Effectiveness of Ice Pack Application on Pain and Bruise among Patients Receiving Subcutaneous Heparin Injections

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Abstract: Heparin preparations are widely used for the post surgical prophylaxis, deep vein thrombosis and pulmonary emboli. Subcutaneous heparin injection often causes problems such as bruise and pain at the injection site. Bruising may lead to anxiety in patients, and reduction of the reliance of patient to nurse. The study intended to assess pain and bruise in patients receiving subcutaneous heparin injection with standard care and ice application. Further to evaluate the effectiveness of ice application on prevention/ reduction of pain and bruise in patients receiving subcutaneous heparin injection and to identify the association between the post test scores of pain and bruise in patients receiving subcutaneous heparin with ice application and standard care and their selected demographic and clinical variables. Hence using Quantitative approach, an experimental study with post - test control group design was undertaken with 120 samples in general medical and surgical wards. Patients who were available for atleast 3 days after starting injections were included in the study. Patients with cognitive impairment, dermatological disorders and on insulin were excluded from the study. Subjects were randomly allocated into control and experimental group using block randomization. Consecutive sampling technique was used to select the subjects. Control group received injection using standard care and experimental group received injection with ice application. Numerical rating scale was used to assess pain and bruise was measured using Bruise measurement scale at 48 hours and 72 hours. Results demonstrated that the median pain among subjects in control group was 2.0 and with experimental group was 1.0. The median difference in pain was 1.0 and was found to be statistically significant (p <.000). Similarly median score of bruising was 1.0 with control group and with experimental group was 2.0 and there was an evidence of statistical significance (p<.000) at 48 hours. The median score of bruising at 72 hours was 1.0 and 2.0 with ice pack application and standard care respectively. There was an evidence of statistical significance (p<.000). Bruising was significantly associated with the age and gender of the subjects. The study findings highlighted that ice application was found to be effective in reducing pain and bruising in the patients receiving subcutaneous heparin injection.

Keywords: Ice pack, Pain, Bruise, Subcutaneous Heparin injection

1. Introduction

Patients get admitted in a health care setting to get treatment for a wide range of acute or chronic illness and injuries. Holistic nursing care promotes comfort for the patient while causing least harm or distress. Medication management includes the efforts by nurses to prevent adverse events that threatens patient's safety, and not merely encompassed with prescription and administration of drug. Hence management of this zone of medicine is very important in all the fields of nursing practice and requires special attention (Hemingway, Baxter, Smith, Dawson, & Dewhirst, 2011). In the view of safe establishment of medication management and reduction of probable adverse effects of medication administration nurses are in a pre - eminent position (Smeulers, Onderwater, Zwieten, & Vermeulen, 2014).

Among the many complications pain and bruising are commonly detected at the injection site due to subcutaneous administration of heparin (Chan, 2001). This leads to physical and psychological discomfort to the patient predisposing them to avoid future injections and also decrease in the number of injection sites for administration of heparin subcutaneously (Hirsh et al., 2001). There are 16 billion injections administered every year of which 90% of injections were given intramuscular, subcutaneous or intradermal. About 4 - 5 billion injections administered annually in India. Frequency of injections administered was 2.9 per person per year (WHO, 2016). A national survey performed among French infectious diseases and geriatric practitioners reported that 70.8% verbalized pain at the injection site after subcutaneous injection (Forestier, Paccalin, Roubaud, Fraisse, Gavazzi & Gaillat, 2015). The incidence level of local bruising after administration of low molecular weight heparin is between 26.6 – 88.9% (de Campos, da Silva, Beck, Secoli & de Melo, 2013).

Ice application has had its place among many physical therapies to reduce pain. Ice has a very short term analgesic effect to reduce pain. Hadley, Chang and Rogers (1996) reported that up to 90% of individuals develop pain and bruise due to subcutaneous administration of heparin. Ice application for cooling and analgesic effect is very beneficial, which causes numbness and relieves pain. Varghese, Walia, Sharma, Kaur (2006) reported that application of moist ice pack was effective in preventing and reducing pain and bruise when subcutaneous heparin was given. Sendir, Buyukyilmaz, Çelik & Taskopru, (2015) also reported that 2 to 5 minutes of local dry cold application for patients receiving low molecular weight heparin injections reduced pain intensity and bruising size.

Since patients receive any number of subcutaneous heparin injections, it is important that the nurses use strategies to minimize the incidence of the adverse outcomes when administering subcutaneous heparin injections. This helps to provide nurses with more potential sites for injection administration and in turn this helps to gain confidence and trust by the patients on care givers (Chenicek, 2004). Nurses are playing an important role in the delivery of health care. They need to adopt novice and innovative techniques in order to provide effective and best possible care to their patients. In current scenario, nurses are involved in evidence based care and hence to provide evidence - based care for

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the patients they are actively involved in research just like other disciplines. (Heater, Becker & Olson, 1988). Therefore, the researcher is interested in utilizing innovative technique to reduce pain and bruise in patients receiving subcutaneous heparin injection.

The strength of existing research on the use of non pharmacologic interventions for procedural pain management is limited, and more rigorous clinical trials are needed (Klassen, Liang, Tjosvold, Klassen & Hartling, 2008). Nurses have the key responsibility of providing non pharmacological therapies to patients as adjuvant to pharmacological interventions to maximize relief of pain and bruise. The non - pharmacological interventions for pain relief are grouped as cognitive and physical. Physical techniques focus on altering physiological processes to reduce pain which includes application of heat and cold. Ice pack application is one of the simplest, safest, effective and most widely used techniques in pain reduction and occurrence of bruise. Therefore the present study was conducted with the following objectives:

- To assess pain and bruise in patients receiving subcutaneous heparin injection after standard care.
- To assess pain and bruise in patients receiving subcutaneous heparin injection after ice pack application.
- To evaluate the effectiveness of ice pack application on pain and bruise in patients receiving subcutaneous heparin injection.
- To identify the association between post test scores of pain and bruise in patients receiving subcutaneous heparin with their selected demographic variables and clinical variables in both groups.

2. Conceptual Framework

The conceptual framework used was based on Donadedian's structure, process and outcome model. In this study, the structure includes group of patients who are receiving subcutaneous heparin injection having measured by the selected variables such as age, gender education, occupation, body mass index, injection site and medication such as antiplatelet drugs. Process refers to the administration of only subcutaneous heparin injection in the control group and the intervention done on the study participants by the investigator in the experimental group. Outcome refers to absence or reduction in pain and bruise in patients receiving subcutaneous heparin injections with ice pack application when compared to patients receiving the injection with standard care.

3. Method

Post – test control group design was adopted. All adult patients on subcutaneous heparin injection and are admitted in the general Medical and Surgical wards for a minimum of 3 days, can communicate fluently in Tamil, English, Telugu, Hindi and Bengali and who were willing to give consent to participate in the study were included. Patients with cognitive impairment or dermatological disorders and on insulin were excluded from the study. Sample size was estimated according to statistical inputs from two articles for sample size calculation. Sample size for bruise was calculated from the study by Varghese et al., (2006) and for pain from the study conducted by Kuzu & Ucar, (2001). The study required totally 104 patients (n1 = 52 & n2 = 52) to study both bruise and pain. Considering the dropout rate of 10%, the final sample size for the study was estimated as 120 (Experiment = 60: Control = 60) patients. Consecutive sampling was used. The researcher identified and selected the subjects as per the inclusion criteria. The subjects were randomly allocated into both control and experimental group. Block randomization was done in order to allocate subjects equally from medical and surgical areas into control and experimental group.

The instruments for data collection were standardized tool and researcher developed based on literature review. The first component of the instrument included demographic and clinical proforma. Second component was the numerical rating scale to identify the intensity of the pain as perceived by the patient, which is a universally acceptable standardized tool. Finally, bruise measurement scale was used to assess and measure bruising at 48 hours and 72 hours after administration of subcutaneous heparin. Standard care was received by the subjects in control group where subcutaneous heparin injection was administered by the staff nurse without ice application. On the other hand for experimental group ice pack was applied over the site for 5 minutes before injection and after administration of injection by the staff nurse. In both the groups after 15 to 30 minutes of administration of injection pain was assessed using numerical rating scale. Following which the injection site was marked with a water proof tipped pen for assessment of bruise at 48 hours and 72 hours. Only one injection site was assessed for all the subjects. Pain score was rated as no pain, mild, moderate and severe where the minimum was 0 and maximum was 10 score. Similarly for bruise grading was no bruise ($< 2 \text{ mm}^2$), minimum (2 - 5mm²) and moderate bruise $(> 5 \text{mm}^2)$. Pilot study was done to assess the feasibility of the study. High reliability of numerical rating scale was reported by Ferraz et al., (1990), where the High test - retest reported that the internal consistency was high as the Cronbach's Alpha was r = 0.96 and the correlation range was from 0.86 to 0.95. Similarly bruise measure scale was found to be highly were the Internal consistency was reported high with Cronbach's Alpha value of 0.99. Test retest was done to assess the stability of the instrument. The Interclass correlation was 0.99.

4. Data Collection Procedure

The patients within 24 hours of admission were identified by the investigator by checking the audit book every day. The doctor's order sheet of the subject was checked for the order of subcutaneous administration of heparin injection. Then the investigator selected the sample based on the inclusion criteria. The researcher developed a good rapport with the subjects. Information sheet was given in the vernacular language to the subjects. After clarifying their doubts of those who agreed to take part, informed written consent was obtained for the study. The selected subjects were randomly allocated to control or experimental groups based on block randomization method and concealment was done by sealed

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DOI: https://dx.doi.org/10.21275/SR221221124051

envelope method. Standard care was given to the control group whereas intervention (ice pack) was administered for the experimental group. Pain was assessed after 15 - 20 minutes in both the groups and bruise was assessed at 48 hours and 72 hours after injection. The data were analysed using the Statistical Package for Social Sciences (SPSS) Version 17.0 for windows. Descriptive statistics percentage and frequency were used to analyse and summarize the demographic and clinical variables of the subjects in the control and experimental group and also to present the distribution of subjects with regards to pain and bruise. Inferential statistics non parametric Mann Whitney 'U' test was used to determine the difference in pain and bruise between the control and experimental group. Chi - Square and Fisher's Exact tests were used to find out the association between subjects pain and bruise after subcutaneous heparin injection with their demographic and clinical variables.

Protection of Human Rights

The study was performed after getting approval from the Research Committee of College of Nursing and Institutional Review Board of CMC Vellore. Permission was obtained from the Nursing Superintendent, Dean and the Heads of the Departments of various units namely general medical and surgical wards, both nursing and medical. The study was also enrolled in the Clinical Trials Registry of India (CTRI). An informed consent was obtained from all the subjects after informing them about the details of the study. Privacy during the injection procedure was maintained. Confidentiality of the information was achieved by maintaining anonymity of the subjects and assigning sample numbers so that the responses of the subjects could not be traced.

5. Results and Discussion

The investigator found that among the subjects, maximum patients were in the age group of 41 - 60 (47.5%) years of age. This implies that majority of the patients were admitted in surgical and medical wards with those conditions which subcutaneous heparin injection either required for therapeutic or prophylactic purpose to prevent thrombosis belong to this age group. Moreover patients get admitted with vascular problems in surgical wards and are started on heparin preoperatively to prevent thrombosis. On the other hand those who get admitted in medical wards are with chronic conditions and bed ridden. Hence they are started on subcutaneous heparin injection prophylactically to prevent DVT. Congruent findings were found in studies by Amaniyan et al., (2016), Varghese et al., (2006) and Kuzu & Ucar, (2001) where majority of the subjects were in the age group of 41 - 60 years.

The study subjects constituted a large number of male subjects (57.5%), with female patients comprising of 42.5%. This was in congruence with the study done by Avsar and Kasiksi, (2013) which reported that 73.7% were male and 26.3% were female. Though the findings are congruent, there is considerable increase in the percentage of female patients seeking medical aid which could be due to more awareness among the public as well as the educational and technological revolution that has occurred in recent times. Discordant findings were found in studies done by

Amaniyan et al., (2016), Varghese et al., (2006), 77.8% were female and 22.2% were male.

The literacy level in majority of the patients was found to be of secondary and higher secondary level (47.6%); followed by uneducated 25.8% and a small proportion of graduates and post graduate (13.3%). A similar study done by Kattunilam & Rohini, (2016) has reported discordant findings where 56.66% of the subjects had either primary or secondary education. Similarly study by Varghese et al., (2006) has disclosed that majority of the subjects were illiterates. The smaller proportion of graduates could be due to lower economic status where they tend to discontinue their education after primary level in order to meet the needs of their daily living and share the needs of their family.

On assessing the type of occupation, majority of the patients were non professional (53.3 %) workers, followed by housewives (29.2 %). Dissonance was found in the study done by Varghese et al., (2006), were majority where unemployed and non professional workers in the control and experimental groups. This sought of discrepancy could be due to the influence of education where they get opportunity only for non professional work rather than professional employment.

In view of injection site, 50% of heparin injections were administered in the abdomen, followed by arms 35% and a few injections in thighs (15%). This is because in the clinical area, for the patients with medical condition the site for injection administration is in the abdomen, whereas in the surgical area injections were administered in the arms and the thighs.

The subjects of the study constituted a disproportionately large number of patients not on any antiplatelets (70 %) and, with patients on antiplatelets comprising only 18 (30 %). Though this difference is in ordination, this could be due to the administration of heparin subcutaneously for prophylactic reasons for a short duration of time when the patients are hospitalized. That small proportion of patients on antiplatelets could be those with other co morbid conditions that require additional antiplatelet aggregators. Dissonance was found in a study by Chan (2001), where 49.3% of the subjects were already on aspirin before hospitalization and continued with the drug and 43.3% had started taking aspirin after hospitalization.

The current study projects that maximum subjects in this study had normal BMI (45.5 %) and 30% were overweight. The study finding by Ahmadi, Ahmadi, Saadati & Mehrpour, (2016) was in accordance with the current findings where BMI was normal for majority of the subjects. Since patients with surgical condition and other medical condition with less morbidity get admitted in the general wards, they mostly have a normal BMI. Mostly, in the general medical and surgical wards the subjects receive heparin injection subcutaneously for prophylactic purposes for a short period of hospitalization.

Among the subjects who received standard care the researcher found that majority of the patients experienced mild pain (70 %) after heparin injection was administered subcutaneously. Congruent findings were noted in a study

International Journal of Science and Research (IJSR) ISSN: 2319-7064 SJIF (2022): 7.942

by Varghese et al., (2006) where 57% & 35% subjects had mild and moderate pain after the administration of heparin injection subcutaneously with standard care.

Observations for bruise made at 48 hours divulged that 33.3% of the subjects had no bruise and 35% of the subjects developed minimum bruise with standard care. Similarly an assessment made at 72 hours also revealed that 28.3% and 38.4% of the subjects had no bruises and moderate bruises respectively with standard care. This could be due to the collection of blood underneath the skin because of the damage caused to the blood vessels beneath the skin leading to its rupture and bleeding. The study findings were discordant with the findings of Varghese et al., (2006) where the results revealed that 64% of the subjects who received subcutaneous heparin injection with standard care had no bruise at 48 hours and 54% of the subjects had no bruise at 72 hours of post assessment. Thus it is evident that pain and the bruising were higher in the group which received subcutaneous heparin injection with standard care.



Figure 1: Distribution of subjects based on pain with ice pack application



Figure 2: Distribution of subjects based on bruising at 48 hour with ice pack application

On the other hand in the experimental group the researcher observed that 76.7% of the subjects experienced no pain when subcutaneous heparin injection was administered with ice pack application (Figure 1). Congruent findings were noted in a study by Varghese et al., (2006) where 66% of subjects experienced no pain in the experimental group. Cold application reduces the severity of pain by decreasing the level of catecholamines, increasing endorphin levels and delaying the transmission of pain signals to the central nervous system. Similarly assessment for bruising done at 48 hours and 72 hours divulged that 66.7% (Fig.2) and 63.3% of the subjects had no bruise at 48 hours and 72 hours respectively. Whereas a minor percentage that is 23.3% and 20% of the subjects developed minimum bruise at 48 hours and 72 hours respectively.

Congruent finding were found in the study by Amaniyan et al., (2016) where the average size of bruising was significantly less than the size of the bruise in the control group. Similarly Varghese et al., (2006) study findings also revealed that the incidence of bruise was less with moist ice application at the injection site. Cold application constricts the peripheral blood vessels, reduces the blood flow to the tissues and reduces bruising. Hence, this could be the reason for absence of bruise in the subjects who received subcutaneous heparin injection with ice application. The finding of the study is dissonant with the study findings by Kuzu & Ucar (2001), where no statistical difference was found among the groups when the occurrence of bruising after LMWH injections was evaluated. It appeared that cold application at different times was not effective in preventing or reducing the occurrence of bruising. Thus it is evident that the pain response and the bruising was less among the subjects who received subcutaneous heparin injections with ice pack application.

Table 1: Comparison of pain between subjects receiving subcutaneous heparin injection with ice pack application and standard (N = 120)

Group	n	Median (IQR)	Median Difference	Z value	p value	
Control	60	2.0 (2.0 - 2.0)	1.0	- 5.879 ^a	< 000***	
Experimental	60	1.0 (1.0 – 1.0)	1.0		<.000****	

^aMann Whitney 'U' test Value***p <.001

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International Journal of Science and Research (IJSR) ISSN: 2319-7064 SJIF (2022): 7.942

On evaluating the effectiveness of ice pack application on pain and bruise in patients receiving subcutaneous heparin injection the researcher found that the median pain was 2.0 (IQR 2.0 - 2.0) among the subjects who received subcutaneous heparin injection using standard care and 1.0 (IQR 1.0 - 1.0) and among the subjects who received subcutaneous heparin injection with ice pack application. The median difference in pain was 1.0 and there was an evidence of statistical significance (p<.000) (Table 1). Congruent findings were noted in a study by Sendir et al., (2015) and Varghese et al., (2006) that cold application is effective in decreasing the intensity of pain. This discloses that ice application is effective in reducing the pain perception in the subjects receiving subcutaneous heparin injection.

Table 2: Comparison of bruising at 48 hours and 72 hours between subjects receiving subcutaneous heparin injection with ice pack application and standard care (N = 120)

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	Group	n	Median (IQR) 48 hours	Median Difference 48 hours	p value	Median (IQR) 72 hours	Median Difference 72 hours	p value				
	Control	60	2.0 (1.0 - 3.0)	1.0	<.000***	2.0 (1.0 - 3.0)	1.0	<.000***				
	Experimental	60	1.0(1.0-2.0)	1.0		1.0(1.0-2.0)						
XX7 % (TT% / X7 1 444 .001												

^aMann Whitney 'U' test Value***p <.001

On the other hand the median bruising was 2.0 (IQR 1.0 -3.0) in the subjects after subcutaneous heparin injection with standard care and 1.0 (1.0 - 2.0) in the subjects after the injection with ice pack application at 48 hours. The median difference in bruising was 1.0 and there was an evidence of statistical significance (p<.000). The median was 1.0 (1.0 -2.0) and 2.0 (IQR 1.0 - 3.0) in the subjects after subcutaneous heparin injection with ice pack application and standard care respectively at 72 hours of post assessment. The median difference was 1.0 and there was an evidence of statistical significance (p<.000) (Table 2). The study finding were congruent with the findings of the studies done by Sendir et al., (2015), Amaniyan et al., (2016) and Varghese et al., (2006), that cold applications were effective in reducing the occurrence of bruising at 48 and 72 hours. This shows that ice application was effective in absence or reduction of bruising in subjects where heparin was administered via subcutaneous route with ice application. The present study findings indicates that there is significant reduction in pain and bruise in patients receiving ice pack application compared to patients receiving standard care in patients after administration of subcutaneous heparin injection.

The demographic variables did not influence the level of pain perception in the patients receiving subcutaneous heparin injection with ice application and standard care. This shows that there is no statistical evidence of significant relationship of pain with the demographic and selected clinical variables.

This was congruent with the findings of the studies by Pourghaznein, Azimi & Jafarabadi, (2014) with a sample size of 90 andDadaeen et al., (2015) with a sample size of 100, where the relationship between age and gender had no effect on the pain intensity and was not significant (P>.05). Disparity was revealed, where there was a significant influence of age in pain response in a study done by Kattunilam & Rohini (2016) with a population of 60. Likewise Neziril et al., (2011) and Kang et al., (2010) studies unveiled that female patients were more sensitive than their male counterpartswith respect to pain. According to their study findings, with respect to the gender the severity of pain decreases with aging, so younger female patients are more sensitive to pain. Whereas a significant consortium between age of the subjects receiving subcutaneous heparin injection and bruising, was observed at 48 hours (p<.044) and (p<.012) 72 hours respectively with standard care. Apparently this could be because majority of the subjects were above 41 years of age and had either minimum or moderate bruise. There is a tendency for bruising as the age increases. Indistinguishably significant association was revealed between age (p<.029) and gender (p<.030) of the subjects and bruising in subjects receiving subcutaneous heparin injection with ice application at 48 hours. Correspondingly significant relationship was revealed between age (p<.009) and gender (p<.023) of the subjects and bruising, when heparin injection was administered subcutaneously with ice application during 72 hours of assessment. Majority of the subjects were above 41 years of age with no bruises when the heparin injection was administered with ice application. Gender of the subjects predisposes bruising, where female tend to bruise more than the males, whereas in the experimental group males were more in number when compared to females. This gives evidence that ice application was effective in reducing bruising.

The study findings were congruent with the findings by Kattunilam et al., (2016) and Dadaeen et al., (2015) which revealed a significant correlation between age and bruise. The extent of bruise increased with age. Similarly the extent of bruising was significantly higher in women than in men (Chan, 2001). Discordant results were reported by Zaybak & Khorshid (2008), study which revealed that there was no significant association between age of the subject with bruise. Likewise Pourghaznein et al., (2014) in their study revealed that there was no difference between gender of the subject and bruise size.

The other demographic and clinical variables did not have any significant association with bruising in subjects when heparin was administered subcutaneously with standard care at both 48 hours and 72 hours of observation. Probably this could be because maximum subjects were males, who received majority of the injections over the abdomen and were not on any antiplatelet drugs and had a normal BMI. On the other hand, no significant association was revealed between education, occupation, injection site, medications and BMI of the subjects receiving subcutaneous heparin injection with ice application at both 48 hours and 72 hours.

DOI: https://dx.doi.org/10.21275/SR221221124051

Potentially it could be due to more injections administered over the abdomen. The subjects were mostly within normal BMI and were not on antiplatelet drugs and had the injection administered subcutaneously with ice application. Pourghaznein et al., (2014) and Zaybak & Khorshid's (2008), studies revealed that there is no relationship between BMI of the subjects and bruising.

The study findings indicated that there was a significant association between age and gender with bruising. However the other demographic variables namely education, occupation and clinical variables injection site, BMI and medication did not seem to have any significant association with bruising. Similarly the study findings also indicated that there is no significant association between demographic variables such as age, gender, occupation and education and clinical variables injection site, BMI and medications with pain perception.

The study was limited to assess only the effect of ice pack application to reduce pain and bruise. Other limitations include, study did not assess the technique of injection administration. Subjects were limited to only the first injection site and subjects admitted within 24 hours of admission. Multiple injections in a single site were not assessed. Long term follow up of the subjects was not done. Generalization was limited to only general medical and surgical wards.

Implications to nursing education, practice and research: Nursing care is a combination of knowledge and skills and this can be imparted only through education. The findings necessitate the need for nurses to equip themselves with the adequate skill and knowledge for preventing and reducing pain and bruise due to subcutaneous heparin injection. Ice pack application for 5 minutes before and after administration of heparin injection does not require a doctor's order and can be easily performed by the nurses, care giver or the patients themselves. This promotes comfort for the patients, reduces anxiety and prevents from body image disturbance. This subsequently ensures availability of site for injection administration. Moreover the lacuna that is present among the nurses in knowledge and skill for following proper technique to administer subcutaneous heparin injection can be rectified by periodic inservice education and skill assessment. The findings of the study might help the future researchers to replicate the study in overall hospital setting to determine the pain response and bruising and also explore the other factors associated for occurrence of pain and bruising due to subcutaneous administration of heparin. Further research can be done to assess the knowledge attitude and practice of nurses on administration of heparin injection.

6. Conclusion

Subcutaneous administration of heparin injection leads to various complication of which pain and bruise at the injection site is predominant. The health care members need to be aware of the risk factors due to subcutaneous heparin injection. Preventive measures are to be followed in order to alleviate pain and prevent/reduce bruise formation which provides more sites for injection administration for nurses and also reduces the anxiety among the patients due to discoloration that occurs. The findings of the current study demonstrates the evidence of an effective intervention for management of pain and bruise formation. Application of ice before and after administration of heparin injection does not require a doctor's order and the nurse can independently perform this nursing intervention.

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International Journal of Science and Research (IJSR) ISSN: 2319-7064 SJIF (2022): 7.942

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