rates of DVT of 0.34% and 0.38% are most likely related to a combination of current medical practice and a possible overestimate in the past [7].

Freedman and colleagues performed a meta-analysis of thrombo-embolic prophylaxis in 10,929 patients after elective THA [7].The results demonstrated that compared to placebo, pneumatic compression significantly reduced the risk of distal and proximal DVT and symptomatic PE. The data revealed the three prophylactic agents responsible with this lowered risk as:

1. Low molecular weight Heparin
2. Pneumatic compression
3. Warfarin (Coumadin)

They concluded that the best prophylactic agent for efficacy and safety was Warfarin followed by pneumatic compression devices [7]. The incidence of fatal and non-fatal PE cannot be extrapolated from the reduction rate of DVT. Thrombo-embolic disease has other serious consequences such as venous outflow obstruction in the lower limbs and chronic post phlebitic or post thrombo-embolic limb syndrome with venous hypertension, swelling, pain, and possible ulceration. Post thrombotic limb syndrome may occur within 5 years in 60-70% of patients who develop a proximal DVT, and within 2 years in 16% of patients who develop a distal DVT.

If mechanical DVT prophylaxis could reduce DVT, it would be valuable in the longterm even with no proven effect on the incidence of fatal PE.

Pneumatic leg compression devices have been proven in several studies where the rate of DVT has been more than halved, 50-65% reductions, ($p < 0.05$) in fracture of the hip and elective arthroplasty of the hip and knee.

The new pneumatic compression device with a built in monitoring and corrective feed back loop to accurately achieve the target parameters reduces variability in delivery of therapy. This self monitoring capability may reduce complications associated with the devices.

Conclusion

Pharmacologic prophylaxis therapy in the prevention of DVT and PE in patients undergoing THA or TKA is easily controlled by the physician and managed medically. Intermittent pneumatic compression device therapy remains variable as to control of patient and staff compliance as well as consistent delivery and correction of the optimal pressures to be delivered to the patient. New devices need to be designed and developed which may be applied intra-operatively where thrombi are thought to begin forming. On the post-operative end there needs to be improvements in intermittent pneumatic compression devices which are more mobile, more comfortable, and more consistent in pressure delivery and correction.

Further randomized studies will then need to be carried out with these improved devices which have been proven to be effective in DVT and PE reduction without the associated risks of bleeding events.

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