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Original Research Article

Effects of Cold Application on Pain and Bruising Complications Associated with Subcutaneous Heparin in Intensive Care Patients

Emine Korkmaz Kilic[1], Tulay Sagkal Midilli[2]

[1]A Critical Care Nurse in Bornova Türkan Özilhan State Hospital, Izmir, Turkey
[2]Assistant Professor, Department of Fundamentals Nursing,
Manisa Celal Bayar University Faculty of Health Sciences, Manisa, Turkey, zip code: 45000

Corresponding Author: Tulay Sagkal Midilli

ABSTRACT

Aim: The aim of the study was to investigate the effects of cold application on pain and bruising complications associated with subcutaneous heparin in intensive care patients.
Design and method: The research was conducted as an experimental, post-test, double blind study in which each patient constituted their own control. It was performed with 60 patients receiving subcutaneous heparin treatment in the Anesthesia Intensive Care Unit. Cold application was performed on the patient's right side abdominal region for two minutes each before and after the injection. Twenty-four hours later, an injection was performed on the left side of the abdominal region of the same patient without any cold application. The pain of the subcutaneous heparin injection was assessed at the time of the injection, and the size of bruises was measured 48 and 72 hours after the injection.
Results: It was observed that the patients' total pain scores were significantly lower with the cold application intervention (z=-6.60, p=0.0001), and bruise size after 72 hours with cold application intervention was also significantly less than at 48 hours (z= -6.2, p=0.0001). The size of patients' bruises after 48 and 72 hours in the intervention without cold application was found to be greater ((z= -6.2, p=0.0001).
Conclusions: It was found that two-minute cold application before and after subcutaneous heparin injections reduced pain score and the size of bruises 48 and 72 hours after heparin.

Keywords: intensive care patients, subcutaneous heparin injection, cold application, nursing intervention, pain, bruising

INTRODUCTION

Nurses have a primary responsibility for drug administration, but it is not only nurses who administer drugs. This is also done by physicians, certified drug technicians and patients and members of their families. [1] Nurses are responsible for receiving the order from the doctor, recording the order in the appropriate place, obtaining, preparing and administering the drug, evaluating the treatment by observing the response shown by the patient, and at the stage of deciding on the necessity of the treatment for preparing the necessary records and reports. [1,2] One of the interventions which is most performed by nurses is the administration of drugs. This is done either orally or parenterally. [2-4] One of the routes of parenteral drug administration is subcutaneous injection, which is generally used for inoculation and for such drugs as insulin, hormones and

heparin. [5,6] Heparin is of benefit in preventing thromboembolisms, increasing the quality of life and prolonging life. [7] In terms of side effects it is a drug which can put a patient's life at risk, but it is among the most widely used anticoagulants. [8]

In intensive care patients, one of the most important causes of mortality and morbidity is venous thromboembolism, and to reduce the risk of this, unfractionated heparin or low molecular weight heparin is administered. [7,9] All types of heparin are administered to the body parenterally by the intravenous or subcutaneous routes. [10] Heparin can cause not only systemic complications such as bleeding and thrombocytopenia but also local bruising, hematoma and pain at the injection site. [7,10-16] These treatment-related bruises and hematomas not only constitute physical trauma, but also cause changes in body awareness and make it difficult to choose a site for future injections. This is because use of the traumatized area for later injections both causes pain and has a negative effect on the absorption of drugs. [10,16,17] Among the reasons for these complications are the site of administration of the subcutaneous heparin injection, [18-21] the time taken to perform the injection, [7,17,18,22-27] the length of time the needle remains in the tissue, [12,15,16] and airlock and aspiration techniques. [12,15,16,18] Alongside these injection techniques, one of the applications preventing the formation of these complications is cold application. [10,12,15-17,26-30] Cold application at the site of subcutaneous injection controls bleeding by causing vasoconstriction in the arterioles, increases clotting by lowering the speed of blood flow and increasing viscosity, and makes the control of bleeding easier by reducing capillary permeability and metabolic needs. This reduces the development of bruising and hematoma. When the needle enters the skin, acute pain is felt. Cold application also inhibits the spread of pain from the original source. This localized sensory effect causes the attention to be drawn from the pain to the cold itself, and in this way pain is also relieved by the anesthetic effect of the cold. [15,31]

It has been found that patients in intensive care units experience pain from interventions and applications performed for medicinal and treatment purposes, [32-35] and in fact effective pain management is the most important aspect of the care of intensive care patients. It is necessary to pay attention to these problems especially with the critically ill in intensive care. [34-36] Examining previous studies, very few were found investigating the effect of cold application in the administration of subcutaneous heparin injections in intensive care patients on pain and bruising using different scales in the assessment of pain, [26-30] but specifically none were found using Behavioral Pain Scale (BPS) in the assessment of pain in intensive care patients attached to mechanical ventilation. [37]

In a study by Alabdalhai et al [28] with 30 patients in intensive care units and using a spoken pain scale comparing the effect of cold application on pain and hematoma in the administration of subcutaneous heparin injections, it was found that the pain score was 0.20 ± 0.40in interventions with cold application, and 2.20 ± 0.41 in interventions without cold application, i.e. the pain score in the group without cold application was higher than in the group with cold application ($p<0.0001$). Also, it was stated that less pain was observed in the abdominal area when cold application was performed than in the arm or leg. In a study by Ahmadi et al [26] examining the effect of the duration of subcutaneous heparin injection on the size of bruises at 24 and 48 hours in 86 patients in a cardiology and coronary intensive care unit, the mean pain score using the McGill Pain Scale after a 10-second injection was 2.79±1.42, which was higher than the mean pain score following a 30-second injection (0.77 ± 0.91). In a study by Pourghaznein et al [27] comparing the effects of four methods of subcutaneous heparin injection on pain (VAS) and bruising (48 hours) in the arm and abdominal region in 90 patients in

intensive units because of Chronic Obstructive Pulmonary Disease (COPD), the severity of pain was found to be greater in the arm than in the abdomen. A study by Cortes et al [29] conducted to determine local complications of heparin administered to 172 patients in a clinical and coronary intensive care unit showed that 10% of patients experienced pain. Also, in a study by Varghese et al, [30] an investigation was made of the effect of the application of wet ice packages on pain, using a numerical pain rating scale, bruising and hematoma in 200 patients in an experimental and a control group in coronary intensive care and a cardiology thoracic ward. It was found that a five-minute application of a wet ice package to the experimental group reduced pain.

Accordingly, this study was conducted in light of the fact that there are no studies in the literature examining the effect of cold application on avoiding possible complications relating to subcutaneous heparin injections in intensive care patients and assessing the pain of injection using the BPS.

OBJECTIVE

The aim of the study was to examine the effects of cold application on pain and bruising complications of the administration of subcutaneous heparin in intensive care patients. The hypotheses of the study were as follows:

H_1: In subcutaneous heparin injections in intensive care patients, pain severity is less in a region where cold application is performed than in a region where cold application is not performed.

H_2: In subcutaneous heparin injections in intensive care patients, the size of bruises is less in a region where cold application is performed than in a group in which cold application is not performed.

METHODS

Research Design

The experimental with post-test, control group double-blind study was performed between February and August 2015 with 60 patients admitted to the Anesthesia Intensive Care Unit of a government hospital in the province of Manisa, Turkey. The patients were receiving subcutaneous heparin treatment, they accorded with the sampling criteria, and their first-degree relatives agreed to their participation. In the study, each patient constituted his or her own control group. In planning the study it was very important to determine and avoid possible sources of bias. The main purpose in planning must be to reduce to a minimum the possibility of bias in a study, and in this study the double blind method was used. [38] This was achieved as follows: (a) measurement of pain during the injection and measuring bruising 48 and 72 hours after the injection was performed by a nurse who was not one of the researchers, had no information about the study, and did not know what application was being performed on the patient; (b) the patients participating in the study were unconscious, and so they had no information about the hypotheses and the interventions applied.

Sample

The size of the research sample was determined using data from a pilot study with five patients on the pain and the differences in bruise size relating to heparin injections in the right side with cold application and the left side without cold application of the patients' abdominal region. Power analysis was conducted in determining the study sample. By considering a confidence level of 95% and power of 80%, a sample size of at least 54 cases was determined. Of 79 patients participating in the study, 14 were excluded because they did not conform to the selection criteria, while five died, and finally, the study was conducted on 60 patients. A sample size of 60 achieved 100% power to detect a difference of -1.68 between the null hypothesis mean of 0.00 and the alternative hypothesis mean of 1.68 with an estimated standard deviation of 0.87

and with a significance level (alpha) of 0.05 using a two-sided one-sample t-test.

Research sample selection criteria were (a) unconscious and intubated patients, (b) age 18 years or over, (c) 0.6 ml Enoxaparin 1x1 / day, (d) thrombocyte count normal (15 000 – 400 000 per 1 mm^3 of blood). *Research exclusion criteria* were (a) first-degree relatives not accepting the patient's participation in the study, (b) any injection administered in the abdominal region during the days of the study, (c) any incision or scar tissue in the abdominal region, (d) person with coagulopathy, (e) treatment with any anticoagulant drug within the previous week, (f) receiving heparin treatment of other than 0.6 ml Enoxaparin 1x1.

Data collection instruments and data collection

In collecting research data, use was made of a Patient Identification Form containing patients' socio-demographic details, the BPS to assess pain, and a Patient Report Form to record the bruising and pain results. The forms were completed at the time of the applications to the patients and 48 and 72 hours after the heparin injections.

Patient Description Form: This was prepared by the researchers in line with the literature after taking into account similar studies evaluating patients receiving heparin treatment, [10,12,16,17,34,39] and consisted of eight questions on patients' socio-demographic characteristics and illness, such as age, gender, marital status, educational level, Glasgow coma scale, body mass index (BMI), the presence of chronic illness, prothrombin count. Information on the age, BMI, clinical symptoms, laboratory values, etc. of the patients included in the study were obtained from the patients' file records. Patients' socio-demographic characteristics and illness-related information were recorded when the patients were first accepted into the study and before the injections.

The *Behavioral Pain Scale (BPS*): It was designed for intensive care patients by Payen et al. (2001). The behavioral items consist of three subscales on facial expression, upper extremity movements and ventilation conformity. Each subscale has four sub-items and thus there are twelve items in total. Each subscale is scored from 1 (no response to pain) to 4 (total response to pain). The lowest score on the scale is 3 and the highest is 12. A high score indicates a high level of pain. The first items on each scale describe a lack of pain, the second slight pain, the third medium pain, and the fourth a high level of pain. Validity and reliability study of the Turkish version of the scale was carried out by Vatansever and Aslan in Turkey. BPS' Cronbach's alpha coefficient was reported 0.71-0.93. [37] This scale was completed by evaluating the pain behavior occurring during the administration of the subcutaneous heparin injection to the patient.

Patient Report Form: This form was developed by the researchers. Measurements relating to pain (BPS) and bruising (using *OpSiteFlexifix* clear film bandaging) in each patient were recorded on this form.

Measurements

In this study two different injection interventions were given to the same patient at an interval of 24 hours. The first injection was given with cold application, and the second without cold application. The cold application was performed on the patient's right abdominal area for two minutes before and two minutes after the injection. For the cold application, a cold hot pack of dimensions 10 x 10 cm (UK-England) was used. Injection without cold application was performed on the left side of the patient's abdominal area. The pain of the subcutaneous injection was measured during the injection using the BPS. Bruising developing in relation to subcutaneous heparin injection is clearest at 48 hours after the administration of the injection and begins to disappear after 72 hours, [13,16] and so the size (mm) of bruising was measured twice, 48 and 72 hours after the intervention, using *OpSiteFlexifix* clear film

bandaging. After marking the site of the injection with a pen, the Opsiteflim bandaging was applied and the measurement was taken.

Intervention

All interventions in the study were performed by one of the researchers, an intensive care nurse. Cold application was performed on the left side of the patient's abdominal area for two minutes before the injection. The subcutaneous heparin injection was performed according to the protocol in Table 1. During the injection, the patient's pain was assessed using the BPS. Following the injection, a further two minutes of cold application were performed. The Opsite film bandage was applied to the site of the injection after the site had been marked with a pen, and after that bruise measurement was performed. The pain during the injection and the measurement of the bruises 48 and 72 hours after the injection were assessed by a nurse working in the clinic who did not know about the study and who did not know which intervention (with or without cold application) had been performed on which side (left or right) of the patient's abdominal area. All of the same procedures were followed on the left side of the patient's abdominal area except for the cold application. So as not to affect the study results, care were taken not to perform further subcutaneous heparin injections in the patient's abdominal area for 72 hours following the two injection interventions of the study.

Data Analysis

Data analysis was conducted using the statistics package SPSS 22.0. When examining data measurement levels and normal distributions, the data were not showed normal distributions. Therefore, the non-parametric Wilcoxon signed test was used. When the differences between groups were examined, it was found that the variables did not conform to normal distribution and so In interpreting the results a significance level of 0.05 was used and $p<0.05$ was taken as a significant difference.

Ethical considerations

Before starting the research, written permission was obtained from the Clinical Ethics Committee of Celal Bayar University Medical Faculty (Approval No:85.252.386), from the General Secretariat of the Manisa Province Public Hospitals Association of the Turkish Public Hospitals Foundation of the Ministry of Health, and from the Chief Physician of The Government Hospital. The patients receiving the subcutaneous heparin injections were not conscious, and therefore an explanation of the study was first given to their first-degree relatives or guardians, and they were asked to sign an approval from allowing the patients to participate in the study.

RESULTS

Patients' Socio-demographic and disease-related characteristics

The mean age of the patients was 71.55±11.65 years; 43.3% were aged 76 and over; 50% were female; 68.3% were married; 75.0% had no formal education; and 60% had a BMI which was above normal. It was found that 61.7% had medium-level neurological damage, 73.3% had a normal prothrombin count, and 50% had cardiovascular disease as a chronic illness (Table 2).

Table 1.Subcutaneous injection protocol for all patients

Heparin type	Enoksaparin Sodyum (Low Molecular Weight Heparin-LMWH)
Heparin dose	1 X 6.000 IU
Syringe type	Filled syringe
Amount of drug	0.6 ml
Needle number	25 gauge
Injection site	Abdominal area
Skin cleaning	Wipe with alcohol-soaked cotton swab, wait for drying
Needle entry angle to tissue	90˚
Bleeding control (Aspiration)	Not performed
Airlock	Performed using airlock in syringe (0.2-0.3ml)
Duration of drug administration	Drug injected over 30 seconds and needle left in tissue for 10 seconds before withdrawal
Post-injection site	Lightly pressed with dry cotton swab for 10 seconds

Table 2. Distribution of patients by socio-demographic and disease-related characteristics (n= 60)

Socio-demographic characteristics	***n***	***%***
Age group		
65 or less	20	33.3
66-75	14	23.3
76 and above	26	43.4
Age (Mean±sd): 71.55±11.65		
Gender		
Female	30	50.0
Male	30	50.0
Marital status		
Married	41	68.3
Single	19	31.7
Education		
Illiterate	13	21.7
Literate	32	53.3
Primary school	12	20.0
High school	3	5.0
Body Mass Index		
18.5- 24.9 (normal weight)	24	40
25-29.9 (overweight)	20	33
30-40 (obese)	16	27
Disease-related characteristics	***n***	***%***
Glasgow Coma Scale		
3-8 (significant neurological damage)	21	35.0
9-12 (medium neurological damage)	37	61.7
13-14 (slight neurological damage)	2	3.3
Prothrombin count		
High	16	26.7
Normal	44	73.3
Chronic illness		
Cardiovascular diseases	30	50.0
Neurological diseases	12	20.0
Metabolic diseases	9	15.0
Musculo-skeletal system diseases	3	5.0
Urinary system diseases	6	10.0

Patients' mean behavioral pain scores

The comparison of patients' mean behavioral pain scores was examined (Table 3), and a statistically significant difference a found between the cold application intervention (min: 4.00-max: 10.00) and the intervention without cold application (min: 4.00-max: 11.00) (z=-6.60, p=0.0001). Behavioral pain scores were seen to be significantly lower in the intervention with cold application (p<0.05).

The size of bruising 48 and 72 hours after heparin

The comparison of the size of patients' bruising 48 and 72 hours after heparin was examined. In the cold application intervention, a significant difference was found between the sizes of bruising in patients 48 and 72 hours after heparin (z=-6.2, p=0.0001). When cold application was not used, there was a significant difference between the sizes of bruising in patients 48 and 72 hours after heparin (z=-6.2, p=0.0001). With the cold application intervention, the size of bruising was seen to be significantly less at 72 hours than at 48 hours. With the intervention without cold application, the size of the bruising at 72 hours was seen to be significantly greater at 72 hours than at 48 hours. There was a significant difference between the sizes of bruising in interventions with and without cold application 48 hours after heparin (z=-6.8, p=0.0001), and 72 hours after heparin there was a significant difference between the sizes of bruising in interventions with and without cold application (z=-6.75, p=0.0001). When the sizes of bruising of the intervention with cold application and the intervention without cold application at 48 hours were compared, it was seen that the size of bruising in the intervention without cold application was significantly greater. When the sizes of bruising of the intervention with cold application and the intervention without cold application at 72 hours were compared, it was seen that the size of bruising in the intervention without cold application was significantly greater.

Table 3. Comparison of patients' mean behavioral pain scores (n=60)

Patients' behavioral pain scores							Wilcoxon signed test	
	n	Mean	Median	Minimum	Maximum	SD	z	P
With cold application	60	6.93	7.00	4.00	10.00	1.31	-6.60	0.0001*
Without cold application	60	8.62	8.00	4.00	11.00	1.35		

*P <0.001

Table 4.Comparison of bruise sizes 48 and 72 hours after heparin (n= 60)

Bruise sizes (mm)	With cold application				Without cold application				Wilcoxon signed test	
	Mean	SD	Median	Min-Max	Mean	SD	Median	Min-Max	z	P*
48 hours after heparin	3.14	1.00	3.00	1.50-5.50	5.19	1.12	5.25	3.00-7.00	-6.80	0.0001
72 hours after heparin	2.33	1.08	2.00	1.00-4.50	6.19	1.36	6.50	3.00-8.00	-6.75	0.0001
Test*	z= -6.2 P=0.0001*				z= -6.2 P= 0.0001*					

*P <0.001

DISCUSSION

Reduction of pain is important from the point of view of both the patient group and also the nursing group. There are various methods of reducing the pain of injections in intensive care. It is stated in the literature that cold application before and after an injection reduces the pain and bruising associated with it. [12,17]

Comparison of Patients' Mean Behavioral Pain Scores

It was found in the study that the pain scores in the intervention with cold application were lower than those in the intervention without cold application. The reason for this is thought to arise from the physiological effects of the cold application. The pain reducing effects of cold application are explained by the Melzack Gate Control theory. According to this theory, mechanical receptors in the skin, stimulated by local cold application, help to prevent the spread of pain to the T cells and to prevent the sensation of pain by stimulating the cells of the substantia gelatinosa. [17,37,40,41] Few studies were found in the literature examining the effect of cold application on pain and bruising in the administration of subcutaneous heparin injections in intensive care patients. [26-30] Examining these studies, it is seen that their mean pain scores are different because different pain scales such as VAS, the McGill Pain Scale and the Numeric Pain Scale were used to evaluate the pain of subcutaneous heparin injection in patients admitted to intensive care units with various clinical findings. However, it was seen in these studies that cold application reduced the pain of subcutaneous injection in intensive care patients. These findings corroborate the hypothesis that "with subcutaneous injections in intensive care patients, the intensity of the pain of injection is less in an area where cold is applied than in an area where it is not applied."

Also, examining study which investigated the effect on pain and bruising of subcutaneous heparin injection when different pain scales and different subcutaneous injection techniques were used, it was seen that cold application reduced pain. [16] It was also reported in studies comparing the subcutaneous heparin injection area in patients in clinics other than intensive care that patients felt less pain in subcutaneous injections in the abdominal region. [20,21] It is thought that the lower severity of pain in the abdominal region is because there are fewer nerve endings in that area. It was because studies had shown that less pain is felt in the abdominal region than in the arm that subcutaneous injections in this study were carried out in the abdominal region.

Examining studies in the literature, it is found that in administering subcutaneous heparin injections to patients in clinics other than intensive care, injecting a drug in 30 seconds [22,23] and injecting a drug in 30 seconds with cold application before and after the injection reduce pain, [17,24] while injecting a drug in 10 seconds and giving five minutes of cold application before the injection did not reduce pain. [25] Before commencing the study, literature relating to subcutaneous heparin injection was scanned and the pain severity and bruise size of injections with and without cold application using a standard injection technique were examined and research results and recommendations were noted. It was seen that pain was experienced and bruises formed in patients when no cold application was given even though a standard injection technique was used. However, it was determined that with the pain-reducing effects of cold application while using a standard injection technique, less pain was experienced and the size of bruising was less.

The size of bruising 48 and 72 hours after heparin

An investigation was made of the comparison of the size of bruises in patients 48 and 72 hours after heparin. It was seen that in the cold application intervention the size of bruises was less at 72 hours than at 48 hours ($p < 0.05$). In the intervention without cold application, the size of the

bruising at 72 hours was seen to be greater than at 48 hours ($p < 0.05$). In addition, it was seen that at 48 hours, the size of bruising in the intervention without cold application was greater than in the intervention with cold application ($p < 0.05$), while at 72 hours, the size of bruising in the intervention without cold application was found to be greater than in the intervention with cold application ($p < 0.05$).

It has been found in some studies that more than half of patients develop bruising after subcutaneous injections. [11,42] In the present study it was seen that the size of bruising in the area of the injection with cold application was min: 1.50-max: 5.50mm 48 hours after heparin and min: 1.00-max: 4.50mm 72 hours after heparin, while in the area without cold application it was min: 3.00-max: 7.00mm after 48 hours and min: 3.00-max: 8.00mm after 72 hours. It was seen from these results that bruising occurred in the injection area in all patients. It can be said from our results that in interventions with cold application the visible signs of bruising change over time and that the mean amount of bruising is reduced over time in connection with the effects of the cold application. These findings corroborate the research hypothesis that "in subcutaneous heparin injections in intensive care patients, the size of bruising in the area with cold application is less than in the group without cold application". This shows that the positive effect of cold application on bruising can be made use of in clinical applications. A very few studies were found in the literature examining the effect on bruising [30] and hematoma [28] of cold application in the administration of subcutaneous heparin injections in intensive care patients, but whether they used similar or different instruments to measure bruising, it was found in these studies that cold application reduced bruise formation or the size of bruises. It has also been found that bruise formation or the size of bruises was reduced in intensive care patients by the duration of subcutaneous heparin injection, [26,27,43] and in non-intensive care patients by cold application. [12,16,17] It has also been asserted that in administration of subcutaneous injections to the abdominal area bruising is less frequent or bruises are smaller than with injections to the arm or other areas such as the thigh [21] and that subcutaneous heparin injection duration of 30 seconds results in less frequent or smaller bruises. [10,17,22,24,44] These results are similar to those of the present study. These results, which confirm the positive effects of cold application on the formation of bruising in relation to its physiological effects, can be shown as evidence in nursing practices. The first reaction to cooling the skin in studies which have been conducted is vasoconstriction in surface arterioles. As a result of this, blood flow in capillaries in the area and capillary permeability are reduced, leucocytes leave the blood vessel wall with greater difficulty, and in this way hemorrhaging in reduced. This reduces the formation of bruising. [5,12,15,45] There are also studies which are dissimilar to the literature and to our study, planned with the aim of benefitting from the physiological effects of cold application on the skin and injection technique, but which at the same time were unable to obtain a significant difference. [5,20,46] It is thought that the dissimilarity between the results of these studies and those of our study arise from differences in the drug dose administered, the frequency, airlock and aspiration technique, the injection area, the duration of administering the drug, the time the needle was left in the tissue before withdrawal, and the bruise measuring instrument.

Limitations of the study

The results of this study cannot be generalized to all patients given subcutaneous heparin injections. It is thought that the data obtained as a result of this study can make a contribution as a method to reduce pain severity and protect from bruising when subcutaneous heparin injections are given to intensive care patients in all other hospitals. Also, it is believed that the results of this study can be a guide to the development of standard

nursing care protocols at all stages in the administration of subcutaneous heparin.

CONCLUSION

In this study, in which the effect of cold application on the pain and bruising of subcutaneous heparin injection in intensive care patients was examined, it was found that in an injection whose protocol included creating an airlock without aspiration, injecting the drug over 30 seconds, leaving the needle in the tissue for 10 seconds after injecting the drug and before withdrawing, and pressing the injection area with a dry cotton swab for ten seconds, cold application for two minutes before and two minutes after the injection reduced pain severity and the size of bruising 48 and 72 hours after heparin. These results show that as well as paying attention to injection technique, cold application is also important in reducing pain and the formation of bruises when nurses are administering subcutaneous heparin injections. Therefore it is recommended that in clinical application fields cold application should be included in the subcutaneous injection protocol.

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