Comparative Study of Deep Vein Thrombosis Recanalization Using Doppler Ultrasound in Different Post-Treatment Intervals in Traumatic Patients

Nazanin Farshchian[1], Negin Farshchian[2], Parisa Bahrami Kamangar[1]

[1] *Department of Radiology, Clinical Research Development Center, Imam Reza Hospital, Kermanshah University of Medical Sciences, Kermanshah, Iran*

[2] *Department of Radiation Oncology, Clinical Research Development Center, Imam Reza Hospital, Kermanshah University of Medical Sciences, Kermanshah, Iran*

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Abstract- Deep vein thrombosis (DVT) is a prevalent vascular disease characterized by pelvic and limb deep vein thrombophlebitis, and it has a high incidence in traumatic patients. Contrary to older studies, recent research has reported that recanalization in DVT is not a slow process. The present study aimed at the comparative examination of DVT recanalization with Doppler ultrasound in different intervals following treatment with heparin or enoxaparin. This prospective study was conducted on all traumatic patients hospitalized in Imam Reza Hospital of Kermanshah, Iran, with the clinical and sonographic diagnosis of DVT in limb veins. Doppler ultrasound was performed two weeks, one month, and three months following treatment in order to examine recanalization. Data were analyzed using statistical tests in SPSS16 at the significance level of <0.05. Based on Doppler ultrasound, a significant difference was found between the degree of recanalization in patients aged <45 years and those aged >45 years, between male and female patients, and between different DVT locations (P<0.05). After three months of treatment with heparin and enoxaparin, the degree of recanalization was increased in DVT. Moreover, it was found that Doppler ultrasound is a useful tool for the diagnosis of recanalization in patients with DVT.

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Keywords: Deep vein thrombosis; Recanalization; Doppler ultrasound; Trauma

Introduction

Traumatic patients are prone to DVT, and the incidence of DVT in major trauma is about 58% to 65% (1-3). The reasons for the high incidence of DVT in these patients are hypercoagulable state by severe injury as well as combat casualties, including early transfusion of blood products, transfusion of old blood (≥28 days), and surgery (1,4-8).

Deep vein thrombosis (DVT) is a prevalent vascular disease characterized by pelvic and limb deep vein thrombophlebitis. Approximately 2,000,000 people develop DVT in the United States every year (9). Several factors, including obesity, lack of exercise, oral contraceptives, smoking, and intravenous drug use and trauma, affect the increasing prevalence of this disease (10-12). Pulmonary embolism is a complication of DVT with numerous risks for patients; annually, 600,000 cases of pulmonary embolism and 60,000 cases of mortality as a result of pulmonary embolism occur in the US (13). Another complication of this disease is the post-thrombotic syndrome (PTS), decreasing patients' physical ability due to foot edema and heaviness and leading to disease relapse (10,11). The long treatment period of DVT with warfarin has complications such as an increased risk of hemorrhage (14). Therefore, accurate control and timely and precise treatment greatly assist patients' life.

The DVT recanalization process is of utmost importance in examining the efficiency of DVT treatment

Corresponding Author: N. Farshchian
Department of Radiology, Clinical Research Development Center, Imam Reza Hospital, Kermanshah University of Medical Sciences, Kermanshah, Iran
Tel: +98 9123757729, Fax: +98 34276355, E-mail address: N_Farshchian2000@yahoo.com

methods such as anti-coagulant and compression treatment (15). It was formerly believed that recanalization occurs later in DVT (16). However, recent research reports that recanalization in lower limb DVT is not a slow process (17,18). Evidence suggests that recanalization in vascular parts can be observed even in the first post-treatment week (18). The use of phlebography for monitoring the DVT period is less common due to its invasive nature. Thus, the use of non-invasive imaging methods for examining the course of DVT has increased as they can be performed with no limitation (19). In many previous studies, imaging methods, especially Duplex ultrasound, have been used for examining the degree of recanalization in DVT (19-24). However, no study has so far evaluated recanalization in DVT using Doppler ultrasound in different post-treatment intervals. Thus, the present study aimed at the comparative examination of recanalization in DVT using Doppler ultrasound in different post-treatment intervals.

Materials and Methods

This prospective study using convenience sampling was conducted in 2017 on all consenting patients with the clinical diagnosis of DVT in limb veins visiting the ultrasound ward of Imam Reza Hospital of Kermanshah, Iran, for whom the definitive diagnosis was made using Doppler ultrasound. They underwent Doppler ultrasound (Siemens G40 with Convex 3-5 and linear 8-12 MHZ probes), and recanalization was examined in the two weeks, one month, and three months after treatment (20).

Inclusion criteria were the clinical and ultrasound diagnosis of limb DVT and history of trauma, and exclusion criteria were renal failure, allergy to heparin or enoxaparin, pregnancy, endocarditis, liver disease or uncontrolled hypertension, blood diseases, or a history of thromboembolism in the past three months treated with heparin, enoxaparin, or other anticoagulants. Following the routine method, heparin or enoxaparin was first injected. Enoxaparin (1 mg/kg) was subcutaneously injected every 12 hours. Alternatively, the hourly infusion treatment dose (iv5000) of heparin was injected every 4-6 hours. Warfarin was started either simultaneously with the first drug (2.5-5 mg daily) or 5-7 days after the first drug. The combination method was used in most cases. After the patients' INR reached the treatment level of 2-2.5 after 3-5 days, the first drug (enoxaparin or heparin) was discontinued, and treatment was continued with warfarin. If warfarin was discontinued, e.g., due to pregnancy, enoxaparin or heparin were continued. Finally, the data (age, sex, history of smoking, history of cardiac disease, history of major surgery, history of receiving heparin or enoxaparin, unilateral or bilateral lower limb involvement, site of DVT, and canalization status) were entered into a checklist developed based on the main variables of the study and analyzed in SPSS.

The degree of vein opening was measured as follows:

First, the cross-section of the vein was calculated at the site of thrombosis. Then, the degree of vein opening (%) was determined using ultrasound. This measurement was performed in proximal, medial, and distal thrombosis sites, and maximum vein opening was considered as the criterion. The presence of color or spect in the thrombosed vein was considered as recanalization criteria.

Sample size formula

Based on previous studies (21) and considering the confidence level of 95%, power of 90%, and recanalization degree of respectively 39% and 82% in one month and six months, the sample size for each treatment group (with heparin or enoxaparin) was calculated as 25 (50 in total).

Statistical analysis

The gathered data were analyzed by SPSS V16. The Friedman test was run for the comparative examination of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin. $P<0.05$ was considered significant.

Results

In this study, 50 eligible traumatic patients with the clinical diagnosis of DVT in limb veins (Tables 1 and 2) visiting the ultrasound ward of Imam Reza Hospital of Kermanshah in 2017 were examined. Their age was 20-81 years (mean and SD of 50.57±16.73 years).

Twenty-four patients (48%) were male, and 26 (52%) were female. Of the 50 patients participating in this study, 21 (42%) had a history of smoking, 5 (10%) had a history of cardiac disease, 26 (52%) had a history of surgery, 10 (20%) had a history of receiving heparin or enoxaparin, 48 (96%) unilateral involvement and 2 (4%) bilateral involvement of lower limb.

The Friedman test was run for the comparative examination of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin (Table 3).

Table 1. Frequency distribution of the DVT site in patients visiting Imam Reza Hospital of Kermanshah

Site of DVT in patient	Number of the patient (%)
Common femoral, Femoral, Pupliteal	26(50%)
Femoral and Pupliteal	5(10%)
Common iliac and External iliac, Common femoral, Femoral, Pupliteal	2(4%)
Common femoral, Femoral, Deep femoral, Pupliteal	2(4%)
Common femoral, Femoral	2(4%)
External iliac, Common femoral	2(4%)
Pupliteal	7(14%)
Femoral, Pupliteal, Dorsal tibialis	2(4%)
Femoral, Pupliteal, Small Saphenous vein	2(4%)

Table 2. Number and percentage of patients in terms of the involved vein

Involved veins	Patient number	%
Dorsal tibialis	2	1.526
Pupliteal	46	35.114
Femoral	41	31.297
Deep femoral	2	1.526
Common femoral	34	25.954
Common iliac	2	1.526
External iliac	4	3.053
Total	131	100

Table 3. Descriptive characteristics and comparison of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin

	Rate of recanalization				T	*P*
	0%	**<50%**	**>50%**	**100%**		
After 2 weeks	104(80%)	20(15.5%)	4(3%)	2(1.5%)		
After 1 month	39(30%)	50(38.5%)	29(22.3%)	12(9.2%)	85.5	<0.001
After 3 months	14(10.7%)	29(22.3%)	39(30%)	48(37%)		

The Friedman test was run for the comparative examination of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin in terms of age (Table 4).

Table 4. Descriptive characteristics and comparison of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin in patients aged below and above 45 years.

Findings showed that a significant difference exists in the degree of vein opening in DVT based on Doppler ultrasound in different intervals following treatment with heparin or enoxaparin between patients aged below and above 45 years (P<0.05). In the >45 years group, the degree of recanalization in thrombotic veins was higher (73%) one month after treatment compared to those below 45 years (67%).

Moreover, the Friedman test was run for the comparative examination of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin in terms of sex and DVT site (Tables 5 and 6).

Findings indicated that a significant difference exists in the degree of vein opening in DVT based on Doppler ultrasound in different intervals following treatment with heparin or enoxaparin between male and female patients (P<0.05). The degree of recanalization was higher in women than men one month (80%) and three months (93%) after treatment.

A significant difference existed in the degree of vein opening in DVT based on Doppler ultrasound in different intervals following treatment with heparin or enoxaparin between femoral and common popliteal and femoral veins (P<0.001). For instance, the level of complete recanalization was higher in the femoral vein than in

common femoral and popliteal veins two weeks (5%) and three months (40%) after treatment.

Table 4. Descriptive characteristics and comparison of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin in patients aged below and above 45 years

	Rate of recanalization												T	*P*
	After 2 weeks				After 1 month				After 3 months					
	0%	<50 %	>50 %	100 %	0%	<50 %	>50%	100%	0%	<50%	>50%	100%		
45> year	62(80 %)	13(16 .7%)	0(0%)	2(3.3 %)	26(33 .3%)	29(37 .2%)	18(23%)	5(6.5%)	8(10.3%)	23(29.5%)	18(23%)	29(37.2%)	46.06	<0.001
45< year	42(80 %)	6(11. 5%)	4(8.5 %)	0(0%)	14(27 %)	21(40 .5%)	10(19%)	7(13.5%)	8(10.3%)	23(29.5%)	18(23%)	29(37.2%)	39.51	<0.001

Table 5. Descriptive characteristics and comparison of DVT recanalization using Doppler ultrasound in different intervals following treatment with heparin or enoxaparin in male and female patients

	Rate of recanalization												T	*P*
	After 2 weeks				After 1 month				After 3 months					
	0%	<50 %	>50 %	100 %	0%	<50%	>50%	100%	0 %	<50%	>50%	100%		
Female	57(80 %)	7(10 %)	5(7 %)	2(3 %)	14(19.7 %)	28(39.4 %)	19(26.7 %)	10(14.2 %)	5(7 %)	10(14.2 %)	31(43.6 %)	25(35.2 %)	48. 63	<0.001
Male	47(80 %)	12(2 0%)	0(0 %)	0(0%)	26(44%)	21(35.5 %)	9(15.3%)	3(5.2%)	9(1 5.3 %)	20(33.9 %)	9(15.3%)	21(35.5 %)	37.32	<0.001

A significant difference exists in the degree of vein opening in DVT based on Doppler ultrasound in different intervals following treatment with heparin or enoxaparin between male and female patients ($P<0.05$). The degree of recanalization was higher in women than men one month (80%) and three months (93%) after treatment

Table 6. Descriptive characteristics and comparison of DVT recanalization using Doppler ultrasound in femoral and common popliteal and femoral veins in different intervals following treatment with heparin or enoxaparin

	Rate of recanalization												T	*P*
	After 2 weeks				After 1 month				After 3 months					
	0%	<50 %	>50 %	100%	0%	<50 %	>50 %	100%	0%	<50 %	>50 %	100%		
Pupliteal	32(76 .3%)	10(23 .7%)	0(0%)	0(0%)	14(33 .3%)	16(38 . %)	10(23 .7%)	2(5%)	2(5%)	16(38 %)	12(28 .5%)	12(28 .5%)	29	<0.001
Femoral	30(75 %)	6(15 %)	2 (5%)	2 (5%)	14(35 %)	9(22. 5%)	12(30 %)	5(12. 5%)	7 (17.5 %)	5(12. 5%)	12(30 %)	16(40 %)	23	<0.001
Common femoral	26(78 .8%)	5(15 %)	2(2.2 %)	0(0%)	9(27. 3%)	12 (36.4 %)	7(21. 3%)	5(15 %)	5(15 %)	5(15 %)	9(27. 3%)	14(42 .7%)	22	<0.001

Discussion

In the present prospective study on 50 traumatic patients with lower limb DVT visiting Imam Reza Hospital of Kermanshah in 2017, it was concluded that 20%, 70%, and 89% of thrombotic veins were recanalized two weeks, one month, and three months after the onset of treatment, respectively. Ezelsoy *et al*., (2015) reported consistent results, i.e., 84% recanalization six months after treatment in patients with DVT (25). Moreover, Sultanov *et al*., reported an 83% recanalization in patients with acute DVT six months after the onset of treatment, consistent with the present study (26). Lee *et al*., (2013) also reported consistent results; the level of recanalization (based on Duplex ultrasound) in patients with DVT was respectively 43% and 70% one week and three months after treatment with catheter-directed intra-thrombus thrombolysis with heparin. However, this was 15% and 38% three and six months after treatment in the group treated with anti-coagulants, respectively (23). In a study examining patients with DVT receiving standard treatment (heparin) and enoxaparin using Duplex ultrasound, results revealed that all patients showed recanalization three months after treatment, consistent with the present study. Nevertheless, no recanalization was observed in 20% of patients receiving standard

treatment, even after 12 months (27). In the study by Jia *et al*., the degree of recanalization was 100% and 70% in endovascular and aspiration treatment groups, respectively (28). Puskas *et al*., concluded that the degree of recanalization was 39%, 64%, 82%, and 90% one month, three months, six months, and 12 months after treatment (21). Consistent results were also reported by Guarnera *et al*.; they found that the level of slight recanalization (based on Duplex scan) was 31% and 60% after one week of treatment in tibial DVT and gastrocnemius DVT, respectively, and the level of complete recanalization after one month of treatment was respectively 52% and 60% in tibial DVT and gastrocnemius DVT. Moreover, the degree of complete recanalization was 56% in all patients (29). Lack of consistency in the degree of recanalization between our and some other studies can be due to the difference in the type of treatment. We used a combination of heparin or enoxaparin, followed by warfarin. However, Ezelsoy *et al*., used heparin followed by warfarin (25); Sultanov *et al*., used heparin followed by warfarin (26); and Lee *et al*., used two methods of catheter-directed intra-thrombus thrombolysis with heparin and anticoagulants (23). In the study by Vorobo Eva *et al*., patients in the two groups received standard treatment (heparin for 5 days) and enoxaparin (1 mg daily every 12 hours) for 30 days (23). In addition, Puskas *et al*., used tinzaparin followed by warfarin (21). The mean age of patients was 50.57 years in the present study. In other studies, the mean age of patients was higher or lower than our study (24,28,30). Furthermore, in our study, the degree of recanalization in clotted veins was 20%, 67%, and 90% two weeks, one month, and three months after the onset of treatment in those aged <45 years, respectively. Also, the degree of recanalization in clotted veins was 20%, 73%, and 90% two weeks, one month, and three months after the onset of treatment in those aged >45 years, respectively. Therefore, the degree of recanalization three months after treatment was the same in patients aged below and those aged above 45 years. Of course, this result was not examined by other studies and, therefore, could not be compared with the literature. In the present study, 48% of patients were male, and 52% were female. On the other hand, 67% of patients were male in the study by Strijkers *et al*., (24); 55% of patients were male in the study by Majdi Nassab *et al*., (30); and 54% of patients were female in the study by Jia *et al*., (28). In our study, the degree of recanalization in clotted veins was 20%, 56%, and 85% two weeks, one month, and three months after the onset of treatment in men. Moreover, the degree of recanalization in clotted veins was 20%, 80%, and 93% two weeks, one month, and three months after the onset of treatment in women. Thus, the degree of recanalization was higher in women than men three months after treatment, a result which was not examined in previous studies and, therefore, could not be compared with the literature. In the present study, DVT mostly occurred in popliteal (32.7%), femoral (30%), and common femoral (25%) veins, respectively. In the study by Lee *et al*., DVT had occurred in femoral veins in all patients (23); in the study by Guarnera, DVT was observed in gastrocnemius or tibial veins (29); and in the study by Jia *et al*., DVT occurred 45% in iliofemoral and 42% in popliteal veins (28). The degree of recanalization in clotted veins was 21%, 72%, and 85% two weeks, one month, and three months after the onset of treatment in terms of thrombosis site. Moreover, the degree of recanalization in clotted veins was 25%, 65%, and 82% two weeks, one month, and three months after the onset of treatment in femoral veins. Also, the degree of recanalization in clotted veins was 23%, 67%, and 95% two weeks, one month, and three months after the onset of treatment in popliteal veins. Thus, it can be concluded that the degree of recanalization was higher in popliteal than femoral and common femoral veins three months after treatment. This finding was not examined in previous studies and, thus, could not be compared with the literature.

Limitations

This study had a three-month follow-up. It is recommended that it be continued as a cohort study to judge the effect of heparin or enoxaparin on recanalization in patients with DVT in the long term. Also, previous studies did not examine recanalization in patients with DVT in terms of age, sex, and DVT site, thereby limiting the possibility of comparing our results with the literature.

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