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Comparison of the Effects of Injectable Enoxaparin With Oral Rivaroxaban in Deep Vein Thrombotic Prophylaxis in Patients With Femoral Peritrochanteric Fracture: A Randomized Clinical Trial

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Abstract

Objectives: The prevalence of deep vein thrombosis (DVT) following orthopedic major surgery, such as peritrochanteric femoral fracture, is high. Also, there is a lack of accurate information about the results of using rivaroxaban in Iran. This study aimed to compare the effects of injectable enoxaparin with oral rivaroxaban in DVT prophylaxis in patients with femoral peritrochanteric fracture.

Materials and Methods: This randomized single-blind clinical trial included 88 patients with femoral peritrochanteric fracture in Shohada Hospital of Tabriz, Iran from January 2019 to December 2019. The participants were randomly allocated into two equal groups (n=44 each) receiving enoxaparin (40 mg subcutaneously once daily for 28 days) and rivaroxaban (10 mg orally once daily for 28 days). Using independent t test in SPSS version 20, the results of clinical examinations and ultrasonography for the diagnosis of DVT at the end of intervention were compared between the two groups. A *P* value less than 0.05 was considered as statistically significant.

Results: No significant differences were observed in laboratory results and DVT-related symptoms between the two groups, as well as before and after the intervention (intragroup). Also, the prevalence of DVT at the end of the study was zero.

Conclusions: According to our results, there was no difference in the prevalence of DVT and short-term (one-month) complications between the two groups receiving rivaroxaban and enoxaparin after the peritrochanteric femur fracture.

Keywords: Rivaroxaban, Enoxaparin, Deep vein thrombosis, Peritrochanteric femur fracture

Introduction

Venous thrombosis may occur in more than 50% of patients undergoing orthopedic surgery, especially hip or knee surgery, and in 10%-40% of patients who have had abdominal or thoracic surgery (1-3). The most important consequences of this disorder are pulmonary embolism and chronic pulmonary insufficiency syndrome. Pulmonary embolism is the third most common cause of mortality in the world after heart attack and stroke (4,5).

Diagnosis is based on clinical examination and laboratory tests, including measurement of fibrin degradation products (D-dimer) and Doppler ultrasonography. The positive predictive value of intravenous ultrasound for deep vein thrombosis (DVT) of proximal veins reaches 95%. However, this value is only 75% in the leg because the veins in this area are more difficult to detect than in the proximal veins. DVT is diagnosed by ultrasound through observing a defect in deep vein filling (6-8).

In high-risk patients, preventive measures should be taken to prevent DVT. Such measures include the use of anticoagulants (aspirin, heparin, and low-molecular-weight heparin [LMWH]) and mechanical non-pharmacological agents, including compression stockings, intermittent pneumatic compression, and filters placed in the inferior vena cava. In addition to high-risk individuals, prophylactic measures to eliminate this complication in other patients are also on the caregivers' agenda due to the adverse effects of DVT (9-11).

Considering the high prevalence of femoral head and femoral peritrochanteric fractures, especially in the elderly, and long-term hospitalization of these patients, choosing the appropriate anticoagulant treatment method to prevent DVT and its subsequent complications is necessary (12-14). Meanwhile, the side effects of treatment with anticoagulants should also be considered. Currently, there is disagreement about the choice, effectiveness, and side effects of each treatment. The serious side effects can be prevented in post-thrombotic disease (PTD) patients by proper preventive strategies. Due to the high incidence of DVT in many patients treated with heparin, it is necessary to use newer anticoagulants that are both more effective in preventing DVT and less likely to cause complications such as subsequent bleeding (15, 16).

Recently, some new anticoagulants have emerged to prevent the side effects of heparin (thrombocytopenia). Enoxaparin (LMWH), rivaroxaban, and warfarin are

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Key Messages

- Deep vein thrombosis has a high prevalence after femoral peritrochanteric fracture.
- DVT prevention methods are very important after femoral peritrochanteric fracture.
- Enoxaparin and rivaroxaban were effective in preventing DVT, but rivaroxaban was more popular.

other anticoagulants, which may be used depending on the patient's condition and the physician's recommendation (17,18).

In recent years, enoxaparin has been used more than heparin. The benefits of this drug include lower risk of bleeding due to low immunogenicity, reduced risk of thrombocytopenia, higher bioavailability due to lower binding to plasma proteins, plasma, and endothelium, predictable anticoagulant effects, and ease of use. This drug is routinely used subcutaneously in Iran after orthopedic surgery (19-21). The use of rivaroxaban has also increased in orthopedic major surgery recently. Since using this drug does not require regular blood tests to detect bleeding complications, it is considered safe by physicians (22,23). Controversial data has been reported in several studies about the usefulness of each of these drugs, causing health care providers to face a dilemma (14,19,22,24-26).

It should also be noted that rivaroxaban is received well by the patients and it is easier to take rivaroxaban (oral) than enoxaparin (subcutaneous injection). Moreover, there is a lack of accurate information about the results of using rivaroxaban in Iran. Accordingly, the present study aimed to compare the effects of injectable enoxaparin with oral rivaroxaban in DVT prophylaxis in patients with femoral peritrochanteric fractures so as to find out which of the two drugs is more effective, has less side effects, and can prevent DVT more effectively.

Materials and Methods

Study Design

This randomized single-blind clinical trial included 88 patients with femoral peritrochanteric fracture in Shohada Hospital of Tabriz, Iran from January 2019 to December 2019. Given the number of hospital visits for peritrochanteric hip fractures, using the G*Power software, and considering the alpha and beta errors equal to 5% and 0.2, respectively, the sample size was calculated as 88 patients. Also, the difference of DVT prevalence in the two groups of enoxaparin and rivaroxaban was considered at 5% (25). Finally, considering the probability of 10% sample loss, the sample size was determined to be 88 individuals.

Inclusion and Exclusion Criteria

In this clinical trial, we included all patients with peritrochanteric femoral fracture who signed an informed consent prior to study. The exclusion criteria were as follows: renal failure, sensitivity to one of the prescribed drugs in the intervention, endocarditis, liver disease, uncontrolled blood pressure, blood diseases, history of thromboembolism in the past three months treated with anticoagulants, receiving corticosteroids five days before the surgery, hip replacement surgery during the last six months, and pregnancy.

Intervention

Patients entered the study by random sampling method. To do so, the patients took a piece of paper from a bag containing 100 pieces of black and white papers. All patients who took a white paper were included in the study. This procedure was performed similarly for all patients. Using https://www.random.org and Gaussian function, the participants were randomly assigned into two groups of enoxaparin and rivaroxaban.

The procedure was performed in such a way that patients received the intervention immediately after surgery. In the enoxaparin group, 28 ampoules of enoxaparin (40 mg) (27) purchased by the researcher were given to the participants. Injection of this drug in the first three days of hospitalization after surgery was instructed to patients' companions to inject the drug at home. Every day at a certain time, the researcher would remind the patient to inject the drug by phone so that the drug would be injected and make sure to inject it again during the call. For the rivaroxaban group, 28 rivaroxaban tablets (10 mg) were purchased by the researcher and given once daily immediately after surgery (28). The researcher also reminded the patients to take the medicine in a certain hour and in a second call he obtained the assurance of drug use. It should be noted that due to the use of these drugs, the anesthesiologist was informed of this protocol so that he would not use the epidural catheter implantation method for painless procedures. Thus, other painless procedures were performed during and after the surgery. Also, the surgical procedure was performed in the same way for all patients.

Follow-up

After surgery, all patients were examined daily (until discharge) by the relevant resident (member of the research team) and if symptoms of DVT (pain, swelling, weak pulse or absence of pulse in the ankle artery and cyanosis of the limb) were observed, additional diagnosis (D-dimer test and ultrasound scan) was performed. Blood tests, including complete blood counts, international normalized ratio (INR), partial thromboplastin time (PTT), prothrombin time (PT), and D-dimer were performed one day before the surgery and at the end of the study. All patients were followed up for four weeks after surgery. The resident also performed periodic examinations weekly, and, in the presence of DVT symptoms, diagnostic procedures such as ultrasound and laboratory tests were performed. DVT symptoms were

also taught to the patient to refer if symptoms occurred. For blood sampling, 5 ml of blood was taken from an arm vein by a skilled nurse and sent to a reputable laboratory for examination. The cost of the laboratory tests was borne by the researcher. Ultrasound was also performed by a radiologist (not a member of the research team) at the end of the fourth week. All ultrasounds were performed by the same radiologist and the costs were borne by the researcher.

The patients' data, including age, gender, body mass index (BMI), history of diabetes, controlled blood pressure, heart disease, chemotherapy and history of cancer, hospital stay, waiting time for laboratory test results, and ultrasound findings were recorded by the resident.

Data Analysis

The information was entered into the SPSS version 20. The statistical consultant was completely unaware of the type of grouping, as well as the type of intervention. Using an independent *t* test, percentage, mean, and standard deviation were used to compare the data. A *P* value less than 0.05 was considered as a significant level.

Results

Out of a total of 109 patients visited for peritrochanteric hip surgery, 21 patients were excluded due to renal failure (n=3), liver disease(n=6), uncontrolled blood pressure(n=11) and history of thromboembolism (n=1). The mean age of participants was 68.12 ± 4.19 years, most of whom were male (56). Moreover, the BMI of all the participants was in the obese range. There were no significant differences between the two groups in terms of the history of the disease, demographic characteristics, and blood indicators (Table 1).

Postoperative examinations showed that all patients had been hospitalized for three days after surgery and none of them required hospitalization in the intensive care unit (ICU). Also, the length of the surgery, amount of bleeding, hemoglobin concentration, and hematocrit did not indicate a statistically significant difference between the two groups (Table 2).

According to the examinations performed by the

Table 1. Comparison of Demographic Information, Pathological Results, and Blood Tests Before the Intervention

Variables	Rivaroxaban Group (n=44)	Enoxaparin Group (n=44)	*P* Value
Age (y)	68.79 ± 4.19	67.45 ± 4.49	0.269[a]
Male, No. (%)	29 (65.90)	27 (61.36)	0.113[b]
Height (cm)	168.44 ± 10.41	172.25 ± 11.03	0.254[a]
Weight (kg)	81.15 ± 7.29	83.16 ± 7.41	0.118[a]
BMI (kg/m^2)	28.35 ± 3.03	28.98 ± 3.12	0.201[a]
Co-morbidities			
Hypertension, No. (%)	5 (11.36%)	7 (15.90%)	0.303[b]
Diabetes, No. (%)	9 (20.45%)	8 (18.18%)	0.119[b]
COPD, No. (%)	4 (09.09%)	6 (13.63%)	0.209[b]
Aspirin, No. (%)	10 (22.72%)	12 (27.27%)	0.189[b]
ASA grade	1.6 ± 0.40	1.7 ± 0.35	0.503[a]
Pre-HB	14.81 ± 1.31	13.49 ± 1.91	0.203[a]
Pre-Hct	4.1 ± 0.10	4.01 ± 0.15	0.098[a]
Pre-PLT	193.52 ± 40.25	188.25 ± 36.12	0.107[a]
Pre-APPT	26.12 ± 2.11	25.88 ± 2.40	0.409[a]
Pre-PT	10.91 ± 1.45	11.15 ± 1.31	0.259[a]
Pre-INR	1.05 ± 0.09	1.03 ± 0.10	0.112[a]
Pre-D-dimer	1.01 ± 0.03	1.03 ± 0.06	0.118[a]

BMI: body mass index; COPD: Chronic obstructive pulmonary disease; Pre-Hb: preoperative hemoglobin; Pre-Hct: preoperative hematocrit; Pre-PLT: preoperative platelet; Pre-APTT: preoperative activated partial thromboplastin time; Pre-PT: preoperative prothrombin time.
[a] T test, [b] Chi-square.

Table 2. Comparison of Bleeding Determinants Between Two Study Groups

Variables	Rivaroxaban Group (n=44)	Enoxaparin Group (n=44)	*P* Value[a]
Post-HB	12.25 ± 1.40	11.95 ± 1.25	0.115
Post-Hct	3.95 ± 0.15	3.87 ± 0.10	0.110
Post-PLT	180.25 ± 38.83	172.23 ± 35.15	0.203
Post-APPT	25.50 ± 2.19	25.00 ± 2.36	0.389
Post-PT	10.11 ± 1.12	10.93 ± 1.15	0.116
Post-INR	1.06 ± 0.05	1.04 ± 0.12	0.159
Duration of operation (min)	96.19 ± 20.36	100.12 ± 21.13	0.119

Post-Hb: Postoperative hemoglobin; Post-Hct: Postoperative hematocrit; Post-LT: Postoperative platelet; Post –APTT: Postoperative activated partial thromboplastin time; Post–PT: Postoperative prothrombin time.
[a] T test.

resident, five people in the rivaroxaban group and three people in the enoxaparin group had DVT symptoms. Due to the symptoms of DVT, diagnostic tests were performed on these individuals, and the laboratory results indicated that DVT was absent. To ensure this issue, the patients were examined by a vascular specialist using an ultrasound device (Table 3).

Finally, after the intervention, laboratory tests confirming DVT and examinations indicated no significant differences between the two groups ($P>0.05$). Also, the results of in-group studies showed no significant differences in laboratory tests before and after the intervention (Table 4).

Discussion

This study aimed to compare the effects of injectable enoxaparin with oral rivaroxaban in the prevention of DVT in patients with femoral peritrochanteric fracture. The results indicated no significant differences between the two groups in laboratory and hematology results before the study. This suggests that random allocation successfully minimized the differences between the two groups. After the intervention and the hospitalization of the patients, we observed the symptoms of DVT. However, the laboratory results and ultrasound findings showed that none of these patients had DVT. Perhaps this can be explained by the fact that the resident, who was himself a member of the research team, may have been very sensitive in examining, such that the results of the study would go in the direction he expected.

Since enoxaparin and rivaroxaban were first assessed for peritrochanteric femoral fractures, no similar studies were found in the literature. Thus, we had to compare the

Table 3. Comparison of Symptoms of DVT Between Two Study Groups

Variables	Rivaroxaban Group (n=5)	Enoxaparin Group (n=3)	*P* Value
Pain, No. (%)	3 (60%)	2 (66.66%)	0.251[a]
Weak pulse, No. (%)	1 (20%)	0 (0%)	0.500[a]
Swell, No. (%)	2 (40%)	1 (33.33%)	0.115[a]
Coldness, No. (%)	2 (40%)	2(66.66%)	0.389[a]
Post-PT	9.88±1.10	10.01±1.20	0.202[b]
Post-APPT	24.82±2.21	25.10±2.15	0.302[b]
Post-INR	1.05±0.04	1.04±0.05	0.311[b]
D-dimer	97.25±20.18	99.15±21.40	0.2011[b]
Positive ultrasound results	0	0	0.999[a]

Post-Hb: Postoperative hemoglobin; Post-Hct: Postoperative hematocrit; Post-LT: Postoperative platelet; Post–APTT: Postoperative activated partial thromboplastin time; Post–PT: Postoperative prothrombin time.
[a] Chi-square, [b] T test.

Table 4. Comparison of Laboratory Tests Confirming DVT Between the Two Study Groups

Variables		Rivaroxaban Group (n=44)	Enoxaparin Group (n=44)	*P* Value[a]
HB	Pre	14.81±1.31	13.49±1.91	0.203
	Post	13.13±1.45	13.11±1.02	0.113
	P value	0.306	0.501	-
Hct	Pre	4.1±0.10	4.01±0.15	0.098
	Post	3.99±0.18	3.96±0.12	0.145
	P value	0.403	0.419	-
PLT	Pre	193.52±40.25	188.25±36.12	0.107
	Post	188.63±39.30	185.39±35.45	0.290
	P value	0.118	0.403	-
APPT	Pre	26.12±2.11	25.88±2.40	0.409
	Post	25.69±2.59	25.12±2.85	0.423
	P value	0.389	0.407	-
PT	Pre	10.91±1.45	11.15±1.31	0.259
	Post	10.51±1.40	10.99±1.45	0.223
	P value	0.369	0.407	-
INR	Pre	1.05±0.09	1.03±0.10	0.112
	Post	1.03±0.03	1.01±0.10	0.456
	P value	0.400	0.411	-
D-Dimer	Pre	1.01±0.03	1.03±0.06	0.118
	Post	0.98±0.02	1.00±0.01	0.403
	P value	0.315	0.298	-
Positive DVT result		0	0	0.999

BMI: body mass index; COPD: Chronic obstructive pulmonary disease; Pre-Hb: preoperative hemoglobin; Pre-Hct: preoperative hematocrit; Pre-PLT: preoperative platelet; Pre-APTT: preoperative activated partial thromboplastin time; Pre-PT: preoperative prothrombin time.
[a] T test.

results with other orthopedic surgeries. The results of our study are consistent with the results of a study by Xie et al (27), that reported no statistical difference between the two groups in terms of the prevalence of DVT. In their study, unlike the present study, they compared the effects of rivaroxaban and enoxaparin in knee replacement. They concluded that the side effects of rivaroxaban were greater than those of enoxaparin.

Contrary to our study, in a meta-analysis in 2018 to compare the effect of rivaroxaban and enoxaparin in the prevention of DVT (28), the researchers stated that rivaroxaban was a safer drug than enoxaparin, and postoperative mortality and complications were less likely to occur after taking rivaroxaban. Since our study was conducted in a short period of time (within one month) and we did not perform a long-term follow-up, it is not possible to say exactly whether our results are consistent with the results of this meta-analysis or not.

In our study, we observed signs of thrombosis after surgery on examination, and there were no significant differences between the two groups. This is consistent with the results of a study by Bagherifard et al (29). In their study, they divided patients into low-, medium-, and high-risk groups and evaluated the effects of the intervention in each group. However, in our study, we simply included low-risk patients in the study and observed similar results.

Femoral peritrochanteric fracture is one of the major surgeries in orthopedics, which is more common in older people who are more prone to cardiovascular disease, atherosclerosis, and other diseases than younger people. Therefore, these factors can affect the risk of DVT at different ages. However, in our study, the incidence of this complication and the occurrence of DVT symptoms in the short term did not differ between the two groups. Nonetheless, some of the limitations that could disrupt the study results include the following: not assessing the amount of bleeding and hematoma during and after surgery, short duration of follow-up, and the lack of long-term follow-up of complications.

Limitations

The short duration of the study and the lack of long-term study of the complications are the limitations of the present study, which can overshadow the results of the use of this study.

Suggestions for Future Studies

Further studies with long-term follow-up are suggested. It is also recommended to design studies with larger sample sizes and enroll patients with medium and high risks.

Conclusions

According to our results, since the prevalence of DVT in our study was zero for enoxaparin and rivaroxaban, both drugs had similar effects. However, rivaroxaban seems to be more popular among patients.

Authors' Contribution

MB: Study design, intervention, follow-up, article writing, MH: Study design, follow-up, article submission.

Conflict of Interests

Authors have no conflict of interest.

Ethical Issues

The research project was approved by the Ethics Committee of Tabriz University of Medical Sciences (code: IR.TBZMED.REC.1398.969). Also, the patients paid no charges for the tests and their participation was completely voluntary.

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