

# **Effect of Cryotherapy Application Post Anticoagulant Subcutaneous Injection to Reduce Pain and Hematoma among Women: A Quantitative Study**

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## **I. Introduction**

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are examples of Venous thromboembolism (VTE). DVT is a blood clot that occurs in the deep veins in the body such as in the lower leg, thighs, arms or pelvis; however, it can also develop in the arms (CDC, 2020). While DVT and PE are predominantly dangerous and are often underdiagnosed medical conditions, they are treatable and preventable conditions (CDC, 2020). These conditions can lead to dangerous diseases, multi-organ failure, and in some instances death; however, they can be treated and prevented if diagnosed early (CDC, 2020). The incidence rate of PE/DVT in the United States, as well as the number of affected people with PE/DVT is unknown, although 900,000 people can be affected by 1 to 2 per 1000 people annually, claiming 60,000–100,000 Americans lives each year (CDC, 2020). According to the CDC (2020), 25% of patients with PE will experience sudden death. In the kingdom of Saudi Arabia, the rate of VTE is 25,000 annually affected (AlHameed et al., 2015).

Medication therapy is the primary treatment for this condition, while the drug administration depends on the accountability and safety of nurses (Amaniyan et al., 2016). The common forum of treatment for these conditions is anticoagulant therapy (CDC, 2020). The most common types of anticoagulant medications are heparin and low-molecular-weight heparin (Alabdahai, Mokabel and Al-ghuneimy, 2017). The evidence shows that low-molecular-weight heparin, namely, enoxaparin sodium, has an effect on clot formation and it has economical differences compared to standard heparin (Amaniyan et al., 2016). The method of medication administration can be an oral or parenteral route (Korkmaz Kilic and Sagkal Midilli, 2017). The parenteral route includes the subcutaneous injection, which is the usual route for administrating anticoagulant medications (Korkmaz Kilic and Sagkal Midilli, 2017). Nurses are primarily responsible for the preparation and administration of drugs; however, physicians and pharmacists also have equal responsibility (Korkmaz Kilic and Sagkal Midilli, 2017). The nurse has the responsibility of assessing the patient's response to treatment and recording any side effects.

Drug administration safety is one of the fundamentals of nursing practice and competency (Pourghaznein, Azimi and Jafarabadi, 2013). On the other hand, subcutaneous anticoagulant injections can cause local complications such as hematoma and pain at the injection site (Alabdahai, Mokabel and Al-ghuneimy, 2017). Based on the evidence, the occurrence rate of local hematoma after administering low-molecular weight heparin was reported to range between 40% and 88%, and 26.6% and 88.9% with bruising; these side effects ingrates the safety of medication administration as rejection of the treatment (Amaniyan et al., 2016). Consequently, this affects patients both psychologically and physically (El-Deen and Youssef, 2018). Furthermore, it results in the disruption of trust among patients that nurses are efficient in terms of their

competency and skills (El-Deen and Youssef, 2018). Occurrence of hematoma is a result of tissue injury due to administration of anticoagulant injections (El-Deen and Youssef, 2018). Therefore, it results in negative body image and anxiety, as well as affects compliance to treatment (El-Deen and Youssef, 2018). There are multiple suggestions regarding interventions that reduce pain and hematoma, although many institutions lack policy or a standard of care based on research.

The literature suggests methods to reduce these complications and side effects, such as needle length, injection timing, airlock and cold aspiration techniques (Korkmaz Kilic and Sagkal Midilli, 2017). Besides these injection techniques, cold application is an option for preventing these complications (Korkmaz Kilic and Sagkal Midilli, 2017). Based on the evidence, the application of cold therapy at the injection site has an effect on controlling bleeding through vasoconstriction in arterioles, thereby producing clotting by increasing viscosity so that the development of hematoma and bruising is reduced (Korkmaz Kilic and Sagkal Midilli, 2017). Pain occurs when the needle penetrates the skin; therefore, cold therapy also has an effect on pain through preventing spread of local pain. In addition, the pain can subside from the anesthetic effect of cold therapy (Korkmaz Kilic and Sagkal Midilli, 2017). Thus far, both hot and cold applications have been used as pain relievers. Both block stimulation and impulses related to pain. Cold application can be administered through different methods, such as ice bags, packs, gels and electronic cooling devices.

Cold therapy is used for acute injury and inflammation (Metules, 2007). Cryotherapy is a form of non-pharmacological management that has effects on pain, swelling, hematoma and bruising (Alabdahai, Mokabel and Al-ghuneimy, 2017). Cold therapy is a safe, inexpensive and simple practice (El-Deen and Youssef, 2018). The author found that cold application is an effective method for reducing and preventing hematoma at the site of injection (Alabdahai, Mokabel and Al-ghuneimy, 2017). Several studies have examined and compared the effect of cold therapy on the adverse effect of anticoagulant therapy, and have found that cryotherapy application has a positive impact on side effects (Korkmaz Kilic and Sagkal Midilli, 2017; El-Deen and Youssef, 2018).

## **II. Background**

The wide use of anticoagulants and the responsibility of nurses in safely administering medication makes it important to investigate methods in drug administration with the least risk for complication (Korkmaz Kilic and Sagkal Midilli, 2017). Subcutaneous injection of anticoagulants leads to reduced chance of clot formation during hospitalization and can also be used for therapeutic purposes (Amanian, Ghobadi and Vaismoradi, 2020). It can make the anticoagulant more effective, increase the bioavailability of the subcutaneous injection site, and reduce the frequency of the medication (Amanian, Ghobadi and Vaismoradi, 2020). Furthermore, it can simplify the process of administration and prescription (Amanian, Ghobadi and Vaismoradi, 2020). Conversely, the anticoagulant subcutaneous injection has side effects, such as local skin hematoma, lesions, pain and irritation (Amanian, Ghobadi and Vaismoradi, 2020). Additionally, it can lead to patients developing negative body image, higher anxiety, refusal of treatment, and to interrupt a nurse's competency in the administration of medication (Amanian, Ghobadi and Vaismoradi, 2020). For many years, hot and cold applications have had therapeutic impacts on pain relief and reducing swelling; based on their physiological effects, they have traditionally been used for these purposes (Korkmaz Kilic and Sagkal Midilli, 2017). Meanwhile, cold therapy has an impact on relieving complications resulting from subcutaneous injections.

The mechanism of cold application on the site of injection initially reduces the primary inflammatory phase of pain related to trauma. It can also be observed that cold application is simple, safe and effective (Rupam, Sheoran and Sharma, 2018). This is based on the idea that pain reduction should meet target standards of nursing care and patient comfort (Korkmaz Kilic and Sagkal Midilli, 2017). It is important to treat pain and alleviate patient discomfort, considering that pain and bruising are major complaints among patients who have received subcutaneous anticoagulant injections (Ahmadi et al. 2016).

Cryotherapy originates from the Greek phrase meaning 'cold cure' (El-Deen and Youssef, 2018). The purpose of cryotherapy is to reduce inflammation, pain and vasoconstriction, and thus increase the permanence of cells (El-Deen and Youssef, 2018). As found in previous studies, it is effective for pain and hematoma after the anticoagulant subcutaneous injections have been administered to the site (El-Deen and Youssef, 2018). This practice is safe and inexpensive, and can improve the quality of care and increase patients' rate of satisfaction in clinical settings (El-Deen and Youssef, 2018).

### *Statement of problem*

Through observation and exposure to the inpatient ward while working with women receiving low-molecular-weight heparin or heparin, the frequent and major complaint was local hematoma and pain at the injection site, even with a rotation of sites, due to a lack of record of these side effects or further interventions in place in health care settings to prevent or manage such complaints related to post-anticoagulant subcutaneous

injections. It is therefore important that the ideas proposed in the project be recognized and further explored. In Saudi Arabia, health care systems have demonstrated local improvement. Despite the improvement of care in the Kingdom of Saudi Arabia, there have been calls for health care to expand its research and continue to improve; these complaints were not recorded but had interfered with levels of patient satisfaction. In order to develop the country, complaints require practice guidelines to be addressed and prevented. For future research, the literature proposes some interventions to deal with these side effects, while the evidence represents conclusive impacts on managing adverse effects, such as cold therapy.

#### *Purpose of the Problem*

Based on the evidence, the current study will assess the effect of cryotherapy application on reducing pain and hematoma post anticoagulant subcutaneous injection among hospitalized women. The purpose of this experimental study will be to test the effect of cold therapy on experimental and control groups. The study will focus on pain intensity and the size or occurrence of hematoma compared to the control group. Regarding the clinical experience for bedside nurses, and practice-based nurses working with a patient receiving anticoagulant injections in which the most common and frequent complaints include pain and hematoma at the injection site, it is important to investigate methods to improve practices that lead to increasing patient satisfaction. This proposal therefore intends to implement the cold therapy guideline in Saudi Arabia. Cold therapy provides a safe and simple practice to decrease pain and hematoma. Consequently, the effect of cryotherapy on pain and hematoma among patients receiving subcutaneous anticoagulant injections must be studied in order to provide simple and effective practices in healthcare settings. It is important for nurses to explore and utilise the available evidence to establish simple and effective practices to improve and minimize the incidence of side effects in order to improve local and global healthcare standards. As such, the study will be carried out in Saudi Arabia to establish standard care for patients who are receiving subcutaneous anticoagulant injections, and to implement a database reporting the effects of cold therapy in order to increase the application of cold therapy for different conditions.

#### *Research question*

In women patients aged 18 to 45 years old who are receiving subcutaneous anticoagulant injections (P), is a 5-minute application of cryotherapy post subcutaneous anticoagulant injection on the left or right thigh (I) an effective treatment as opposed to routine care at the site post subcutaneous anticoagulant injection (C) to reduce pain intensity and size and occurrence of hematoma (O)?

### **III. Literature Review**

A literature review consists of an appraisal report of knowledge established in the literature that is relevant to the selected area of the project. This review appraises, evaluates and illustrates the basis of the research and will help to define the quality of future research. In this review of the literature of quantitative studies, the database accessed include PubMed, CINHL, Google Scholar, and the Saudi digital library using the keywords: 'effect', 'cold application', 'cryotherapy', 'subcutaneous injection', 'low molecular heparin', 'enoxaparin', 'anticoagulant', 'bruise', 'hematoma' and 'pain'. The date range was between 2013 to current research, since there are limited studies carried out in the last five years, which allows us to conduct more research to support the application in practice. Anticoagulants are widely used among patients as prophylaxis or treatment therapy. The most common side effect of these medications is pain and hematoma at the injection site (El-Deen and Youssef, 2018). The literature review identified several non-invasive techniques that reduce these side effects; for example, cold therapy is a non-pharmacological management that has effects on pain, swelling, hematoma and bruising. Some studies demonstrated the effect of cryotherapy on pain intensity and hematoma formation (Alabdhalhi, Mokabel and Al-ghuneimy, 2017). For the future research proposal, conceptual categories related to the topic of inquiry were compared with compound techniques to prevent pain and bruising of heparin subcutaneous injections, such as the effect of cold therapy application on reducing pain and hematoma for anticoagulant subcutaneous injections, the effect of cold-hot application on bruising post subcutaneous anticoagulant injection, and impact of cold therapy on pain severity and hematoma, before and after subcutaneous anticoagulant injection. A total of ten articles were reviewed, all of which were quantitative in design. The themes of the reviewed articles examined the effect of cold application on anticoagulant injections. There were no studies examining the timing of cold therapy application.

#### *Compound Techniques*

Şendir et al. (2015) conducted a study that examined slow and fast injections, as well as dry cold application. In a randomized controlled study, the researcher analyzed three methods of reducing pain and bruising post heparin injection in 60 orthopaedic patients divided into three experimental groups (the duration of injection 30-second, 30-second injection duration and 5 minutes of localized dry cold application and 10-

second injection duration without intervention (dry cold application). While the researchers found significant differences in pain and bruising among the three study groups, it was concluded that the 30-second injection duration and the dry cold application of 5 minutes before and after can have a successful impact on decreasing pain duration and incidence of bruising.

A similar quasi-experiential study compared four techniques in subcutaneous heparin affecting pain and bruising in which each participant received four different techniques for administering a subcutaneous heparin injection (injection without aspiration, the use of airlock without aspiration, injection with aspiration and without airlock, injection without aspiration and with airlock, and two-minute cold application) Conducted in Turkey with 95 participants, bruising was assessed at 48 and 72 hours post injection, while verbal pain was also measured. The researcher found that the technique of using heparin with air lock without aspiration along with a two-minute application had a benefit in reducing the bruising and pain resulting from the injection (Avşar and Kaşıkçı, 2013). Both studies agree with the findings regarding the positive effect of cold application on pain and bruising caused by anticoagulant subcutaneous injections.

On the other hand, Dadaeen et al. (2015) conducted a study to test the effect of injection duration on the extent of pain and bruising at the site of enoxaparin injections. It involved a convenient sampling technique of 100 participants, as well as a randomised, self-controlled clinical trial design, based on comparing the two methods of injection duration of 10-second and 30-second intervals administered to the experimental and control groups. Bruising was assessed at 48 and 72 hours, while pain was assessed immediately after injection. The study findings signify that increased injection length has an effect on reducing the pain and bruising at the site of enoxaparin injection.

#### *Cold Therapy Application*

Four studies examined the use of cold therapy application on pain and the formation of hematoma. Alabdahai, Mokabel and Al-ghuneimy (2017) focused on the effect pre- and post-cold therapy on decreasing pain and hematoma. In Saudi Arabia, the study was done to assess the impact of cold treatment of enoxaparin injection site on pain and hematoma

with a sample of 30 participants, in which the cold therapy was applied 5 minutes before and after injection, and found the cold application to have an effect on reducing pain and hematoma in patients who receive enoxaparin injections. The author recommended that proper education and explanation would reduce anxiety, which in turn would cause a reduction in pain intensity.

Similarly, Korkmaz Kilic and Sagkal Midilli (2017) found that a two-minute application of cold therapy administered to 60 patients in Turkey in an intensive care unit receiving heparin subcutaneous injections had significant reduction in pain and measurement of bruises, results which support the positive effect of pre- and post-cold application on subcutaneous injections. The author found the two minutes application of cold before and after injection has an effect on reduce pain and bruising size at 48- 72 hours post heparin injection.

Another quasi-experimental study was conducted at the medical ICU in a hospital at Mullana Ambala to examine and compare the effect of 20 minutes of dry cold application on pain intensity and bruising at different intervals (12, 48 and 72 hours after injection) among 60 hospitalised patients receiving subcutaneous injections and low-molecular-weight heparin. Findings showed that dry cold therapy had an effect on pain and bruising (Rupam, Sheoran and Sharma, 2018).

In this systematic review, the effect of cold application on bruising with heparin injections was demonstrated. This review thus provides vital knowledge regarding the prevention of bruising as a result of subcutaneous injections, which recommends that nurses use cold application to reduce side effects. Cold application is safe and inexpensive. The majority of the reviewed studies were in support, finding that cold therapy had a positive effect on the size and occurrence of hematoma (Amaniyan, Ghobadi and Vaismoradi, 2020).

#### *Cold-hot Application*

Conflicting research exists regarding the effect of the combined therapy of cold and hot application on the occurrence and the size of bruising as a result of enoxaparin sodium injections (Amaniyan et al., 2016; Ebrahimi-Shalmani et al., 2019). The author studies and compares the effect of local cold and cold-hot application with a sample of 180 participants enrolled in the study in an urban area of a Middle Eastern country. The research findings concluded that the localised cold-hot treatment was more effective than local cold treatment on decreasing bruises resulting from enoxaparin injections; therefore, this will lead to improving the quality of care (Amaniyan et al., 2016).

In addition, there were studies that combined cold application therapy after the injection and the application of cold-hot 12 hours after cold application for 20 minutes with a sample of 74 participants at Rasht hospital. The outcome of the study reveals that the use of local cold-hot applications compared to cold alone is effective in regard to the size of bruises as a result of enoxaparin sodium injections (Ebrahimi-Shalmani et al.,

2019). These findings challenge previous studies regarding the effect of cold application alone, and have shown that hot combined with cold-hot applications has an increased effect on bruise measurement.

#### *Comparison of Pre- Versus Post-Cold Application*

A study was conducted on the effect of cryotherapy on pain and hematoma. In a study conducted in Egypt to examine the effect of cryotherapy before versus after subcutaneous injection, they found no significant difference in pain intensity whether cryotherapy had been applied before or after injection. However, they found a significant difference in hematoma formation and size, and that applying cryotherapy after injection decreases hematoma formation (El-Deen and Youssef, 2018).

The reviewed studies were in agreement regarding the positive effect of cold therapy application on pain and hematoma size and occurrence. There was agreement between two studies using the same quantitative design for investigating the effect of cold therapy on pain and hematoma in which similar findings were reported (Korkmaz Kilic and Sagkal Midilli, 2017), (Rupam et al., 2018).

In contrast, two studies used the same design to examine the effect of cold-hot therapy; both studies used quantitative approaches, and divided their sample according to control and intervention groups. In addition, they conclude the same findings that the cold-hot application has positive effects on bruising (Amaniyan et al., 2016), (Ebrahimi-Shalmani et al., 2019). This showed disagreement in the reviewed literature. Since the studies did not report the duration of time for cold application, it is vital to establish standard periods of time to generalize the practice. In a study conducted by El-Deen and Youssef (2018), the findings were appropriate to the methodology, which was quasi-experimental. The author asserts the implication of cold therapy being an effective and safe technique post-anticoagulant injection (El-Deen and Youssef, 2018). On the other hand, some studies reported limitations, such as insufficient sample size and the application of practice in a single session, and recommended to repeat the study using a larger sample size and an alternative setting to generalize the practice (El-Deen and Youssef, 2018). In a study conducted in SA, the author found that cold therapy had an effect on pain and hematoma, which supports the proposed study focused on the same population (Alabdahai, Mokabel and Al-ghuneimy, 2017). However, the reviewed studies do not focus on issues related to the use of cold therapy or possible effects on patients to maintain patient safety. The research aims to establish the importance and applicability of the practice, as well as patient outcome to achieve medication compliance, reduce side effects and improve patient satisfaction. In summary, the reviewed literature supports the idea that cold therapy application has an impact on pain and hematoma reduction, and it is thus recommended by the research to establish general practices and applications in the healthcare system to improve the quality of care in both Saudi Arabia and the world.

#### *Conceptual framework*

The conceptual framework of the proposed project will be based on the 1963 book, *The Helping Art of Nursing Theory* by Ernestine Wiedenbach. The theory was selected because it focuses on patients' needs and complaints through observation, which is the main concern of this proposed study. Furthermore, it focuses on preventing such complications. The theory is based on three concepts of nursing practices: identification, ministraton and validation (Wiedenbach, 1963). According to Wiedenbach (1963), the essential nursing practice elements include identifying a patient in need of help, administering the help needed, and validating the motivation for help if indeed the help was needed. The framework will be implemented through these three theoretical concepts, in which identification includes observing patients' needs in order to study and conceptualise their conditions (Shijila and Tresa, 2016).

The identification phase is based on four different phases; the first phase depends on close observation of patient needs; the second is an interpretation of patients' behaviours confirmed by patients themselves, thus allowing the nurse to clarify what she observes; the third phase concludes the reasons for patient discomfort; and, finally, to determine whether the patient requires help (Wiedenbach, 1963). In this proposed study, the identification phase involves discussing the selection of patients who will be receiving anticoagulant subcutaneous injections (i.e., those who require help) based on the data collection of demographic and clinical variables and determining the help needed regarding intervention related to the injection sites (Shijila and Tresa, 2016).

After the need for help is identified, the next step is ministraton; in this phase, the nurse uses available resources and implements an action plan using her skills, knowledge and beliefs to achieve patient comfort (Wiedenbach, 1963). In this proposed study, the author randomly divided the sample into experimental and control groups in which a 5-minute cold application was administered to the experimental group of patients, with an assessment for hematoma and pain, which is the plan to provide comfort to patients (Shijila and Tresa, 2016).

The validation phase measures the improvement of the action (Wiedenbach, 1963). In this proposed study, discusses the evidence that current patients' needs are achieved and demonstrates the result of

ministration in regard to the effect of application of cold therapy on pain and hematoma (Shijila and Tresa, 2016).

#### **IV. Methodology**

##### *Aim*

To examine the effect of cryotherapy application on pain intensity and occurrence of hematoma as a result of subcutaneous anticoagulant injection.

##### *Objectives*

Assess baseline pain intensity post-anticoagulant injection among women in the gynae ward.

Assess baseline occurrence of hematoma post-anticoagulant injection among women in the gynae ward.

Evaluate pain intensity of anticoagulant injection post-application of cold therapy in women in the gynae ward.

Evaluate occurrence of hematoma resulting from anticoagulant injection post-application of cold therapy in women in the gynae ward.

##### *Research approach*

Through the use of statistics to test the effect of cold therapy, a quantitative research approach will be used. The proposed study intends to investigate the effect of a 5-minute cryotherapy application on post-subcutaneous anticoagulant injection sites to reduce pain intensity and occurrence of hematoma among women. A quantitative research approach will be selected to meet the study's objectives.

##### *Research design*

The research design used is a quasi-experimental (pre-test and post-test) control group design. In the proposed study, the sample will be selected by systematic randomized sampling, in which every participant is assigned to either an experimental or control group. To control unbiased representation of the groups using sampling technique to ensure that each participant has an equal probability of being allocated to one of the two groups. Cryotherapy will be applied to the experimental group for 5 minutes post-subcutaneous anticoagulant at the injection site. The post-test survey will be administered to both the study and control group to examine the effect of cryotherapy on pain intensity and incidence of hematoma post-subcutaneous anticoagulant injection.

##### *Setting*

The proposed study will be conducted in the King Fahad Medical City (KFMC) government hospital, in a women-specialised unit (WSH) with a gynae ward bed capacity of 19 beds in Riyadh city. KFMC hospital serves the Riyadh population, which is around 6.5 million as of 2017 ([Ruo.gov.sa](http://Ruo.gov.sa), 2017). It is one of the largest medical cities in the Middle East, with a total capacity of 1200 beds (KFMC Home, 2020).

##### *Population*

The target population for the future study includes women (pregnant or not pregnant) who are admitted and receiving subcutaneous anticoagulant injections during the study period. These patients routinely receive the anticoagulant as prophylaxis post-operatively, treatment for a coagulation condition during pregnancy, or treatment for venous thrombosis.

##### *Sample*

An approach of total systematic sampling of every other person will be used to capture the samples. The total target sample is 30 patients (15 participants for experimental group and 15 participants for control group) will be either pregnant or not pregnant women who are receiving subcutaneous anticoagulant injections and who have signed the Consent and Informational Letter for Participants within the data collection period. All 30 patients who are eligible according to inclusion criteria are randomly assigned to control and experimental groups.

##### *Inclusion criteria*

Have signed the Consent and Informational Letter for Participants see Appendix (A).

Patients are women who are receiving subcutaneous anticoagulant injections (heparin or low-molecular-weight heparin).

Aged 18–45 years old.

Conscious patients.

Normal PTT level and coagulation profile.

##### *Exclusion criteria*

Unconscious patients.

Allergy and blood-related diseases.

Discharged earlier than 72 hours.

Abnormality in PTT level or in other coagulation profile.  
Old scar tissue or hematoma at the site of injection.

#### *Study variable*

The independent variable in the proposed study will be the cryotherapy application. The dependent variable in the proposed study will be pain intensity and occurrence of hematoma among hospitalised women receiving subcutaneous anticoagulant injections.

#### *Data Collection*

##### *Data collection form*

The study variable of the data collection will be divided into parts. The first part includes demographic data, while the second part includes clinical data. They consist of two written English questionnaires, which will be translated to Arabic to be completed by the Arabic participants who complete the demographic profile and clinical profile questionnaires (see Appendix C and D), after sending request for permission to use data collection questionnaires (see Appendix B) (Shijila and Tresa, 2016). The assessment will be documented at 24, 48 and 72 hours for the hematoma and pain to take place before receiving the injection to obtain baseline data, immediately after, and 5 minutes after receiving the injection for both groups.

#### *Tools/instruments*

Tools will be used for the proposed study after sending a request for permission to use data collection instruments (Shijila and Tresa, 2016) (see Appendix B), and two scales (numerical rating scale and transparent ruler). These tools have been selected based on the literature. Hence, these tools will be used for data collection to examine the effect of cryotherapy on reducing pain intensity and occurrence of hematoma among hospitalized women receiving subcutaneous anticoagulant injections.

#### *Questionnaire on demographic profile (see Appendix C)*

Demographic profile contains five items: age, educational status, marital status, religion, language and occupation.

#### *Questionnaire on clinical profile (see Appendix D).*

Clinical profile contains seven items: medical diagnosis and gestational age (if pregnant), name of injection, dose, frequency of injection, PTT level (if done) and medical history.

#### *Numerical Pain Rating Scale (see Appendix E).*

The numerical pain rating scale will be used to assess pain intensity among hospitalized women before and after receiving subcutaneous anticoagulant injections. Pain intensity will be assessed in patients who are receiving the injection into the right or left thigh. The scale has five divisions; for example, 0 refers to no pain, 1–3 refers to mild pain, 4–6 refers to moderate pain, 7–8 refers to severe pain, and 9–10 refers to unbearable pain. Using a score of 0–10, the Arabic language pain assessment version will be considered.

#### *Transparent Ruler (see Appendix F).*

Hematoma is defined as blood collection outside the blood vessels due to injury of the blood vessel wall (El-Deen and Youssef, 2018). Therefore, hematoma will be assessed at 24, 48 and 72 hours from point of occurrence or size. Hematoma will be classified as follows: pink, red, blue, purple, light green, yellow and brown at the selected injection site (El-Deen and Youssef, 2018). In order to assess the size of hematoma, the ruler will be used to assess patients who are receiving the injection into the right or left thigh. The interpretation of the ruler measurement consists of the length and width of hematoma in which the total will be calculated in  $\text{cm}^2$ . The area=length X width (lxw)(Shijila and Tresa, 2016, p.36-38).

#### *Validity and reliability of the tools.*

Validity means that a tool will accurately measure what it intends to measure. The tool will be validated by expert nurses and researchers by allowing them to offer their suggestions regarding suitability, relevance, reliability and stage of compact in each section of the tool. The instructions and expert guidance will be approved and modified. According to Shijila and Tresa (2016), content validity is high if reported to be 0.83 according to the content validity index interpretation. The test and re-test reliability will be calculated for the pain numerical rating scale (Shijila and Tresa, 2016).

#### *Inter-rater reliability*

Train two nursing staff on the measurement of the pain scale, which is the numerical rating scale from 0–10 and its interpretation as defined above, along with size of hematoma measurement in centimeters (multiplying the length by width of the area), the injection technique for the subcutaneous injection, as well as the presence of

hematoma according to the documentation criteria.

#### *Ethical considerations*

Ethical approval will be submitted to the Institutional Review Board (IRB), which will be offered to King Fahad Medical City. Afterwards, the approval for this proposed study will be accepted by the hospital ethical committee and research center in King Fahad Medical City. Participants who have met the inclusion criteria will be enrolled in the proposed study. The researcher will insure that they have full acknowledgment and awareness of the research process and objective. Participants will be informed that they can withdraw from the study at any time and for any reason, and that the information will be confidential for those who will be enrolled in the study.

#### *Data Collection Procedure*

This study will be conducted in three stages:

##### *Assessment stage:*

The study will be conducted for three months at KFMC (gynae ward) in Riyadh. The sample will consist of 30 patients who are eligible and have signed the Consent and Informational Letter for Participants (see Appendix A) to be included in the study. Using systematic randomization, each person will be placed into either the control group or experimental group after the researcher interviews each participant and explains the aim of the study and procedure. The participant will enroll in the study and will complete two questionnaires (the demographic profile and clinical profile). The clinical questionnaire will be completed and assigned by nurses involved in the research and will then be collected during admission once meeting the inclusion criteria. The injection site will be assessed for any previous scars or hematoma before administration. The injection site will be selected on either thigh (left or right).

##### *Intervention stage:*

###### *injection technique*

The injection will be given slowly over 30 seconds using a stopwatch, with a prefilled syringe and an insertion angle of 90 degrees, with no aspiration prior to injection. The syringe will be held between the thumb and index finger (El-Deen and Youssef, 2018).

#### *The cryotherapy application procedure*

At this stage, the researcher or trained nursing staff will administer the injection by following the injection technique as mentioned above. The pre-pain assessment will be assessed for both groups before administering the injection. After the injection is administered by trained nurses, a cotton balls will be placed on the site of injection and will be removed without massage or rubbing being applied to the site. A circle will be drawn with a marker to assess the presence or size of hematoma for all participants. The patient will be instructed to abstain from itching, touching or massaging the injection site. The pain will be assessed immediately after withdrawing the needle. Next, a plastic ice-filled bag rubbed with dry gauze will be applied for 5 minutes at the injection site of the right or left thigh of participants in the experimental group by the researcher or trained nurses for 3 consecutive days for patients who will be hospitalized for 4 days, and for 2 consecutive days for patients who will be hospitalized for 3 days. An individualized ice bag will be labelled with the name of each participant to avoid transmitting infection (El-Deen and Youssef, 2018). For controlling confounders, pain will be assessed prior to injection and both groups will receive the injection using the same injection technique.

#### *Assessment stage*

Post-testing will be done for both groups to assess pain intensity at the injection site at 4 hours and 8 hours according to the numerical rating scale. The size of the hematoma will be assessed using a transparent ruler along with occurrence, as mentioned above, at 24, 48 and 72 hours for both groups.

#### *Data Analysis Plan*

After collecting the data from the 30 participants receiving heparin or low-molecular-weight heparin, the data will be analyzed to assess the aim of the study on the effect of cryotherapy application on pain intensity and the occurrence of hematoma with subcutaneous anticoagulant injections at King Fahad Medical City, Riyadh. Thirty patients selected by systematic randomization sampling will be women, based on randomized assignments into experimental and control groups. The application of cryotherapy will take place for 5 minutes at the injection sites for the study group. The descriptive statistics include the means, standard deviation and ranges. Inferential statistics are used to examine the objective, such as analysis of variance test (ANOVA) (Creswell, 2018). The data of quantitative experimental design will be entered into the computer program, Statistical Package for Social Sciences (SPSS, recent version) (IBM: SPSS trials) (Alabdahai, Mokabel and Alghuneimy, 2017). The descriptive statistics of the demographic and clinical variables will be ranked to summaries the data. The ANOVA nonparametric statistical test (Kruskal-Wallis Test) will be used to assess and compare the effect of cryotherapy on pain intensity before the injection, immediately afterwards, after 4 hours



and after 8 hours, along with hematoma occurrence and size for both experimental and control groups (El-Deen and Youssef, 2018). As such, should the Kruskal-Wallis Test finding present significant statistics, the Mann-Whitney will be used to compare the difference between the two groups at the same assessment range for pain and hematoma. Afterwards, the Chi-square will be used to test the relationships between categorical variables; the formation of hematoma at 24, 48 and 72 hours after the injection for both groups, as well as pain intensity before, immediately after and 4–8 hours after injection for both groups. The P value will be computed at  $P < 0.05$  (El-Deen and Youssef, 2018).

The expected outcome will be divided into the following categories: the first and second section include the demographic clinical variable of patients receiving heparin and low-molecular-weight heparin in both experimental and control groups. The third and fourth section consist of assessment of pain intensity and occurrence and size of hematoma after application of cryotherapy among patients receiving heparin and low-molecular-weight heparin in both experimental and control groups. The fifth and sixth section include the effect of cryotherapy on pain intensity and occurrence and size of hematoma among patients receiving heparin and low-molecular-weight heparin in both experimental and control groups. The findings of the pain and hematoma assessment will be analysed in the right and left thigh (Shijila and Tresa, 2016).

The data of pain assessment before injection, immediately after, 4 hours after and 8 hours after injection will be based on numerical data and will be categorized as either no pain, mild pain, moderate pain, severe pain or unbearable pain after dividing the pain intensity according to the assessment periods and injection sites as right thigh and left thigh for both groups, while present of hematoma will be document as the recorded color above and size will be based on the size of the area after 24, 48 and 72 hours by using the transparent ruler that will be calculated in  $\text{cm}^2$  afterwards according to the assessment periods and injection sites of right thigh and left thigh for both groups.

Additionally, analyzing the effect of cryotherapy on pain will be done by comparing the two groups at the two different injection sites; namely, the right or left thigh. Finally, the effect of cryotherapy on hematoma between two groups at the two different injection sites (the right thigh and left thigh) will be compared. As such, the author will test the objectives (Shijila and Tresa, 2016). The proposed study will be conducted within 3 months after obtaining the Consent and Informational Letter for Participants who meet the inclusion criteria, and have completed the both the demographic and clinical profile questionnaires. The application of cryotherapy and the assessment of the variable will take place during which the data will be collected. Finally, the data will be analyzed through the interpretation process (El-Deen and Youssef, 2018). A backup of the recorded data will be ordered along with the analysis operation. The collected data will be confidential and remain in a secure place to maintain confidentiality.

#### Anticipation of results

According to the evidence produced by studies establishing the effect of cold therapy on reducing pain and hematoma as a result of subcutaneous anticoagulant injections, it is expected that this proposed study will prove the positive impact of cold therapy. Based on the findings of previous studies indicating that the pain scores of the experimental group using cold therapy were significantly lower than the control group, it can be argued that cold therapy has physiological effects (Korkmaz Kilic and Sagkal Midilli, 2017). The expected results of the proposed study will be supported by the previous study findings, such as the study by Rupam et al. (2018), who found positive effects of cold application post-injection on pain and hematoma based on statistical differences between the intervention and control groups.

Similarly, in studies examining the effect of cold therapy on pre- and post-injection sites, there were no differences between applying the therapy before or after; however, in both cases there was an effect on pain and hematoma (El-Deen and Youssef, 2018). According to El-Deen and Youssef (2018), definite subcutaneous injection techniques has an effect on decreasing pain and hematoma; these findings will be followed up in this study, as mentioned in the methodology. In addition, the results indicating the analgesic effect of cold leading to pain relief was supported (El-Deen and Youssef, 2018).

On the other hand, there were several studies examining the effect of cold application on bruising reviewed by Amaniyan, Ghobadi and Vaismoradi (2020) that emphasised the significant effect of the therapy on the occurrence and size of bruising. The importance of the application therapy to the practice was therefore mentioned (Amaniyan, Ghobadi and Vaismoradi, 2020). These current findings will prove the study outcome in monitoring the pain before, immediately after, 4 hours and 8 hours' post-injection, as well as monitoring hematoma size and occurrence after 24, 48 and 72 hours. As such, the main goal of the proposed study is to achieve the establishment of new practices that help patients by improving their care and level of satisfaction. Based on the reviewed literature, the effect of cold therapy has a positive impact on pain and hematoma at the injection site of anticoagulants. Furthermore, this proposed study is based on previous research. It will therefore be applied to other populations as in the proposed study, and will include pregnant and non-pregnant women. It will be evidence-based and will apply it to practice, thus generalizing the practice to standard care. In addition, it

intends to handle real problems within the healthcare setting. Finally, it is one of the interests of the author in conducting future research.

## **V. Discussion**

Subcutaneous anticoagulant injections are used to inhibit coagulation in the blood. These injections cause the local onset of pain and the development of hematoma (Yi et al., 2016). The discussion evaluated the result of the effect of five minutes of cold application post-subcutaneous anticoagulant injection. In the proposed study, the aim focuses on reducing pain intensity and hematoma formation post-anticoagulant subcutaneous injection through the application of cold therapy at the injection site among hospitalized women. As found in previous studies, it is confirmed that there is a positive effect on pain and hematoma after cold application on the anticoagulant subcutaneous injection site (El-Deen and Youssef, 2018; Alabdhalhi, Mokabel and Alghuneimy, 2017). Pain and hematoma are significant complaints that should be addressed and treated, which demonstrates the importance of this proposed study to achieve greater patient satisfaction and improve the quality of nursing care.

### *Limitations of study*

In the proposed study, there are limitations due to the implementation of a single health care setting, as well as a focus on a single gender. Another limitation is the small sample size. These limitations will therefore interfere with the stability and generalization of the findings. Furthermore, there is a lack of standard injection techniques in real practice, which will be implemented in this future study. Additionally, there is a lack of previous records regarding the presence of pain and hematoma as a result of subcutaneous anticoagulant injection.

### *Future research*

Based on the expected outcome of this proposed study, cold therapy will become standard care for patients who have received subcutaneous anticoagulant injections. Future research must therefore establish the stability of the effect of cold therapy on reducing pain and hematoma among patients who will receive subcutaneous anticoagulant injections in the future (El-Deen and Youssef, 2018). It is also recommended that the study be replicated to include different genders and multiple healthcare originations in order to generalize the practice across different regions, and to expand research to determine the possible risk involved in the use of cold therapy.

### *Implications for nursing practice*

The future study outcomes will be implemented for health care practitioners and nursing research. Pain and bruising are the most repeated complaints among patients who receive subcutaneous anticoagulant injections. Utilizing the evidence for simple and effective techniques is one of the foundational and critical tasks for the nursing profession (El-Deen and Youssef, 2018). As such, nurses will be able to implement cold therapy post-injection to reduce pain and hematoma. Applying the evidence to practice regarding technique to reduce the hematoma and provide pain relief is important for the improvement of nursing practice and patient satisfaction. Therefore, it will help to implement non-invasive, effective, inexpensive, and straightforward practices to educate and introduce to all age groups.

## **VI. Conclusion**

It can be concluded from the findings of previous studies that the application of cryotherapy has a significant effect on decreasing pain intensity and hematoma formation at the site of an anticoagulant subcutaneous injection. Cryotherapy is an inexpensive, safe and effective technique. Hence, its straightforward application and the available supporting evidence can make a significant impact on nursing care and patient satisfaction level. In addition, cold therapy is one of the interventions that can be decided by nurses. Cold therapy has positive effects on pain and hematoma. It is therefore important to highlight the implementation of the practice in a clinical setting in order to improve clinical and nursing care, as well as patient care and overall satisfaction. Moreover, to support the implementation, the future study will be conducted through true experimental design to present the expected outcome and improve nursing care. The findings of the study are crucial for the growth and development of the nursing practice. The establishment of evidence-based practice has significant value in the improvement of the nursing profession. Today, nurses adopt a developmental approach, aiming to achieve standard and specialized care based on current best practices. For instance, nursing that engages and participates in nursing research can make use of powerful databases in delivering patient care and improving the nursing profession. Evidence-based practices (EBP) move nurses toward the developmental approach, with the aim of obtaining standard guidelines and particular care depending on the best current evidence in providing patient care. Furthermore, hospitals tend to achieve international accreditation and quality

patient care, as evidenced by the presence of research centers and library facilities within healthcare organization centers. As such, both nurses and the healthcare organization will achieve improved national and international standards for the development of care.

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**Appendices(A)**

*Consent and Informational Letter for Participants*

Date 01-07-2020

My name is Khaznah Alanzi from Princess Nora Bint Abdul Rahman University in collaboration with Dublin City University Masters in Nursing program and I am conducting a research study about Effect Of Cryotherapy Application Post Anticoagulant Subcutaneous Injection To Reduce Pain And Hematoma Among Childbearing Women. The purpose of this research is to evaluate the effect of cold application on the sites of injection. This research will help health care providers discover the effect of cold therapy on pain and hematoma. The aim of this research is to examine the effect of cryotherapy application post subcutaneous anticoagulant injection on pain intensity and occurrence of hematoma.

I am requesting your assistance in my research by completing a survey that should take approximately 10 minutes. Your participation is completely voluntary, and you may withdraw from the study at any time.

The benefit to you for participating is knowing you contributed to research that may improve the care toward the care post subcutaneous anticoagulant injection. The risks involved in this study are minimal and no more than one would experience during normal daily activities. There may be the risk of emotional stress when asked about your medical condition or pain. The remedy would be to skip any questions you choose to or discontinue participation in the survey. There are no other known adverse effects of participating in this study. Responses will be completely anonymous, and your name will not appear anywhere in the final write up of the survey results. All documents related to the study will be kept completely confidential in locked storage and only accessible to the researchers. Completion and return of the survey conveys agreement to participate. In addition, please sign below to consent to participate.

If you have any questions regarding this research, please contact me khaznah at (966500571970) or by my email ([khaznaha@gmail.com](mailto:khaznaha@gmail.com)). If you have any questions regarding your rights as a research subject, please contact the Health Sciences Research Center (HSRC) University Division of Research at ([hsrc@pnu.edu.sa](mailto:hsrc@pnu.edu.sa)/ 44768).

Name of student: Khaznah Alanazi.  
Masters Student, Nursing.  
PNU/DCU College of Nursing  
Address of School: Riyadh city.  
Email; ([khaznaha@gmail.com](mailto:khaznaha@gmail.com))  
Cell phone: (966500571970)

*Informed Consent Signature.*

I, \_\_\_\_\_ (Print Name) hereby consent to participate in this study about Effect Of Cryotherapy Application Post Anticoagulant Subcutaneous Injection To Reduce Pain And Hematoma Among Childbearing Women. I have been informed of the purpose, risks, and benefits of the study and understand I may withdraw from this study at any time.

\_\_\_\_\_  
(Signature)

Appendices(B)

Request for Permission to Use Data Collection Instrument

Date 01-07-2

My name is Khaznah Alanazi from Princess Nora Bint Abdul Rahman University in collaboration with Dublin City University Masters in Nursing program and I am conducting a research study about Effect Of Cryotherapy Application Post Anticoagulant Subcutaneous Injection To Reduce Pain And Hematoma Among Childbearing Women. The purpose of this research is to to evaluate the effect of cold application on the sits of injection. This research will help health care providers discover more about effect of cold therapy on pain and hematoma post subcutaneous anticoagulant injection. The aim of this research is to examine the effect of cryotherapy application post subcutaneous anticoagulant injection on pain intensity and occurrence of hematoma.

I am requesting your permission to use Demographic and clinical questioner and instrument of which you are the creator. The Numerical Pain Rating Scale instrument is well suited for my proposed study about the effect of cryotherapy application post subcutaneous anticoagulant injection on pain intensity and occurrence of hematoma because of the same interest in the same topic.

I appreciate your kind consideration for this permission. Please email me with any questions you may have about my proposed research.

Thank you.

Best regards,

Name of student Khaznah Alanazi.  
Masters Student, Nursing.  
PNU/DCU College of Nursing.  
Address of School (Riyadh city).  
Email: khaznaha@gmail.com.  
Cell phone :(966500571970).

Appendices(C)

*Dear participants.*

We would be grateful if you would complete this questionnaire and return it to us. We ask about your general information. Our goal in this questioner to establish baseline data about the participants. Your answers will be strictly confidential and will be used for academic and researcher purposes only. Thank you for your help.

Demographic Variables (Shijila and Tresa 2016, p.22):

Participant Number:

Control or experiment group.

1.Age:

- A). Above 18 years.                      B).18-20 years.  
C).20-30 year.                            D).30- 45 years.

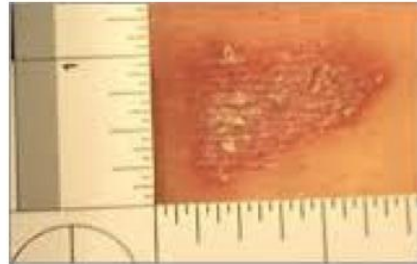
1. Educational status

- A). Illiterate.                              B). Primary school.  
C). High school.                          D). Higher secondary.



Appendices(F).

*Transparent Ruler Scale (Shijila and Tresa 2016, p.25).*



(Khaznah Alanazi). “Effect of Cryotherapy Application Post Anticoagulant Subcutaneous Injection to Reduce Pain and Hematoma among Women: A Quantitative Study.” *IOSR Journal of Nursing and Health Science (IOSR-JNHS)*, 10(05), 2021, pp. 49-63.