Comparative Study of Compression Bandages with Absolute Bed Rest versus Ambulation in Treatment of Acute Proximal Deep Vein Thrombosis

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ABSTRACT

Background: In general, many patients with acute proximal deep vein thrombosis (DVT) are treated with heparin and oral anticoagulant. Many physicians have been taught to admit these patients to absolute bed rest for the first 24-48 hours due to the fear of dislodging clots that may lead to fatal pulmonary embolism (PE).

Objective: The aim of this study is to compare the differences among the changing circumference of affected limb, the severity of pain, and the incidence of symptomatic PE in 3 groups of acute proximal DVT, including absolute bed rest with compression bandages (group 1), ambulation with compression bandages (group 2), and ambulation without compression bandages (group 3).

Methods: Between January 2006 and March 2011, 60 patients were enrolled in this study. In this analysis, the clinical characteristics, the changes of affected limb circumference and pain score during the first week of admission and the incidence of symptomatic PE among 3 groups of this study were analyzed.

Results: There were no statistical differences in the characteristics among 3 groups of patients. The most gender was female and the mean age for 3 groups ranged from 55.1 to 63.7 years. Comparing among 3 groups, it showed a significant difference of calf circumferences between group 1 and group 3. None of pain score differences were statistically significant among 3 groups. In addition, there was no incidence of symptomatic PE in the three groups of the present study.

Conclusion: Our findings confirm that acute proximal DVT treatment with ambulation does not increase the incidence of symptomatic PE, compared with absolute bed rest. Although there is no statistical decrease of the severity of pain between those 3 groups, the group of absolute bed rest and compression can promote the resolution of calf swelling, compared with the group of ambulation without compression bandages.

Keywords: Deep vein thrombosis, ambulation, compression bandages

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INTRODUCTION

n general, the treatment of acute deep vein thrombosis (DVT) is intravenous infusion of unfractionated heparin or subcutaneous

Correspondence to: Khamin Chinsakchai E-mail: khaminc@gmail.com Received 29 March 2016 Revised 29 April 2016 Accepted 2 Mary 2016 administration of low molecular weight heparin (LMWH) for at least 3-5 days, followed by a course of oral anticoagulants for at least 3-6 months. Many physicians have been taught to admit patients with acute DVT to absolute bed rest for the first 24-48 hours due to the fear of dislodging clots that may lead to fatal pulmonary embolism (PE).¹⁻³

From a literature review, there is no consensus regarding ambulation in treatment of acute DVT.

The standard treatment is not routinely addressed whether these patients should have absolute bed rest with compression bandages or ambulation. However, some studies suggested that PE did not increase in patients with acute DVT who were treated with LMWH and ambulation as well as compression bandages. For In addition, the changes of leg circumference and severity of pain have been widely neglected in most studies that usually focused on therapeutic outcome.

The aim of this study is to compare the differences among the changing circumference of affected limb, the severity of pain, and the incidence of symptomatic PE in 3 treatment groups of acute proximal DVT: (1) absolute bed rest and compression bandages, (2) ambulation and compression bandages, and (3) ambulation without compression bandages.

MATERIALS AND METHODS

Patients

Between January 2006 and March 2011, 564 patients at Siriraj Hospital were diagnosed with acute proximal DVT by Color Doppler Ultrasonography (CDU). Of these, 60 were enrolled in this study. The inclusion and exclusion criteria are presented in Table 1. The Siriraj ethical committee for research in humans approved this study and written informed consent was received from all participants.

Study design and procedure

The patients' demographic and characte-

ristic data were collected. All patients were advised to stay in the hospital for at least 7 days during the study. They received subcutaneous injection of Enoxaparine, 0.1 ml/ 10 kg per body weight, once every 12 hours for a minimum of 5 days. They also received oral anticoagulant (Warfarin) on the third day with dose adjusted to reach international normalized ratio values between 2.0 and 2.5.

This research is a randomized, unblinded, controlled trial in which three groups of adjuvant treatment modalities in patients are compared as follows:

Group 1: absolute bed rest and compression bandages with 30° affected leg elevation for up to 2 days following bed rest

Group 2: ambulation with compression bandages

Group 3: ambulation without compression bandages

In group 1 and 2, the 4-inch elastic bandages were applied from the distal part of dorsal foot to the proximal part of thigh. This bandage was changed every morning. For group 1, the patients were advised to only stay in bed in the first 2 days, while group 2 were encouraged to walk as much as possible on the ward. Regarding the patients in group 3, they were advised to ambulate similar to group 2 without compression bandages.

The changes of leg and thigh circumferences compared with contralateral side were measured every morning after 5-minute removing compression bandages. The points of measure-

TABLE 1. Inclusion and exclusion criteria.

Inclusion	Exclusion
Patients diagnosed with acute DVT	Patients already treated with heparin or compression bandage
Duration of symptoms less than 14 days	Patients with symptomatic PE
Ambulated patients	Patients unable to walk
Well-cooperating patients	DVT was documented floating thrombus with Duplex scan
	Patients with severe concomitant cardiopulmonary disease
	Patients with chronic renal failure or renal insufficiency
	Patients with chronic arterial occlusive disease
	Patients with inflammation or infected wound at affected limb
	Patients were pregnant or breast feeding
	There was a contraindication for LMWH
	Poorly cooperating patients

ment were the maximal edematous area at calf and the mid-point between anterior superior iliac spine and superior border of patella. We bilaterally measured the difference at these two points until the circumferences of leg and thigh were equal to the normal limb.

Pain was assessed daily at the same time with the Visual Analogue Scales (VAS). Pain scores were calculated for 0 to 10 levels from no pain to maximal pain.

All patients also were observed regarding the symptoms of PE such as dyspnoea with chest pain, haemoptysis, failing consciousness or lack of consciousness. Subsequent perfusion lung scan with technetium-99m-labeled microspheres and chest radiography were indicated only when symptoms indicating clinically symptomatic PE.

The primary endpoint is the changes of affected leg and thigh circumferences compared with contralateral side from the first day to day 7. The secondary outcomes are the changes of pain scores during the same period and the incidence of symptomatic PE during admission.

Clinical Definition

Acute proximal DVT can be defined as thrombosis of the popliteal or more proximal deep veins of the legs in less than 14 days.

Absolute bed rest is referred to total bed rest without bathroom privileges. Bed rest is generally understood to mean staying in bed but was allowed to get up to use the toilet.

Ambulation can be defined as the ability to walk from place to place independently with or without assistive device.

Symptomatic PE has been applied to the patient having typical symptoms such as chest pain, dyspnoea, cough, haemoptysis, and/or syncope.⁸

Statistical analysis

According to the pilot studies, the average time for decreasing in limb swelling of affected side to normal side in group 1, 2 and 3 are 4, 7 and 10 days, respectively. The study would have sufficient power (80%) and a two-sided 5% significant level for the difference in average timing with a total of 20 patients available for

evaluation per group. Descriptive demographic data analyses are given as mean ± standard deviation for continuous data or as percentages for discrete variables. For the changes of pain score, calf and thigh circumferences, the student's t-test and analysis of variance (ANOVA) were calculated. The Chi-square test was used to compare the incidence of symptomatic PE among the 3 groups of acute DVT. A value of p<0.05 was considered to be statistically significant. Statistical analysis was conducted with SPSS software version 22 (SPSS Inc, Chicago, III).

RESULTS

Of 60 patients, 20 patients were allocated in each 3 group. From the data in Table 2, there was no statistical difference in the characteristics among 3 groups of patients. It is apparent from this table that most gender was female and the mean age for 3 groups in this study ranged from 55.1 to 63.7 years. The left lower extremity was the most common affected side for DVT. In addition, the most common level for DVT in this study was located at the level of iliac vein and below.

Primary end point

Leg and thigh circumferences

To assess the differences between the circumferences of affected leg and thigh from day 0 to day 7 in each group, it showed a significant decrease in circumference of both leg and thigh in group 1, 2 and 3 (Table 3). Comparing among 3 groups, this study showed only a significant difference of calf circumferences between group 1 and 3. In addition, there was no statistical significance of thigh circumferences among 3 groups (Table 4).

Secondary end points

Pain score

The severity of pain as documented by VAS in the 3 treatment groups is showed in table 4. Overall, none of pain score differences were statistically significant.

Symptomatic pulmonary embolism

There was no incidence of symptomatic PE in three groups of the present study (Table 4).

TABLE 2. Characteristics of the study sample.

Characteristic		Study Group		
	Group 1	Group 2	Group 3	
Gender [n (%)]				
Male	9 (45.0)	7 (35.0)	7 (35.0)	0.754
Female	11 (55.0)	13 (65.0)	13 (65.0)	
Age (years) [mean±SD]	55.1±(14.1)	63.7±(12.1)	$53.3 \pm (16.5)$	0.05
Side of DVT [n (%)]				
Right leg	6 (30.0)	7 (35.0)	8 (40.0)	0.803
Left leg	14 (70.0)	13 (65.0)	12 (60.0)	
Level of DVT [n (%)]				
Iliac vein & below	14 (77.8)	11 (61.1)	10 (50.0)	0.142
Femoral vein & below	3 (16.7)	7 (38.9)	6 (30.0)	
Popliteal vein	1 (5.6)	0(0.0)	4 (20.0)	
Duration of symptoms (days) [mo	ean±SD]			
Swell	$6.9 \pm (4.3)$	$10.2 \pm (12.6)$	$4.7 \pm (4.6)$	0.466
Pain	$4.4 \pm (4.4)$	$4.7 \pm (4.6)$	$7.7\pm(7.1)$	0.11
Previous DVT [n (%)]				
No	19 (95.0)	20 (100)	17 (85.0)	0.31
Yes	1 (5.0)	0 (0.0)	3 (15.0)	
Cancer [n (%)]	8 (40.0)	7 (35.0)	2 (10.0)	0.556
Oral contraceptives [n (%)]	2 (9.5)	2 (16.7)	0 (0.0)	0.498
Previous surgery [n (%)]	11 (52.4)	4 (33.3)	3 (18.8)	0.199

Group 1 = Absolute Bed Rest with Compression, Group 2 = Ambulation with Compression, Group 3 = Ambulation without Compression

TABLE 3. Differences in circumference between the affected calf and thigh level (cm) on days 0 and 7 in each group of study.

Data details	Treatment		p-value
	Before	After	
Circumference at calf (cms)	36.6	33.5	<0.001*
Group 1	35.3	31.2	<0.001*
Group 2	37.3	33.7	<0.001*
Group 3	37.3	35.7	<0.001*
Circumference at thigh (cms)	48.6	44.9	<0.001*
Group 1	47.8	42.9	<0.001*
Group 2	48.0	43.6	<0.001*
Group 3	49.9	48.4	<0.001*

Group 1 = Absolute Bed Rest with Compression, Group 2 = Ambulation with Compression, Group 3 = Ambulation without Compression

TABLE 4. Differences in circumference between the affected calf and thigh level (cm) on days 0 and 7 and differences in pain score among three study groups on days 0 and 7 (mean \pm SD).

Data details	Study Group			p-value
	Group 1	Group 2	Group 3	
Circumference at calf (cms)	4.8 ± 2.1	3.7 ± 3.0	2.7 ± 1.6	0.013 ^(a)
Circumference at thigh (cms)	5.3 ± 3.3	4.6 ± 6.2	2.8 ± 1.3	0.100
Pain score	3.7 ± 3.5	2.8 ± 2.5	3.8 ± 2.8	0.487
Symptomatic PE	0	0	0	-

PE = pulmonary embolism, a=difference between Group 1 and Group 3 significant at 0.05 level

Group 1 = Absolute Bed Rest with Compression, Group 2 = Ambulation with Compression, Group 3 = Ambulation without Compression

DISCUSSION

Traditionally, general practitioners favored treatment of acute DVT by absolute bed rest in order to increase resolution of pain and limb swelling. In addition, they had the fear of dislodging clots leading to fatal PE by walking. Our results suggest that the changes of leg swelling in absolute bed rest and bandaging is better than ambulation without bandages. Furthermore, the changes of pain score and the incidence of symptomatic PE are not different in each group of the present study, even with absolute bed rest or ambulation.

This study set out with the aim of assessing the changes of leg and thigh circumferences among the three groups. The results of this study show that there was a significant decrease in calf and thigh swelling in all three groups of patients during the first week of admission. In addition, the results of this study indicate that absolute bed rest with compression bandages (group 1) had the faster reduction of leg circumference than ambulation without compression bandages (group 3). This finding of the current study is consistent with those of Partsch H and et al¹⁰, who found that leg circumference was significantly lower in compression group. It seems possible that this result was due to the strong effect of compression bandages to the calf circumference.

The present study was designed to determine the effect of pain score in 3 groups. What is surprising is that there was no statistical difference in pain score among these groups. In

contrast to earlier findings, Partsch H and et al¹⁰ demonstrated much faster pain reduction in the ambulation group compared with the group of absolute bed rest. Furthermore, W. Blattler and et al¹¹ showed the significant decrease in pain score in the group of compression bandages.

The serious and fatal complication of acute DVT is PE. There was no symptomatic PE occurring in all patients of our study. This result is consistent with those who studied the frequency of new PE in acute DVT with ambulation and bed rest showing no statistical significance compared with the walking group. ¹²⁻¹⁵ In addition, a systematic review supported the clinical benefit of ambulation, which did not increase the risk of developing PE compared with bed rest. ⁹

This study was limited by its small sample size, lack of double blinded randomization, and its relatively short-term nature. In future studies, larger sample sizes might be investigated, with double blinded randomization, and the patients should be monitored the long-term outcomes.

In conclusion, acute DVT treatment with ambulation does not increase the incidence of symptomatic PE compared with absolute bed rest. Although there is no statistical decrease of the severity of pain between those 3 groups, the group of absolute bed rest and compression can promote the resolution of calf swelling compared with the group of ambulation without compression bandages. This ambulation treatment might be adapted to treat acute DVT as outpatients in order to reduce the cost of hospital admission.

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