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"A quasi-experimental study to assess the effect of cold application on pain and bruise associated with subcutaneous injection of low molecular weight heparin among ICU patients at selected hospitals, Navi Mumbai"

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ABSTRACT

LMWH has been a promising drug because of its predictable anticoagulant response in the treatment and prophylaxis of thromboembolic phenomena. Among its local complication, the reported incidence rates of bruises is 26.6% to 88.9% and pain is 93.7-98.7%. Nurses limit the areas that can be injected by avoiding repeated injections in the bruised area. The primary goal of the study was to determine how cold application affected ICU patients pain and bruises caused by subcutaneous injection of low molecular weight heparinat specific hospitals' in Navi Mumbai. A quasi-experimental post-test-only design with Non Probability sampling technique was used to select 50 samples with split body image. Cold application utilizing frozen gel packs was used for 3 minutes before and 5 minutes after the subcutaneous injection of LMWH. The pain was assessed using numerical pain rating scale and the bruise was assessed by using bruise assessment scale. The respondents of the experimental side had a mean pain score of 2.80±0.81. The respondents of the control side had a mean pain score of 4.62±0.85. The results of the Wilcoxon test showed that the pain intensity of the experimental side was significantly lower compared to the control side($P < 0.05$)at 48 and 72 hours; the respondents of the experimental side had a mean bruise score of 0.20±0.61 and the respondents of control side had a mean bruise score of 1.56±0.84. Friedman's test shows that at 78.00 and 10.00 in the control and the experimental side, the level of significance at 5% level is 0.000 and 0.007 respectively. In clinical practice, a cold application utilizing frozen gel packs for 3 minutes before and 5 minutes after the injection of LMWH is effective.

KEYWORDS- LMWH, Pain, Bruise, Numerical pain assessment scale, and bruise assessment scale.

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INTRODUCTION

Patients with acute or ongoing health issues employ a range of techniques to regain or preserve their health. Medication, a substance used in the diagnosis, treatment, cure, alleviation, or prevention of health issues, is one of these tactics. Nurses are crucial to the proper preparation, administration, and assessment of pharmaceutical effects whether patients receive their medical treatment in clinics, hospitals, or at home. In all settings, nurses are in charge of determining how medications affect patients' long-term health status, educating patients about their medications and side effects, ensuring that the medication schedule is followed, and determining whether the patient or a family member is able to self-administer medications.(1)

A sound knowledge base is required for safe medication administration. Nurses need to be prepared to administer medications using a variety of routes. (1) Nurses give parental medication through intradermal and subcutaneous routes because these medications are absorbed more quickly than oral routes. Low molecular weight heparin (LMWH) is one of the types of heparins that is administered subcutaneously. (3)

Due to its high bioavailability in the body, long half-life, and more predictable anticoagulant response, LMWH has been a promising drug used in the treatment of venous thrombo-emboli, coronary artery disease, and neurologically compromised patients. It has also become a drug of choice in a wide range of clinical settings. (3)

Precisely, all thromboembolic phenomena such as acute coronary syndromes, deep vein thrombosis, its prevention, pulmonary embolism, etc. have been approved for it. primary venous thromboembolism prevention, pregnancy-related prosthetic valve thrombosis treatment pregnancy-related VT treatment, Antiphospholipid antibody syndrome, periprocedural anticoagulation,cerebral thromboembolism, prophylaxis against arterial thromboembolism, and percutaneous coronary intervention.(9)

100 units of anti-X an activity are equated to 1 mg of enoxaparin. The typical dosage is 1 mg/kg every 12 hours. The dosage, however, may vary according on the clinical circumstances. For instance, if the patient is under 75 years old, 1 milligram/kg every 12 hours is recommended for acute coronary syndrome. However, if the patient is 75 years of age or above, the dose is 0.75 milligrams/kg every 12 hours. (4)

LMWH can help simplify the treatment and/or prevention of thromboembolic episodes since it is administered subcutaneously and often does not require extensive lab monitoring; however, subcutaneous administration of LMWH is often found to be associated with pain, bruising, and hematoma at the injection site by interfering with the body’s clotting mechanism. (4)

The extravasation of blood into the subcutaneous tissue as a result of trauma to the underlying blood vessels or the fragility of blood vessel walls results in bruising, which is a discoloration of the skin. There are two distinct phenomena that contribute to both the occurrence of pain and its intensification. The needle is first placed into the skin, which stimulates and damages neurons and causes pain. However, the drug's sulphate bonds amplify its acidic qualities, increasing the sensation of discomfort at the injection site.(5)

After subcutaneous LMWH injections, a number of variables can affect whether bruising, hematomas, and discomfort develop at the injection site.[17] Researchers have looked into the injection site [13], injection time [14], injection volume [15], and needle size.[16]

These treatment-related bruises and hematomas not only represent physical trauma but also alter bodily awareness, which makes it challenging to select an injection site in the future. Additionally, using the scarred location for later injections hurts and impairs a drug's ability to be absorbed. [4]

After receiving a subcutaneous injection of LMWH, bruise occurrence rates have been observed to range from 26.6 to 88.9 percent. [7]

In addition, it is important to avoid administering injections to the wounded area repeatedly to limit the injectable areas. [7]

Nurses must be able to recognise high-risk patients due to the prevalence of bruising at the injection site for enoxaparin.

In order to increase patients' happiness with the level of nursing care they receive, build their faith in healthcare professionals, and motivate them to comply with treatment, nurses should utilise techniques and approaches that reduce the likelihood of the above-mentioned bad outcomes.

Following the study of the literature, the researcher concludes that there is a high incidence of pain and bruise associated with subcutaneous injection of LMWH; there are various factors that can influence the causation of pain and bruises. Safe and proper medication administration and injection procedures are critical for nurses to avoid the side effects of LMWH. The researcher after reviewing the available literature decided to select cold applications utilizing frozen gel packs for 3 minutes prior to and 5 minutes after the injection of LMWH. The researcher aims to use a less costly intervention.

STATEMENT OF THE PROBLEM

"A quasi-experimental study to assess the effect of cold application on pain and bruise associated with subcutaneous injection of low molecular weight heparin among ICU patients at selected hospitals, Navi Mumbai"

OBJECTIVES OF THE PROBLEM

- To evaluate the intensity of pain among patients during subcutaneous injection of LMWH in control and experimental group
- To evaluate the size of the bruise after subcutaneous injection of LMWH in the control and experimental group.

HYPOTHESIS

- H_1: There will be a significant difference in the intensity of pain experienced by ICU patients at the subcutaneous injection site of LMWH in the experimental and control sides.
- H_2: There will be a significant difference in the development of the size of bruises by ICU patients at the subcutaneous injection site of LMWH in the experimental and control sides.

RESEARCH APPROACH

The research approach selected for the study is a quantitative approach as it will collect and analyse the numerical data using statistics and provide the results which will be depicted in the form of graphs and tables.

RESEARCH DESIGN

A Quasi-experimental design is used to achieve the causal impact of cold

application on pain and bruise associated with subcutaneous injection of LMWH.

VARIABLES OF THE STUDY

- Independent variable- Cold application
- Dependent variables – Pain and bruise

SETTING OF THE STUDY

- **Setting I:** D.Y. Patil Hospital Nerul, Navi Mumbai is a multispecialty and charitable hospital in Navi Mumbai

- **Setting II**: Terna Speciality Hospital & Research Centre is a 250 bedded multi-speciality tertiary care hospital in Navi Mumbai.

POPULATION

All respondents admitted in the ICU who were prescribed LMWH.

TARGET POPULATION

The target population of this study is respondents admitted in ICU who were prescribed LMWH (Inj Enoxaparin 40/60 mg).

Sample and Sample size:

50 respondents admitted in ICU who were prescribed LMWH (Inj Enoxaparin 40/60 mg).

SAMPLING CRITERIA

In this study, respondents are selected as follows:

Inclusion Criteria

Respondents who are

- between the age group of 18-65 years;
- prescribed injection Enoxaparin (40mg/0.4ml-60 mg/0.6 ml) twice a day;
- with a normal renal function (Creatinine: 0.6–1.5 mg/dl, Urea: 15–50 mg/dl);
- with a normal platelet count (150-350 X 109/L), a normal PTT (25- 35 seconds) and a normal international normalised ratio (0.8-1.2) values for starting injection enoxaparin.
- no previous exposure to injection Enoxaparin.
- not having any hematologic disorders or any bruise or injuries on the abdominal wall;
- receiving no other injections at the abdominal site, other than the injection Enoxaparin, during the research protocol;
- not receiving any analgesics except the prescribed dual antiplatelet therapy- Ecosprin and Clopidogrel.
- not having any history of skin allergy to the use of frozen gel packs.

Exclusion Criteria

Respondents:

- who are pregnant
- who are unconscious, intubated, suffering from cognitive impairment and injuries, or those who are unable to sense and report pain
- not willing to participate in this study

TECHNIQUE AND TOOL

In this study, interview techniques were used for data collection to collect the demographic and clinical variables of the study. The observation technique is used in this study to observe and assess the pain and bruise of the respondent.The numerical pain assessment scale (immediately after administration of injection Enoxaparin) is used to assess pain and the bruise assessment tool (every 24^{th} hour after administration of LMWH injection for three days)is used to assess the bruise. A transparent millimetre ruler is

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used by the researcher to measure the size of the bruise.

CONTENT VALIDITY

To determine the content and construct validity, the tool was given to experts from the Nursing and medical field. After receiving their valuable inputs, the researcher in consultation with the research guide made needed modifications.

RELIABILITY

Numerical pain rating scale was used to assess the pain of the respondents. The Numerical Rating Scale (NPRS-11) is an 11-point scale for self-report of pain. It is the most commonly used unidimensional pain scale. High test-retest reliability has been observed r = 0.96 and 0.95, respectively . The bruise assessment score is based on the calculation of the area of the bruise.

ETHICAL ASPECTS

The main study was conducted after the approval of the Internal Ethical Committee; D Y Patil University School of Nursing (file no:EC/NEW/IND/2021/1547).Confidentiality and anonymity were maintained.

DATA GATHERING PROCESS

The required permission was obtained from the hospital authorities in the respective area The researcher visited the intensive care units of the setting from 15/11/21 to 12/12/21 for the main study. The researcher selected the respondents as per the inclusion criteria. Informed consent was obtained for the respondents who were willing to participate in the study. The respondent's abdomen was divided in two using the split body approach, with the left side serving as the control and the right serving as the experimental side. Rights of the medication were followed and injection enoxaparin(pre-filled syringe) was administered subcutaneously first on the control side without intervention. The second dose was administered subcutaneously on the experimental side with intervention. A cotton bag was used to place the frozen gel packs. On the experimental side of the respondent's abdomen, cold application was given for 3 minutes prior to and 5 minutes after the administration of subcutaneous injection enoxaparin. Infection control practices were followed during the administration of injection enoxaparin. Following injection, skin marker was used to mark the areas up to 5mm.Post-test was conducted immediately after the administration of LMWH injection for pain with numerical pain scale. The respondents were informed that for bruise assessment, the researcher will visit at 24 hours,48 hours, and 72 hours. The gel packs were washed with soap and water after each use. The researcher visited the respondent every 24th hour for 3 days after the administration of subcutaneous injection enoxaparin, using a transparent ruler scale the bruise was assessed.

PLAN FOR DATA ANALYSIS.

The collected data was coded, tabulated, and analysed by using descriptive statistics. The comparison between the respondents of the control and experimental side was done in both descriptive (mean, median, and standard deviation) and inferential statistics (Wilcoxon test for a non-parametric test).

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DATA ANALYSIS

Section 1: Demographic characteristics among respondents receiving subcutaneous injection enoxaparin in both experimental and control side

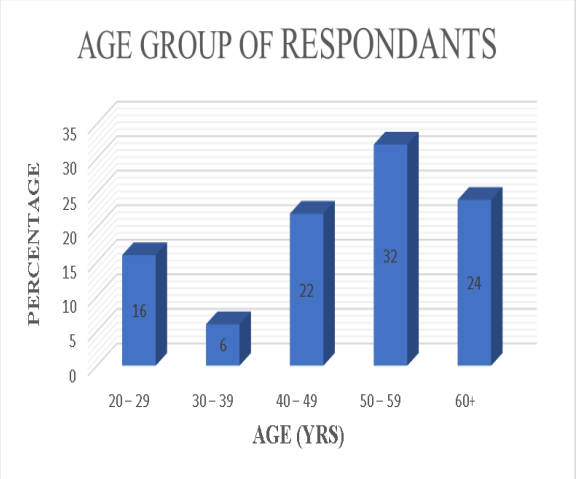


Figure 1: Bar graph showing percentage-wise distribution according to the age of the respondents receiving subcutaneous injection enoxaparin

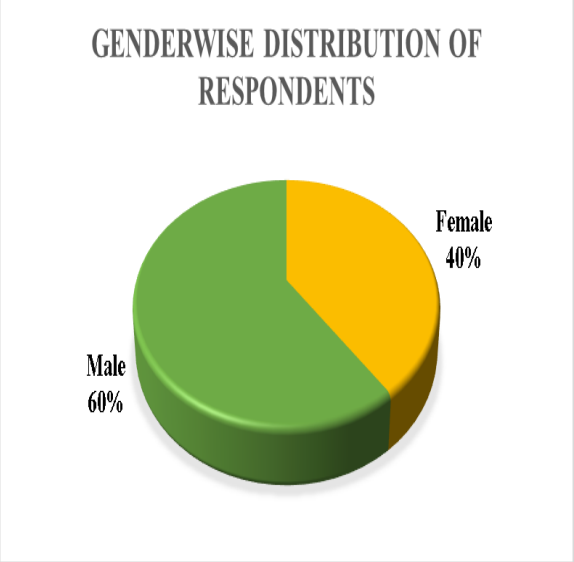


Figure 2: Pie diagram showing percentage-wise distribution according to the gender of the respondents receiving subcutaneous injection enoxaparin

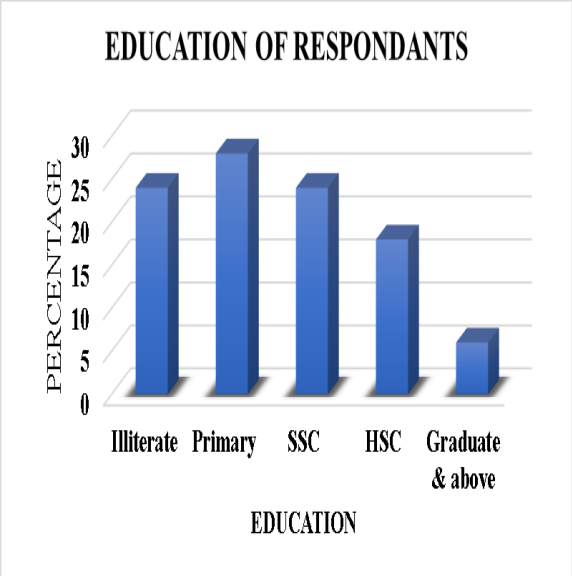
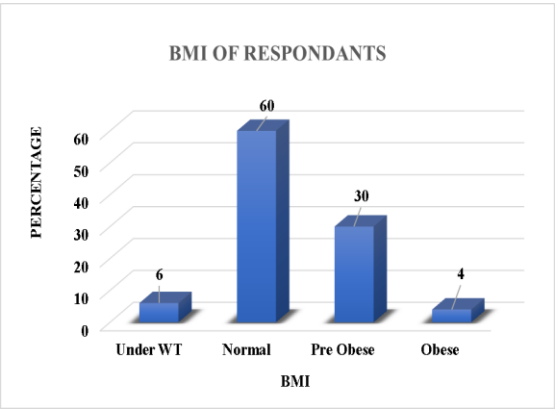


Figure 3: Bar graph showing percentage-wise distribution according to the educational status of the respondents receiving subcutaneous injection enoxaparin.

Figure 7: Bar graph showing percentage-wise distribution according to the BMI status of the respondents receivingsubcutaneous injection enoxaparin.



In this study, the researcher found that the 32% of respondents belonged to the age group of 50-59 years were; male respondents accounted for 60%; primary level educated respondents accounted for 28%, and respondents belonging to the normal BMI category accounted for 60%.

Section 2: Clinical variables among respondentsreceiving

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subcutaneous injection enoxaparin in both experimental and control side.

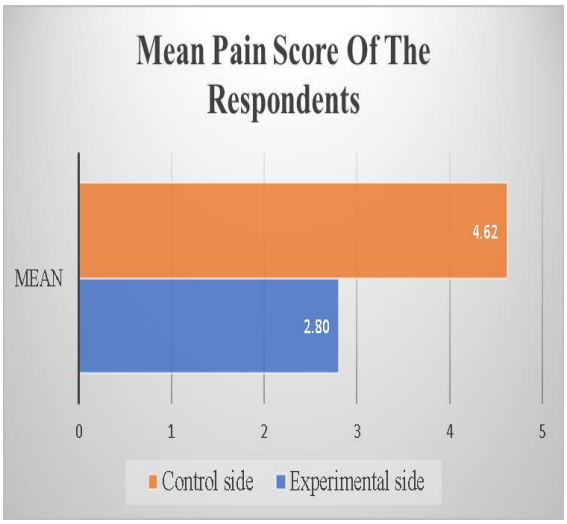
Table 1: Frequency and percentage distribution of clinical variables of respondents receiving subcutaneous injection enoxaparin.

Clinical Data	No. of Patients	Percentage
Diagnosis		
Fracture	18	36.0
Acute coronary syndrome	17	34.0
Congestive cardiac failure	12	24.0
Mitral stenosis	3	6.0
Receiving antiplatelets		
Yes	25	50
No	25	50
If Yes		
Ecosprin 150/Clopitab 75	24	96.0
Ecosprin Atorvastatin 75/20	1	4.0
Total	25	100.0
Dose		
40	13	26.0
60	37	74.0

The highest percentage of the respondents diagnosed with fracture accounted for 36%; Of the total respondents, the respondents receiving anti-platelets accounted for 50% and out of the respondents receiving antiplatelets, 96% were prescribed Ecosprin 150 milligram and clopitab 75 milligrams. The results also revealed that the highest percentage of the respondents were prescribed 60 mg of injection enoxaparin which accounted for 74%.

Section 3: Effectiveness of cold application on pain and bruise among respondents receiving subcutaneous injection enoxaparin in both experimental and control side.

Figure 5-Frequency distribution and chi-square test for pain among respondents who are receiving subcutaneous injection enoxaparin.



***Statistically Significant at 5% level i.e. P<0.05.**

The comparison between the control and experimental group was analyzed by both descriptive (mean, median, and standard deviation) and inferential statistics (Wilcoxon test for the non-parametric test) which showed that the pain intensity of the experimental side was significantly lower compared to the control side($P < 0.05$).

Table 2:Frequency distribution and Friedman test for bruise among respondents who are receiving subcutaneous injection enoxaparin.

Bruise Score	Control side			Experiment side		
	24hrs	48hrs	72hrs	24hrs	48hrs	72hrs
Measurement Score						
0	50(100)	11(22)	11(22)	50(100)	45(90)	45(90)
1	0	0	0	0	0	0
2	0	39(78)	39(78)	0	5(10)	5(10)
Mean	0.00	1.56	1.56	0.00	0.20	0.20
Median	0.00	2.00	2.00	0.00	0.00	0.00
Standard deviation	0.00	0.84	0.84	0.00	0.61	0.61
Friedman Test	78.000*			10.000*		
P – Value	0.000			0.007		
Sig. at 5% level	Yes			Yes		

***Statistically Significant at 5% level i.e. P<0.05.**

The comparison between the control and experimental group was analysed by both descriptive (mean, median, and standard deviation) and inferential statistics (Wilcoxon test for the non-parametric test) which showed that the pain intensity of the experimental side was significantly lower compared to the control side($P < 0.05$). The researcher found that the respondents of the experimental side had a mean pain score of 2.80±0.81 and respondents of the control side had a mean pain score of 4.62±0.85.The researcher found that the respondents of the experimental side had a mean bruise score of 0.20±0.61. The respondents of the control side had a mean bruise score of 1.56±0.84.

DISCUSSION

The respondents of the experimental side had a mean pain score of 2.80±0.81. The respondents of the control side had a mean pain score of 4.62±0.85. The pain intensity scores in the experimental group ranged from 2 to 5. The pain intensity scores in the control group ranged from 4 to 7. The results of the Wilcoxon test showed that the pain intensity of the experimental side was significantly lower compared to the control side($P < 0.05$).

The respondents of the experimental side had a mean bruise score of 0.20±0.61. The respondents of the control side had a mean bruise score of 1.56±0.84. Friedman's test shows that at 78.00 and 10.00 in the control and the experimental side, the level of significance at 5% level is 0.000 and 0.007 respectively. .

The study resultswere inconsistent with many studies as Avsar&Kasikci, Kilic&Midilli, and Gaytri B who showed that adding cold applications to injection procedures had a significant influence on the reduction of pain, and a similar study conducted by Suresh S e.t al, indicated that the 'moist ice pack' application had a statistically significant effect on the prevention and reduction of pain and hematoma in subcutaneous LMWH injection site, while had no effect on bruise. [(3)(4)(8)(25)]

CONCLUSION

The present study was conducted to evaluate the effect of cold application on pain and bruise associated with subcutaneous injection of LMWH. Effective, safe, and resource-constrained pain management therapies during injection are ideal. In clinical practice, a cold application utilizing frozen gel packs for 3 minutes before and 5 minutes after the injection of enoxaparin is effective. This method is less costly and takes less time to get favorable results.

LIMITATIONS

- This was a small study based on only two centers. Therefore, the study involved a small number of patients that is 50.
- The grading of pain in mild, moderate and severe category for analysis was a limitation as some respondentshave reported pain on thehigher scale of of a given category in the pretest and on the lower scale in the posttest but have fallen in the same category . Although the pain is reported reduced after cold application, but the pain analysis has been done in the same category..

NURSING IMPLICATIONS

Nursing education -The nursing curriculum should include information regarding cold application before and after the subcutaneous injection of enoxaparin and these skills will enable nurses to offer high-quality care.

Nursing Administration -Cold application can be introduced as an evidence-based practice protocol by

nursing administrators. Nurse administrators should share this information with clinical personnel and ensure that patients receiving injection enoxaparin receive cold application.

Nursing practice-The results of this study strongly suggest that cold applications effectively reduce pain scale rating and bruises Therefore, before injecting enoxaparin subcutaneously, nurses should be aware and utilize cold application.

- **Nursing research** -The findings of this study are useful for nursing professionals conducting further studies to explore the effectiveness of different techniques and therapies on pain sensation and bruising. It adds valuable knowledge that can be
- A study to assess the effect of cold application on the intensity of pain and bruise among patients receiving

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