International Journal of Nursing Sciences xxx (2018) 1–7

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Contents lists available at ScienceDirect

International Journal of Nursing Sciences

journal homepage: http://www.elsevier.com/journals/international-journal-of-nursing-sciences/2352-0132

Original Article

The effect of cryotherapy application before versus after subcutaneous anticoagulant injection on pain intensity and hematoma formation: A quasi-experimental design

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ARTICLE INFO

Article history:
Received 24 August 2017
Received in revised form
11 May 2018
Accepted 11 July 2018
Available online xxx

Keywords:
Anticoagulants
Cryotherapy
Hematoma
Injections
Subcutaneous
Pain

ABSTRACT

Objective: To investigate the effect of cryotherapy application before versus after subcutaneous anticoagulant injection (SCAI) on pain intensity and hematoma formation.
Methods: A quasi-experimental design was utilized. A convenient sample of 105 adult patients, who were admitted to one of the biggest teaching hospitals in Cairo and receiving SCAI, were recruited over a period of six months. Patients were randomly allocated into three groups: A Control group who received the routine hospital care (G1,$n = 35$) and two intervention group who received cryotherapy for 5-min (G2: cryotherapy applied before SCAI, $n = 35$; G3: cryotherapy applied after SCAI, $n = 35$). Demographic and medical history data sheet, Pain Numeric Rating Scale and Hematoma Formation and Size Assessment Scale were used to collect the data.
Results: The pain intensity among the patients in the two intervention groups (G2: *Median* = 1.0; G3: *Median* = 0) was significantly lower than in the control group (G1, *Median* = 3.0). No significant difference was found between G2 and G3($P = 0.728$). Applying cryotherapy after SCAI (G3) decreased the frequency of hematoma formation (48hrs = 31.4% & 72hrs = 28.5%) compared to applying it before injection (G2, 100%) or not applying it (G1, 100%). The size of hematoma in G3 was smaller than that in G2 ($P < 0.01$).
Conclusion: Applying cryotherapy significantly decreased pain intensity and hematoma occurrence/size. Applying cryotherapy after injection was more effective in preventing hematoma formation and decreasing its size than applying it before injection.

1. Introduction

Anticoagulant is frequently prescribed as prophylaxis or treatment for venous thromboembolism. However, subcutaneous injections (SCI) of anticoagulant often cause complications such as pain and hematoma at the injection site. Previous studies indicated that complications of subcutaneous anticoagulant injections (SCAI) such as hematomas and pain increased the patients' physical and psychological discomfort [1]. Moreover, it may result in the patients' distrust in nurses' competency, which may consequentially result in the avoidance of future injections [1,2].

Hematomas occur frequently because of local tissue injury that follows the administration of an anticoagulant solution [3]. It may lead to anxiety, body image disturbance and rejection of the treatment in patients. Moreover, it can also reduce the opportunities for site rotation for future subcutaneous injections [2,4]. Therefore, nurses should consider the factors that minimize subcutaneous injection complications, including the intensity of site pain and hematoma formation [5].

Several nursing measures have been found to be essential to avoid the occurrence of hematomas and local pain intensity during injection; such as the injection site, injection angle, aspiration before the injection, needle's size, duration of injection, use of an air bubble, and the application of cryotherapy [5–7]. Additionally, injections in the lower abdominal wall, the insertion of the needle into the tissue at a 90° angle, grasping the tissue of injection and injecting the drug without aspirating have been found effective in

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Peer review under responsibility of Chinese Nursing Association.

https://doi.org/10.1016/j.ijnss.2018.07.006

Please cite this article in press as: El-Deen DS, Youssef NFA, The effect of cryotherapy application before versus after subcutaneous anticoagulant injection on pain intensity and hematoma formation: A quasi-experimental design, International Journal of Nursing Sciences (2018), https://doi.org/10.1016/j.ijnss.2018.07.006

reducing pain and hematoma formation [6].

"Cryotherapy" is a Greek word that means cure-using cold. Cryotherapy aims to reduce inflammation, decrease spasm and pain and stimulate blood vessel constriction (vasoconstriction), so it can increase the survival of cells. It is currently debated whether applying cryotherapy at the injection site is effective in decreasing pain intensity and hematoma size [5,8,9]. Cold has a physiological effect that can avoid SCAI related complications by increasing vasoconstriction at the injection site and the inflammatory process. These physiological changes decrease the incidence and size of hematomas. Cold also prevents the intensity of pain through its effect on sensory nociceptors by decreasing the conduction time and the synaptic activity in peripheral nerves. When heat in the nerves is reduced, a decrease in the sensory and motor conduction velocities is observed; thus, the intensity of pain is prevented [3,9,10].

The SCAI is a frequently performed nursing task. The incidence of local hematomas as a result of SCAI varies considerably, as reported in previous studies, where it ranged from 20.6% to 88.9% after SCAI [2,11]. It is really a serious problem, especially for those patients who are scheduled for SCAI over a long time or those who had other SCI, since it can reduce the opportunities for site rotation for future subcutaneous injections as well as affect nurses' quality of care. Therefore, it was crucial to investigate methods to decrease hematoma formation. There is a growing research interest to investigate the effect of cryotherapy application before and after SCAI on pain intensity and incidence of hematoma formation [3,7,12–14]. However, the findings are still contradictory, and there is not enough supporting evidence for the effectiveness of cryotherapy as well as too many methodological limitations and not enough details about the procedure or comparison between the two methods. In addition, there was no available research before conducting the current study, which compared the application of cryotherapy before versus after SCAI in order to prove which time is most effective in reducing pain intensity and the incidence of hematoma formation. Cryotherapy is a safe, noninvasive, pain free, easy to self–administer therapy. It can enhance patients' sense of control over their management of side effects, is cost effective and improves the quality of life. It is also an innovative idea to involve patients in their own care to play a major role in relieving their distressing symptoms through a simple procedure like cryotherapy.

Therefore, this study aimed to investigate the effect of cryotherapy application before versus after SCAI on pain intensity and hematoma formation. In order to accomplish this study aim, five hypotheses were formulated:

H1. The study group who received cryotherapy will have a significant lower pain intensity than the control group who received routine hospital care.

H2. There will be a difference between applying cryotherapy before versus after SCAI on pain intensity among the intervention groups.

H3. The study group who received cryotherapy will have a significant lower incidence of hematoma formation compared with the control group who received routine hospital care.

H4. The study group who received cryotherapy will have a significant smaller size of hematoma than the control group who received routine hospital care.

H5. There will be a difference between applying cryotherapy before versus after SCAI on hematoma formation and size among the intervention groups.

2. Material and methods

2.1. Study design

A quasi-experimental design was utilized to accomplish this study's purpose.

2.2. Participants and sample size

The study participants were adult male and female patients who were receiving SCAI. In total, 133 who met the inclusion criteria over a period of six months (January to June 2017) were invited to participate in the study. Patients were eligible to participate if they were 18 years or older, were alert to be able to express pain, agreed to give informed consent, and received subcutaneous injection of 40 mg enoxaparin with the volume of 0.4 or 60 mg enoxaparin with the volume of 0.6 ml once per day. Patients who had any of the following criteria were ineligible to participate: (1) discharge earlier than 72hrs, (2) any impairment in coagulation profiles such as thrombocytopenia, prothrombin time, platelets count, International Normalized Ratio, (3) Liver function disturbance, (4) Scar tissues or old hematomas at the site of injection, and sensory alteration.

The study sample was calculated based on a pilot study of 12 patients with considering r = 1 (equal sample size for each group), a = 5% and power at 90% were computed using the following formula:

$$N = \frac{(r+1)\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{rd^2}$$

Where the σ and d are the standard deviation and difference of means of two groups, $N = (1 + 1)\ (1.96 + 0.84)^2\ (1.2)^2/[1 \times (1.6–1.4)^2]$.

Then, for 90% of statistical power, the sample size for each group would be 21. An extra, 10–20% of subjects were required to allow for the adjustment of withdrawals, missing data, lost to follow-up [15]. After calculating the required sample size, a block randomization technique was used to allocate the patients into either intervention group (pre or post cryotherapy) or control group, to ensure a close balance of each group size [16]. This technique was used to insure every patient had an equal probability of being assigned to any of the three groups, and to control an unbiased representation of the groups.

Out of 133 patients who were invited and met the inclusion criteria, 128 accepted to participate with a response rate of 96.24% at the baseline phase. Only 105 patients participated three times (response rate 82.03%) and were involved in the data analysis. Based on this sample ($n = 105$), three groups were investigated in this study: (1) Control group [G1, $n = 35$], who received routine hospital care (RHC) and (2) two intervention groups [G2, $n = 35$ & G3, $n = 35$], who followed RHC alongside 5 min cryotherapy application. G2 received 5 min cryotherapy before SCAI, and G3 received cryotherapy after SCAI (Fig. 1).

2.3. The study setting

The study was conducted in the medical, surgical, cardiovascular and orthopedic wards ($n = 8$ wards) in one of the biggest Teaching Hospitals in Cairo City, Egypt. These wards were selected because admitted patients were usually receiving SCAI as a prophylaxis or treatment medicine.

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