The Impact of Cold Therapy on the Pain and Hematoma on the site of Injection of Enoxaparin

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ABSTRACT

Background: Heparin and low molecular weight heparin (LMWH) are anticoagulant medication. Subcutaneous heparin preparation might cause side effects such as pain, hematoma, bruising, thrombocytopenia, hematuria, and melena. All these problems will disturb the patient and rejecting the medication. Aim: to examine the impact of cold therapy on the pain and haematoma on the site of injection of Enoxaparin. Design: A quantitative experimental design was used in this research. Setting: The study was conducted in a University hospital in Saudi Arabia. The patients were randomly selected from Surgical Unit, Coronary Care Unit and Intensive Care Unit. Material and Method: The total number of participants randomly selected was 30 patients and they were divided into two groups, experimental and control groups with 15 participants in each group. The control group received the ordinary routine care for subcutaneous injection of Enoxaparin. On the other hand, the experimental group received a cryotherapy treatment before and after administration of Enoxaparin subcutaneously for 5 minutes, and the pain was measured immediately, but the hematoma was measured after 48 to 72 hours. Results: Mean (±SD) pain score in patients with cold therapy was 0.2 ±0.4 while without cold therapy was 2.2 ± 0.41. Mean pain was significantly high in cases of without cold therapy (p < 0.0001). Regarding presence of hematoma, there was significant association with cold therapy and presence of hematoma (p < 0.0001). Conclusion: It can be conclude from this study that the cold application can reduce the pain intensity and occurrence of hematoma in patient who receives Enoxaparin injection.

Keyword: - Anticoagulant, Enoxaparin, Heparin, Pain, Hematoma, Cold Therapy.

1. Introduction

Heparin and low molecular weight heparin (LMWH) are anticoagulant medication, and they are both used as a rapid prophylactic. Heparin preparation are widely used for patients with venous thrombosis, acute myocardial infraction, unstable angina, patient with open heart surgery, and cardiac angiogram by giving them as intravenous (1). For continuous prophylactic both Heparin and LMWH can be administered subcutaneously. Heparin is used only in the hospital, and it needs laboratory monitoring (2). Also, can be used as preventing measure for deep venous thrombosis (3).
On the other hand, subcutaneous heparin preparation might cause side effects such as pain, hematoma, bruising, thrombocytopenia, hematuria, and melena (4). All these problems will disturb the patient and rejecting the medication. LMWH can cause the same effect at the injection site subcutaneously, but it occurs less than heparin injection (2). The occurrence of hematoma, bruising, and pain are depending on many factors.

First of all, a skilled nurse who is injected the anticoagulant to the patient subcutaneously whether in abdomen or in the thigh. There was a study conducted (5), found out that a technique of 15 seconds injection period and 5 seconds waiting before withdraw the needle of heparin is recommended to decrease the liability occurrence of bruising, hematoma, and pain on the injection site. Moreover, there were a study found out that administration of anticoagulant in the abdomen has less pain than in the thigh (6-7).

Secondly, using large needle, doing aspiration before the drug administered, and massaging the injection site after drug administered will affect the injection site in occurrence of unwanted side effects. Furthermore, there are suggested method to lower the incidence of hematoma, and pain which injected the air bubbles in (Enoxaparin) LMWH (8).

In addition to all these suggested methods to decreases the occurrence of hematoma, and pain, It was an argument regarding using the cryotherapy at the injection site of Enoxaparin (LMWH) to lower the intensity of the pain, and the size of hematoma (10). A cryotherapy is a non pharmacological, inexpensive treatment for many things such as pain, swelling, hematoma, bruising, traumatic injury, and athletics trauma. With cryotherapy, the vessels will be contracted, the blood flow decreased, the inflammatory process reduced, and metabolism of the tissue decreased. All these effects influence the intensity of the pain, and the size of hematoma (9-11).

Two studies were done to evaluate the effect of cold application on the pain and hematoma experience by patient who received anticoagulant injection subcutaneously. The research in this area is limited, and this is a concern for the patients who experience all these side effects from the anticoagulant drugs, and the nurse who is responsible to provide an optimal care to the patients (12-10).

1.1 Aim of the study
The aim of this study was to examine the impact of cold therapy on the pain and hematoma on the site of injection of Enoxaparin.

1.2 Research Hypothesis
The researcher hypothesized that the application of cryotherapy at the injection site of Enoxaparin may reduce the pain intensity at the injection site of Enoxaparin with cryotherapy and the size of hematoma after applying cryotherapy in the injection site of Enoxaparin.

We hypothesize that patients undergoing exercise during hemodialysis will experience improvement in dialysis efficacy.

1.3 Material and Methods
Quantitative experimental design was used in this study. The study was conducted in a teaching hospital in Saudi Arabia. The setting included Surgical Unit, Coronary Care Unit, and Intensive Care Unit. Data collection was done from February to March 2015. The total number of participants who were randomly selected was 30 patients and they were divided into the study group and control group with 15 participants in each group. Patients who were 18 years old or more, who were oriented and able to evaluate the pain intensity and with Enoxaparin subcutaneously injected were included in the study. The exclusion criteria included the following: patients with heparine injection without any anticoagulant treatment and had no coagulopathy, those patients with partial thromboplastin time (PTT) more than 90 second, patients with communication problems, mental or psychiatric disorders, and those who suffered from any abdominal or thigh problems.

One tool was used in this study. The data collection form was divided into four sections. In the first part, data was collected related to the demographic data and information that affect the occurrence of bruising, hematoma, and pain on the patient such as the age, sex, diagnosis, medication, and the treatment duration. In the second part, data was collected at the beginning and end of Enoxaprine treatment which is related to blood test related to platelet value and activated partial thromboplastin time (APTT) of the patient. In the third part, the rotation table was prepared in order to mark the injection sites. In this table, there were sections for the number of
the order of the injection, their location, duration after each injection, and hematoma measurement values at 48 to 72 hours which were recorded on millimitric graph paper. In the fourth part, pain measurement was used with the verbal Descriptor Scale (13) to assess the pain intensity. Immediately after receiving Enoxaprine injection, the patient was asked to rate the intensity of pain at the time of injection (beginning), and at the end period of their pain by using the analogue scale. In order to determine the pain duration, the period was measured with a stopwatch.

Ethical permission was obtained from the research ethical committee of the university. A permission to conduct the study was obtained from the director of the setting. Patient/ or patient’s family permission was obtained to share in this study. Reliability and validity are the two key concepts which examine the strength of a study tool (14). If the questionnaire is not well designed and structured the response from participants may not accurately reflect the reality (15). To assess the quality and adequacy of the tools the researcher applied content validity and construct validity tests. A pilot study was carried out on five patients in order to assess the clarity and the applicability of the tools.

Standard subcutaneous injection technique was applied. The medication injected in the lower abdominal wall, and thigh, the use of 1.25 cm length needle, the insertion of the needle into the tissue at a 90 degree angle, grasping the tissue of injection and loosening it while the drug is injected without aspirating applying a light pressure at the injection site after the injection and not massaging the site. The control group received the ordinary routine care for subcutaneous injection of Enoxaparin, while the study group received a cryotherapy treatment before and after administration of Enoxaparin subcutaneously for 5 minutes, and the pain was measured immediately, but the hematoma was measured after 48 to 72 hours. 10 x10 cm Cold Packs applied to the study group for 5 min before the injection, and 5 min after the injection.

Data Analysis
The researcher entered the data into the computer using Statistical Package for Social Sciences (SPSS. Version 20). Data were analyzed using descriptive statistics, which included frequency, percentage, mean, and standard deviation.

2. Results
A total of 30 patients were included in this study.

Table-1 Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Number of Cases</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (Years)</strong></td>
<td><strong>Mean ±SD</strong></td>
<td>47.5 ±20.7</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td><strong>Mean ±SD</strong></td>
<td>6.6 ±2.1</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>29</td>
<td>96.7%</td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>3.3%</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RTA</td>
<td>6</td>
<td>20.0%</td>
</tr>
<tr>
<td>Fractures</td>
<td>5</td>
<td>16.7%</td>
</tr>
<tr>
<td>ACS</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Postoperative</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Others</td>
<td>11</td>
<td>36.7%</td>
</tr>
</tbody>
</table>
Baseline characteristics are mentioned in Table-1. Mean (±SD) of age was 47.5 ±20.7 years. Gender distribution showed male predominance, out of 30 cases, 29 (96.7%) were male and only 1 (3.3%) were female. Six (20%) cases presented with Road Traffic Accident (RTA) while 5 (16.7%) cases had fracture at different sites, 2 (6.7%) cases presented with acute coronary syndrome (ACS) 2 (6.7%) cases presented with Non-ST-Segment elevation myocardial infarction (NSTEMI) and 2 (6.7%) cases had post-surgery pain. Out of 30 cases, 23 (76.7%) patients had been injected at right thigh and 6 (20%) at left thigh while 1 (3.3%) patient had injection in the abdomen. Mean (±SD) prothrombin time (PT), a partial thromboplastin time (APTT) and hemoglobin was 12.8 ±1.3 sec, 28.1 ±2.5 sec and 12 ±2.5 g/dl respectively.

**Table-2:** Comparison Of Mean Pain Scores Between Two Group

<table>
<thead>
<tr>
<th>Groups</th>
<th>Number</th>
<th>Pain Scale* Mean ±SD</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Cold Therapy</td>
<td>15</td>
<td>0.2 ±0.4</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Without Cold Therapy</td>
<td>15</td>
<td>2.2 ± 0.41</td>
<td></td>
</tr>
</tbody>
</table>

Table-2 illustrated comparison between the two groups. Pain was measured on scale 0 (No Pain), 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (Severe Pain). Mean (±SD) pain score in patients with cold therapy was 0.2 ±0.4 while without cold therapy was 2.2 ± 0.41. Mean pain was significantly high in cases without cold therapy (p < 0.0001).

**Table-3:** Comparison Of Mean Pain Scores Between Injection Sites

<table>
<thead>
<tr>
<th>Injection Site</th>
<th>Number</th>
<th>Pain Scale* Mean ±SD</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Thigh</td>
<td>23</td>
<td>1.17 ±1.2</td>
<td>0.77</td>
</tr>
</tbody>
</table>
Comparison of mean pain scores between injection sites is shown in Table 3. Mean (±SD) pain score in Right Thigh Injection Site was 0.2 ±0.4 while Mean (±SD) pain score in Left Thigh Injection Site was 1.17 ±1 and Mean (±SD) pain score in Abdomen Injection Site was 2 ±0.0. The difference of mean pain score was statistically insignificant between injection sites (p-value = 0.77).

Table 4: Association Between Cold Therapy (With & Without) And Hematoma Comparison Of Mean Pain Scores Between Injection Sites

<table>
<thead>
<tr>
<th>Injection Site</th>
<th>With Cold Therapy</th>
<th>Without Cold Therapy</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>0</td>
<td>15 (100%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>No Hematoma</td>
<td>15 (100%)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Association between cold therapy and presence of hematoma is presented in table 4. Hundred percentage of patients had hematoma in patients group without cold therapy while 100% of patients had no presence of hematoma of patients group with cold therapy. There was significant association with cold therapy and presence of hematoma (p < 0.0001).

3. Discussion

Subcutaneous heparin preparation might cause side effects such as pain, hematoma, bruising, thrombocytopenia, hematuria, and melena(16). All these problems will disturb the patient and reject the medication. Low molecular weight of heparin can cause the same effect at the injection site subcutaneously, but it occurs less than heparin injection. The occurrence of hematomas, bruising, and pain are depending on many factors. First of all, a skilled nurse has injected the anticoagulant to the patient subcutaneously whether in abdomen or in the thigh. There was a study that (17), found out a technique of 15 seconds injection period and 5 seconds waiting before withdrawing the needle of heparin was recommended to decrease the liability occurrence of bruising, hematomas, and pain on the injection site. Secondly, using large needle, doing aspiration before the drug administered, and massaging the injection site after drug administered will affect the injection site in occurrence of unwanted side effects. In addition to all these suggested methods to decreases the occurrence of hematomas, and pain, It was an argument regarding using the cryotherapy at the injection site of Enoxaparin (LMWH) to lower the intensity of the pain, and the size of hematomas. Thus the purpose of this study was to ascertain whether the application of cold therapy would be allowed by significant decrease in pain intensity and hematoma size in patient receiving Enoxaparin (LMWHs). The fact that the pain intensity decreased in the study group, and the hematoma size was from 0 to 1 millimetre; on the other hand, the control group was experienced the pain level which was from 2 to 3 score, and the hematoma size was increased with long using of anticoagulant medication.
As regard to demographic data, baseline characteristics revealed that the gender distribution showed male predominance, out of 30 cases, 29 (96.7%) were male and only 1 (3.3%) was female. A research was done regarding the pain level in deferent gender, and they found out that the female had higher pain intensity, frustration, and fear compared to male. Gender differences in pain perception, and the use of analgesia remain tentative; and the age might be confounding factor (18). The present study revealed that there was no significant correlation between gender and pain before and after applying cold therapy in the injection site of Enoxaparin. As regard to injection site, out of 30 cases, 23 patients had been injected at right thigh 6 at left thigh while one patient had injection in the abdomen. Most of the patients in the hospital were injected in the left or right deltoid of the arm which was painful for them as well as hematoma size was 2 to 3 or 3 to 4 millimetre. There was an evidence that LMWHs must be injected in the thighs or in the abdomen which is two inch away from umbilicus to avoid umbilicus vein injury. The present study presented that injected LMWHs in the thighs or abdomen are safer and less pain and hematoma size.

As regard to laboratory investigation, in this study, some patient did not have any lab investigation for Enoxaprin monitoring, and some patients did have the lab result as a routine due to long term admission. According to a study that was done by Thomas Stief (19), up to now there has been no clinical routine investigation that monitors their efficiency on the generation of plasmatic thrombin; however, LMWH have enormous clinical importance. The activated partial thromboplastin time (APTT) is the routine test to measure the anticoagulant efficiency of un fractionated heparin (UFH) only. As regard to pain score, the study relieved the pain was higher with patients who did not receive the cold therapy. It was statically significant without cold therapy. According to result, it can be said that especially the cold therapy before the injection has both an analgesic effect and is effective in decreasing the pain perception in the study group. Pain was measured by analogue, and numerical scale according to evidence (20). A study done in 2001 by Nevin Kuzu showed that pre and post injection cold therapy is effective in decreasing the pain during the procedure which was statistically significant (21).

As regard to comparison of mean pain scores between injection sites, it was statistically insignificant. There was no relationship between the pain intensity and the injection sites that was used in this study which were the right and left thigh, and the abdomen. However, it was observed that some patients in the hospital received injection in the deltoid of the arm. They reported the pain in the arm is higher than thighs or abdomen. Pain can cause physical and mental discomfort, and the needle shape and size are factors that can increase pain intensity with anticoagulant injection. Furthermore, pain can lead to increasing the patient anxiety, reducing the confidence to the staff nurses, and will lead to refusal of the medication. As regard to the association between the cold therapy and hematoma, it was statistically significant that cold therapy will decrease the hematoma size. The patients in the study group was monitored for 72 hours (3 hours) to measure the hematoma size with cold therapy applied before and after the injection of Enoxaprin. The size of hematoma was 0 to 1 with study group while with control group who did not receive the cold therapy the size was larger which range from 2 to 3, and 3 to 4 millimeters. Some patients were given Enoxaprin in deltoid of the arm before entering this study, and was found that the hematoma size was larger than in the thighs or abdomen which ranged from 4 to 5 millimeters. According to the opinion of the patients that were included in this study, the nurses skills were different. The injection technique, the duration, and the site of the injection are factors that affected their response. A study done by Nevin Kuzu in 2001 (21), showed there were various factors that affected hematoma size, pain, and occurrence of bruising in the injection site of Enoxaprin. Nursing skills, using large needle, wrong site of injection, aspiration before injecting the drug, and expel the air before injecting Enoxaparin affect the occurrence of bruising and hematoma in the injection site. In contrast to this study, many studies were done regarding LMWHs injection and hematoma, and they found out that the first group who applied the injection technique without ice bag can prevent or decrease the incidence of hematoma. Moreover, the other groups with ice bag at the injection site can prevent hematoma. The fact was that there was no difference between the groups with cold bag or the injection technique that could prevent hematoma (20-21-19). As a result of these studies that there was no statistical differences among groups when occurring of bruising or hematoma after LMWHs injection at the site, and it appeared that ice bag was not effective. However, when result of these studies was compared with others studies in the same area, they found out that the bruising and hematoma size smaller than without ice bag. This specially support this study in using ice therapy as an effective way to decrease or prevent the incidence of bruising and hematoma at the injection site of enoxaprin.

4. Conclusion:

It can be concluded from this study that the cold application can reduce the pain intensity and occurrence of hematoma in patient who receives Enoxaprin injection. Cold therapy is one of non-pharmacologic intervention that can be used to reduce the pain intensity which is inexpensive, simple, and easy. Nurses play an important role in deciding which non pharmacologic intervention is suitable for the patient.
5. **Recommendations:**

Based on the result of this study, it can be recommended the pain intensity and occurrence of hematoma could be reduced by:

1. Explaining to the patient about Enoxaprin medication including indications sites of injection, side effects, and complication in order to reduce the anxiety which lead to decrease the pain intensity.
2. Provide the patient an appropriate information regarding the cold therapy, and how it will reduce the pain intensity and the hematoma size.
3. The cold therapy should be covered with gauze in order to prevent skin injury, and apply it before and after Enoxaprin at the injection site for 5 minutes.

6. **ACKNOWLEDGEMENT**

In the name of Allah, most merciful.

The price and the glory to Allah the almighty who alone made this project to be accomplished.

I feel honoured and privileged to glorify his name in the sincerest way through this accomplishment and ask him to accept my effort peace be upon the prophet. I would first like to thank my project advisors Prof. Fatma Mokable and Dr. Yasser Al-Ghuneimy at University of Dammam. Their door office was always open whenever I ran into a trouble spot or had a question about my research or writing. They were consistently allowed this paper to be my own work, but steered me in the right the direction whenever they thought I needed it. I would also like to thank the expert who were helped me in the data analysis Mrs. Muhammed zeeshan ayub. Acknowledgement is due to King Fahad University Hospital; Hospital Directors, Nursing office Directors, Cardiac Care unite, Surgical, Medical, and orthopaedic wards for supporting my project, and extending facilities. Finally, I must express my very profound gratitude to my parents, to my husband, and my brothers, and my friends for providing me with unfailing support and continuous encouragement throughout my years of study and through the process of researching and writing this thesis. This accomplishment would not have been possible without them.

6. **REFERENCES**


