



## **APPLICATION OF COLD COMPRESS DURING FEMORAL SHEATH REMOVAL ON PAIN AND VASOVAGAL REFLEXES IN PATIENTS AFTER PERCUTANEOUS CORONARY INTERVENTION (PCI): A SYSTEMATIC REVIEW**

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### **ABSTRACT**

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Pain due to manual compression during femoral sheath removal procedure is one of the most common problems experienced by patients after transfemoral PCI. Vasovagal reactions may occur when pain during the procedure is not controlled effectively. A non-pharmacological intervention to reduce pain in patients after PCI that has been widely studied is an application of cold compress. Objective: to evaluate the application of cold compress during the femoral sheath removal procedure on pain and vasovagal reflexes in patients post-PCI. By searching literature for research articles related to topics based on research questions using the PICO formula through online databases including ProQuest, PubMed, ScienceDirect, Sage Journal, Scopus, ClinicalKey Nursing, and Google Scholar. Based on a review of research articles, it is known that the application of cold compress has an effect to reducing pain during femoral sheath removal after PCI. However, there has yet to be much evaluation of the effect cold compress on reducing the vasovagal reflexes. Cold compress can be a simple and low-cost intervention to applied during femoral sheath removal procedures after PCI, and also can be combined with other interventions to reduce pain level. There are differences in carrying out cold compress application procedures, especially regarding the time, tools and the procedures. More research is needed to identify the effectiveness of cold compress on the vasovagal reflexes in post-PCI patients, because only one study has been found that assesses the effect of cold compresses on the vasovagal reflex, which is still requires more evidence based, and also researches to identify differences of the effectiveness cold compress between the times of administration, namely before, during, or after femoral sheath removal procedures post-PCI to further strengthen the evidence-based practice.

#### **Keywords:**

Cold compress, Pain, PCI, Vasovagal reflexes

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## BACKGROUND

Coronary Heart Disease (CHD) is still the highest cause of death in the world, reaching 17.9 million deaths or one of three deaths in the world every year caused by coronary heart disease (WHO, 2023). The incidence of coronary heart disease in Indonesia is increasing year by year, it is 1.5% of Indonesians suffer from coronary heart disease (Risksedas, 2018).

Percutaneous coronary intervention (PCI) is the most frequently performed procedure in treating CHD patients, especially for they are unable to undergo cardiac surgery due to considerations of high risk for the patient and the presence of comorbid diseases (Khan & Ludman, 2022). The most frequently methods of PCI procedures are transfemoral and transradial access. The choice access of procedure depends on the characteristics of the patient and the expertise or preference of the operating physician (Chhabra et al., 2023). Transfemoral PCI approach is an easier procedure because the femoral artery has a stronger pulse and anatomically the size of the femoral artery is also larger than the radial artery, so it is the choice of many operating physician (Yee et al., 2018).

The procedure of PCI use "sheath introducer" to maintain access site the artery remains open and controls bleeding, then through this sheath introducer "guiding catheter" is inserted and directed to the end of the coronary artery until the condition and location of the blockage can be determined (Valdes et al., 2023). Sheath removal after transfemoral PCI are performed on average 4 hours (2-6 hours) after heparin administration or after PCI procedure has been completed (Özyurtlu et al., 2022). Control bleeding after femoral sheath removal is more often done by manually applying pressure to the femoral artery access puncture site until there is no bleeding and hemostasis occurs (Dorman & Obaid, 2019). The hemostasis process using manual pressure significantly causes complaints of pain and discomfort in patients is higher compared to the use of vascular closure devices (VCDs) (Su et al., 2019).

Pain and discomfort due to manual compression during femoral sheath removal is one of the most common problems experienced by patients after transfemoral PCI. The previous study showed that patients experienced moderate pain with a mean pain score is  $5.56 \pm 3.08$  during femoral sheath removal (Ghods et al., 2022). The consequence of the uncontrolled pain can affect the patient's compliance with immobilization after release femoral sheath, patients

will tend to move a lot and cause the hemostasis process to take longer, as well as increasing the risk of bleeding from vascular access (Qureshi et al., 2019). Manual compression must be given very strongly to achieve hemostasis and prevent the vascular complications regardless of the pain felt by the patient. This condition can contribute to vasovagal reactions (Xu & Huang, 2021). Vasovagal reaction may occur when pain is caused during the removal procedure of femoral sheath is not controlled effectively. The incidence of vasovagal responses during femoral sheath removal procedures ranges from 9.8% to 10% (Ghods et al., 2022). The most common manifestations of vasovagal reactions are hypotension and bradycardia. Other signs and symptoms include complaints of lightheadedness, weakness, nausea, vomiting, feeling sleepy/ yawning, and pale. Vasovagal reaction is a high-risk condition that can be fatal because it can affect to hemodynamics and cardiovascular status in patients after PCI (Xu & Huang, 2021). Therefore, it is very important for nurses to play a role in reducing the patient's perception of pain during removal femoral sheath procedure head to avoid further complications in the patient.

Non-pharmacological interventions to control pain are one of the nurses' responsibilities. One of nursing intervention that has been widely studied to reduce pain in patients after PCI is the application of cold compresses (Kurt & Kasikçi, 2019; Valikhani et al., 2023). The results of previous study show that there is a significant difference in the mean pain scores felt by patients during the femoral sheath removal procedure between the control group and the intervention group who were given cold compresses with ice bag 20 minutes before sheath removal (Sokhanvar et al., 2023).

Study conducted by Kareem & Hamza (2023) about the implementation of manual compression intervention using cold bag directly to stop bleeding after femoral sheath was removed, showing the results that there was a significant difference in the incidence of vasovagal reflexes between the control group and the intervention group. Based on frequency and percentage, it shows that there was a significant reduction in vasovagal reflexes in patients in the intervention group compared to those in the control group. Patients in the intervention group experienced fewer signs of vasovagal reflex symptoms such as decreases heart rate, blood pressure, pale in patient and decrease feels nausea and cold sweat in patient.

Cold compresses have been an analgesic therapy to reduce acute pain for a long time. Applying a cold compress to the skin can reduce the tem-

perature to a depth of 2-4 cm. Cold temperatures can decrease the activation of tissue nociceptors and slow conduction velocity along peripheral axons (cold-induced neurapraxia). Cold compresses can also trigger vasoconstriction influenced by sympathetic nerves and a decrease in neurogenic inflammation to injured tissue as a result of decreased sensory nerve activity. Cold compresses applied directly to the muscles will inhibit motor reflexes that maintain muscle contractions and spasms, thereby reducing muscle spasms that occur in patients with acute pain and they are the main cause of discomfort (Wright et al., 2020).

Based on the problem statement above, this systematic review was conducted to evaluate the effectiveness of applying cold compresses during femoral sheath removal procedures to reduce the level of pain and the incidence of vasovagal reflexes in patients after transfemoral PCI.

## METHODS

This study used a systematic review approach which is a type of study by searching for literature articles resulting from previous research from various sources related to research questions created using the PICO formula (Table 1). The researcher then carried out an analysis to obtain a conclusion. The research question of this study: "Is the application cold compress during femoral sheath removal effective to reducing pain level and incidence of vasovagal reflexes in patients after transfemoral PCI?"

Literatures are obtained by searching through several online database including ProQuest, PubMed, ScienceDirect, Sage Journal, Scopus, ClinicalKey Nursing, and Google Scholar, using Boolean Operator and keyword including "percutaneous coronary intervention" OR "angioplasty" AND "cold" OR "ice" AND "pain" OR "vasovagal", detailed in table 2. Inclusion criteria in the literature search were research articles from 2019-2024, RCT/Randomized Controlled Trial research design or quasi-experimental and research articles containing abstracts and full text. Meanwhile, the exclusion criteria are articles literature review, scoping review, systematic review and umbrella review. Details of the articles search strategies were reviewed and analyzed using PRISMA flowchart (figure 1).

There were 10 articles found based on the inclusion and exclusion criteria in this study. A critical appraisal was carried out on these articles, 8 articles using the JBI critical appraisal tool for RCTs and 2 articles using the JBI critical appraisal tool for quasi-

experimental studies (table 3 and table 4). Total 9 articles had high grades because the percentages of "yes" in the question checklist over than 65% and were be included in the review. Meanwhile, one article was not included in the review because the critical appraisal value needed to be higher.

## RESULTS

### Characteristics of The Articles

A total of nine articles, most of the research in these articles used a RCT (Randomized Controlled Trial) research design, there were 7 articles, while 2 other articles used a quasi-experimental research design. Based on the JBI tool, have met most of the criteria. Even though there are still some that have not explained in detail the randomization method and blinding process in research, these articles are still included in the analysis of this systematic review. The articles review can be seen in table 5.

Based on the article review, it is known that there are several different methods for providing cold applications to reduce pain and vasovagal reflexes in post-transfemoral PCI patients. One of these methods is giving a cold compress with an ice bag 20 minutes before removing the femoral sheath. Another study applied a cold compress for 15 minutes or 20 minutes after hemostasis of the femoral artery puncture area after removal of the femoral sheath. The other method of cold compress intervention can also be applied directly during the process of pressing the femoral artery after the sheath is removed to allow hemostasis to occur. Cold compresses can also be given repeatedly after removing the femoral sheath 4 times, each time for 20 minutes at 10 minutes intervals for a period of 2 hours.

The method of applying cold compresses mentioned in this review article is also applied in other research articles, namely given for 20 minutes after the femoral sheath is removed. After being given a cold compress for 20 minutes, the patient can be mobilized early after 1 hour of immobilization. The results showed that cold compresses with early ambulation also were known to be more effective in preventing hematoma than immobilization with a sand pillow for 6 hours (Ginanjar et al., 2018).

The research results shown in all of these articles are in accordance with the aim of writing this systematic review, namely evaluating the effectiveness of applying cold compresses during femoral sheath removal procedures to reduce the level of pain, but only one article that evaluating the effectiveness of applying cold compresses to reduce the incidence

Table 1. PICO Formula

Patient/Problem	Intervention	Comparison	Outcome
Patient After PCI Transfemoral	Application cold compress during femoral sheath removal	Without cold compress or standard procedure	Pain and Vasovagal Reflexes

Table 2. Literature Search Keywords

Database	Keywords	Result
Pubmed	(((((Percutaneous Coronary Intervention[Title/Abstract]) OR (angioplasty[Title/Abstract])) AND (Cold[Title/Abstract])) OR (Ice[Title/Abstract])) AND (femoral sheath removal[Title/Abstract])) AND (Pain[Title/Abstract])) OR (Vasovagal[Title/Abstract]))	0
Proquest	percutaneous coronary intervention angioplasty cold ice pain vasovagal	0
Sage Journal	percutaneous AND coronary AND intervention AND cold OR ice AND pain OR vasovagal	0
Sciencedirect	percutaneous AND coronary AND intervention AND cold OR ice AND pain OR vasovagal	1
Scopus	percutaneous AND coronary AND intervention AND cold OR ice AND pain OR vasovagal	1
ClinicalKey Nursing	percutaneous AND coronary AND intervention AND cold OR ice AND pain OR vasovagal	0
Google Scholar	percutaneous coronary intervention, angioplasty, cold, ice, pain, vasovagal	8

of vasovagal reflexes in patients after transfemoral PCI procedures.

### Characteristics of Respondents in The Articles

In this systematic review, there were 922 respondents who took part in 9 studies divided into intervention group and control group. The average age of respondents is middle-age and most of them are men. Table 6 is the characteristics overview of respondents from nine studies.

In table 5 below, a summary of the review article is described including the author, year, and title of the article. It also explains the purpose and method of the research as well as the interventions carried out including the research results in the article.

## DISCUSSION

Pain caused by manual compression during the removal process of femoral sheath is one of the most common problems experienced by patients after transfemoral PCI. The level of pain experienced by the patient during removal of femoral sheath is moderate pain with an average pain scale 5-6 (Ghods et al., 2022). The pain must be well controlled because it can affect the patient's compliance with im-

mobilization after femoral sheath release. When experiencing pain, patients tend to be restless, move a lot, causing the hemostasis process to take longer, as well as increasing the risk of bleeding from vascular access (Qureshi et al., 2019). Manual compression must still be given very strongly to achieve hemostasis and prevent the occurrence of vascular complications regardless of the pain felt by the patient. This can also contribute to vasovagal reactions (Xu & Huang, 2021).

Nurses employ various pain reduction techniques to minimize the discomfort associated with the procedure. Several non-pharmacological techniques can be used to treat pain during post-PCI femoral sheath removal procedures. Relaxation techniques such as deep breathing, meditation, and guided imagery can also help patients manage their pain during the procedure (Sallal & Mousa, 2023). Cold therapy has been shown to be effective in reducing pain intensity in some cases during femoral arterial sheath removal after cardiac catheterization.

Applying a cold compress is known to be effective in reducing pain significantly while also reducing the risk of vasovagal reflexes in patients during the removal sheath procedure after transfemoral PCI (Kareem & Hamza, 2023; Sokhanvar et al.,

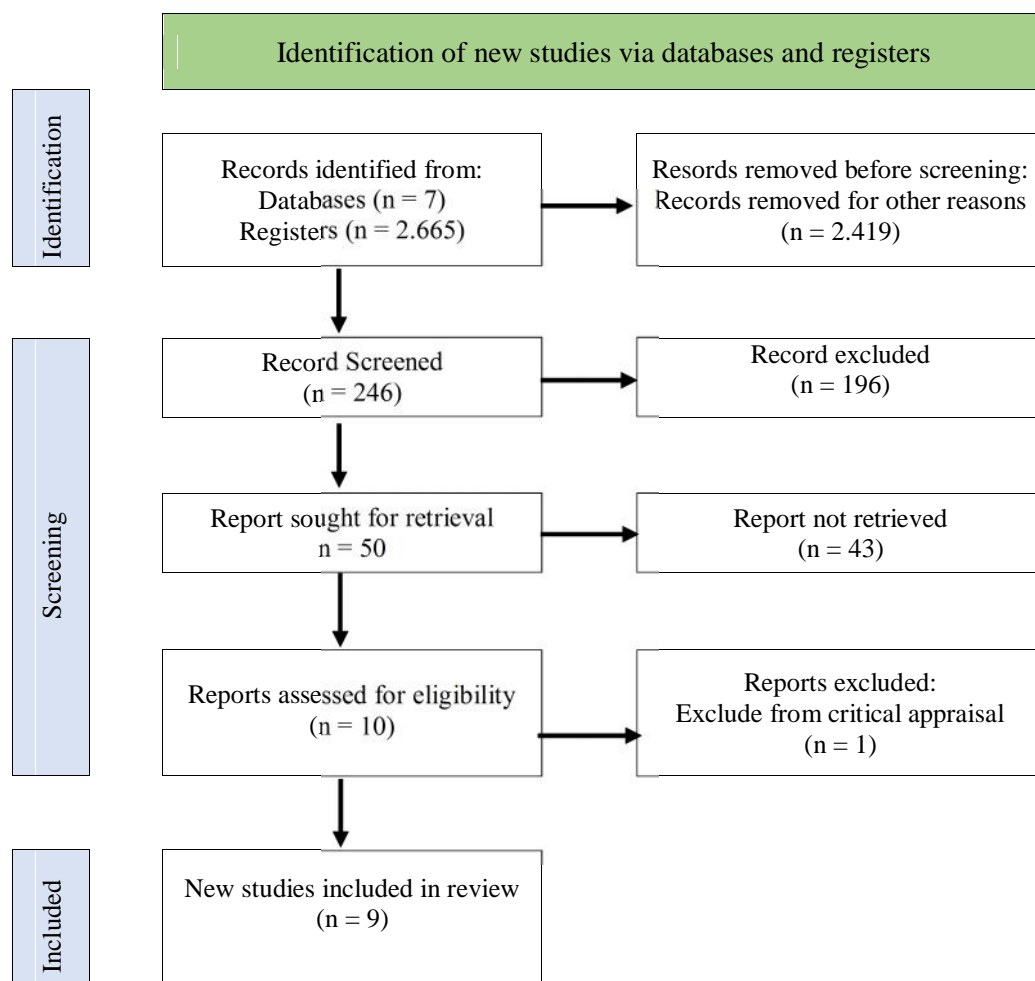


Figure 1. PRISMA flowchart

2023). Cold compresses have an effect on reducing pain through a mechanism that directly reduces skin and muscle temperature. The direct effect of reducing skin and muscle temperature is a decrease in blood flow and metabolism due to vasoconstriction, thereby reducing inflammatory reactions, edema, pain, muscle spasms and elasticity. A physiological decrease in skin temperature can reduce the threshold for activation of tissue nociceptors and slow down the conduction along peripheral axons so that impulse activity in the A-delta and C fibers decreases and pain impulses are reduced. Cold compresses are also known to stimulate a decrease in muscle temperature resulting in loop reflexes in the spinal cord decrease and muscle spasms decrease so that the pain response is also reduced (Malanga et al., 2014).

Post-transfemoral PCI patients receive tissue injury in the inguinal area as access puncture femoral artery using a relatively large needle. It is not uncommon for it to cause bruising/ecchymosis and hematoma, resulting in a bluish discoloration around the skin in the wound area. Application of a cold compress can trigger vasoconstriction of sur-

rounding blood vessels so that it can reduce sensory nerve activity which can inhibit the delivery of neurogenic inflammatory mediators to injured tissue and prevent the formation of edema. It is through such a response that patients feel pain is reduced (Wright et al., 2020). The effect of cold compresses at the impulse channel level works on cold receptors which mediate a safe/harmless cold feeling at a temperature of 18-28 degrees Celsius and can also provide signals via spinal inhibitory interneurons or directly to nociceptors that can induce analgesic effects (Knowlton et al., 2013).

Vasovagal response is one of the cardiovascular complications that often occurs in the process of removal femoral sheath caused by pain due to very strong manual compression to achieve hemostasis (Ghods et al., 2022). Reducing pain due to applying a cold compress can inhibit stimulation of the vagal nerves so that the risk of vagal reflexes can also be reduced. The most common manifestation of a vasovagal reaction is a decrease in blood pressure and heart rate which is also accompanied by other symptoms such as cold sweat, nausea, vomiting, dizziness/

Table 3. The JBI Critical Appraisal Tool for RCTs

The JBI Critical Appraisal Tool for RCTs	Sokhanvar et al., 2023	Kareem & Hamza, 2023	Valikhani et al., 2023	Ebrahimi-shalmi et al., 2020	Wickson et al., 2020	Allahbakhshi et al., 2021	Pamuk & Özkanman, 2024	Manal et al., 2022
Was true randomization used for assignment of participants to treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear
Was allocation to treatment groups concealed?	Yes	No	No	No	No	No	No	No
Were treatment groups similar at the baseline?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Were participants blind to treatment assignment?	Unclear	No	No	No	No	No	Yes	No
Were those delivering the treatment blind to treatment assignment?	Unclear	No	No	No	No	No	No	No
Were treatment groups treated identically other than the intervention of interest?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were outcome assessors blind to treatment assignment?	No	No	No	No	No	No	No	No
Were outcomes measured in the same way for treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were outcomes measured in a reliable way	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were participants analysed in the groups to which they were randomized?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was appropriate statistical analysis used?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the trial design appropriate and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Total Yes	10	9	9	9	9	9	9	5
Percentage (%)	77%	69%	69%	69%	69%	69%	69%	38%

syncope and pale (Xu & Huang, 2021). Vasoconstriction of blood vessels due to the application of cold temperatures can reduce the incidence of bradycardia and hypotension during the femoral sheath removal process in patients after transfemoral PCI.

Cold compresses are an intervention that has

several advantages, including not being necessary therapist with special expertise in its application, very easy to apply, can be carried out by the patient or family independently, is a relatively cheap and efficient method, and can be applied together with other therapy methods (Demir, 2012). However, apart from

Table 4. The JBI Critical Appraisal Tool for Quasi-Experimental Studies

No	The JBI Critical Appraisal Tool for Quasi-Experimental Studies	Kurt & Ka ıkçı, 2019	Prasetya & Handian, 2023
1.	Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	Yes	Yes
2.	Were the participants included in any comparisons similar?	Yes	Unclear
3.	Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Yes	Yes
4.	Was there a control group?	Yes	Yes
5.	Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Yes	Yes
6.	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Yes	Yes
7.	Were the outcomes of participants included in any comparisons measured in the same way?	Yes	Yes
8.	Were outcomes measured in a reliable way?	Yes	Yes
9.	Was appropriate statistical analysis used?	Yes	Yes
Total Yes		9	8
Percentage (%)		100%	89%

its advantages, cold compress intervention also has risks. Applying cold compresses over a long period of time can cause tissue ischemia which can lead to reperfusion injury when blood flow to the tissue is reduced due to prolonged vasoconstriction (Shin et al., 2018). In addition, if it is applied incorrectly, such as at a temperature that is too low, it can actually trigger pain because extreme cold temperatures can be a dangerous stimulus because they can damage tissue (cold pain) (Knowlton et al., 2013; Shin et al., 2018). Before applying a cold compress, a nurse needs to ensure that the patient has no contraindications to cold therapy. It is also important for nurses to consider the choice of tools/materials to be used, ensure the length of time given, the temperature given is appropriate, and ensure the cold compress is placed on the right area (Shin et al., 2018).

Based on several previous studies, it can be seen that the application of cold compresses after PCI can be given before, during, or after the femoral sheath removal procedure. A cold compress can be applied for 15-20 minutes before or after the femoral release procedure sheath (Kurt & Kasikçi, 2019; Sokhanvar et al., 2023). Apart from that, cold compresses can also be applied directly during the process of pressing the femoral artery after sheath removed to allow hemostasis to occur (Kareem & Hamza, 2023). Cold compresses can also be applied repeatedly after femoral release sheath 4 times, each time for 20 minutes with 10 minutes intervals for 2

hours (Ebrahimi-shalmani et al., 2020). Repeated cold compresses can also be given after the bleeding has stopped, a compressive dressing is applied in place of a transparent bandage and an ice bag with a cloth cover (weighing less than 100 g) and a 3 kg sandbag is placed on top for 15 minutes. After 15 minutes, the ice bag was removed leaving only a sand bag remaining which was placed at the location of the femoral artery for 45 minutes. This cycle is then repeated 4 times (total 4 hours) (Valikhani et al., 2023).

Instruments or tools used in administering cold compresses include frozen 100 ml NaCl liquid packages, ice bags (10 × 15 cm, 250 grams), ice pack gel, cold sand pack weight 100 grams or cold pack with dimensions similar to a sandbag (18 × 14 cm) with a flexible structure that can shape the body. The cold temperature used is around 15-18 degrees celsius or 18-20 degrees celsius (Ebrahimi-shalmani et al., 2020; Kurt & Kasikçi, 2019; Pamuk & Özkaraman, 2024; Prasetya and Handian, 2023; Sokhanvar et al., 2023; Valikhani et al., 2023; Wicaksono et al., 2020).

Almost all articles in this literature study compared the intervention of applying cold compresses with standard protocols currently available in hospitals as a control. However, there is one article that also compares cold compresses with acupressure procedures to reduce the patient's pain level during femoral sheath removal after PCI. Results showed that pain score in the cold compress group was lower although it did not show a significant difference with

Table 5. Summary of Articles Review

No	Author, Year, and Title	Goals and Research methods	Interventions and Research Results
1.	The effect of the application of cold on hematoma, ecchymosis, and pain at the catheter site in patients undergoing percutaneous coronary intervention (Kurt & Ka ıkçı, 2019)	To determine the effect of applying cold temperatures on hematoma, ecchymosis, and pain after removal of the femoral artery sheath in patients undergoing PCI. The research design is experimental research with a control group.	After hemostasis of the femoral artery puncture area after the femoral sheath was removed, a cold compress covered with sterile gauze was placed under the sand pillow for 15 minutes. Cold compress using a frozen 100ml NaCl liquid package. The cold compress is then taken after 15 minutes and continued by simply pressing it with a sand pillow for up to 4 hours. The study results showed that there was a significant difference in pain levels between the control and intervention groups at the 15th minute and 4th to 72nd hour of observation ( $P < 0.01$ ).
2.	Effect of Ice Bag Application to Femoral Region on Pain and Vital signs in Patients with Acute Myocardial Infarction Undergoing Percutaneous Coronary (Sokhanvar et al., 2023)	To determine the effect of applying an ice bag compress on vital signs and pain in the femoral area in acute myocardial infarction patients undergoing PCI. RCT research design ( <i>a double-blind controlled trial</i> )	Applying a compress with an ice bag ( $10 \times 15$ cm, 250 g, Beauty Basics Model NT_ 304, Berlianteb Company) on the femoral artery area for 20 minutes before removing the femoral sheath. The research results show: <ul style="list-style-type: none"> <li>The mean pain score during the femoral sheath removal process was <math>5.77 \pm 2.73</math> in the control group and <math>1.1 \pm 1.39</math> in the intervention group, a statistically significant difference (<math>p &lt; 0.0001</math>). Also, the mean pain score after removal of the femoral sheath was <math>1.72 \pm 0.83</math> in the control group and <math>0 \pm 0</math> in the intervention group, a statistically significant difference (<math>P &lt; 0.0001</math>)</li> <li>The mean systolic blood pressure during removal of the femoral sheath in the control and intervention groups was <math>135.50 \pm 14.78</math> and <math>171.97 \pm 17</math>, respectively, there was a statistically significant difference (<math>p &lt; 0.0001</math>). The results also showed that the mean systolic blood pressure after removal of the femoral sheath in the control and intervention groups was <math>128.13 \pm 21.31</math> and <math>114 \pm 24.80</math>, respectively, which also showed a statistically significant difference (<math>p = 0.012</math>).</li> <li>There was no significant difference in HR between the control and intervention groups before, during and after femoral sheath removal (<math>p=0.31</math>; <math>p=0.051</math>; <math>p=0.80</math>).</li> </ul>

the acupuncture group ( $P = 0.065$ ). Both intervention methods, ice compresses and acupressure, are effective in controlling pain (Allahbakhshi et al., 2021).

Behind applying cold compresses, nurse need to ensure patients to remain relaxed and comfortable during the procedure. Patients can also play an ac-

tive role in reducing their pain by managing stress levels and communicating their needs to nurse or healthcare provider. A comprehensive pain management plan can help ensure more comfortable experience for patients during femoral sheath removal procedure (Sallal & Mousa, 2023).



3.	Effectiveness of Clinical Guideline Regarding Post Arterial Sheath Removal on Reduction of Complications in Patients after Cardiac Catheterization: Randomized Control Trial (Kareem & Hamza, 2023)	To design and evaluate clinical guidelines for femoral sheath removal to reduce complications in patients after PCI. Research method using RCT.	Intervention by providing manual compression using a cold bag/ice directly to press the femoral artery after the femoral sheath is removed to prevent bleeding. The research results show: <ul style="list-style-type: none"> <li>There was a significant difference in the occurrence of low back pain between the two control and experimental groups in the measurement periods of the 1st hour, 2nd hour, 3rd hour and 4th hour (p value &lt; 0.05).</li> <li>There was a significant difference in the occurrence of vasovagal reflexes based on HR between the control group and the experimental group in the 1st hour and 2nd hour measurement periods (p value &lt; 0.05).</li> <li>There was a significant difference in the occurrence of vasovagal reflexes based on BP between the control group and the experimental group in the 1st hour and 2nd hour measurement periods (p value &lt; 0.05).</li> <li>There was a significant difference in the occurrence of vasovagal reflexes based on signs and symptoms (nausea, pallor, cold sweat) between the control group and the experimental group in the 1st hour measurement period (p value = 0.022).</li> <li>There was a significant difference in the presence of ecchymosis between the control and experimental groups at the 3rd hour, 4th hour measurements, and after 1 day (p value &lt; 0.05).</li> </ul>
4.	Effectiveness of Cold Compress with Ice Gel on Pain Intensity among Patients with Post Percutaneous Coronary Intervention (PCI) (Wicaksono et al., 2020)	To determine the effect of cold compresses with ice gel on the intensity of patient pain during femoral sheath removal after Percutaneous Coronary Intervention (PCI). Represents <i>True experimental with approach randomized post-test only</i> with the control group.	Intervention was given with cold compress therapy using ice gel for 20 minutes when pressing the femoral artery after the femoral sheath was removed. Study results show: <ul style="list-style-type: none"> <li>There was a difference in the mean reduction in pain before and after receiving treatment in the intervention group. The results of the study found that the average pain in the intervention group before receiving treatment was <math>4.53 \pm 0.915</math> and after receiving treatment was <math>2.40 \pm 0.986</math> with a p value &lt; 0.05.</li> <li>There was no difference in the mean reduction in pain before and after treatment in patients in the control group, <math>4.40 \pm 0.828</math> and <math>4.27 \pm 1.033</math> (p = 0.334).</li> <li>There is a significant difference in pain reduction between the intervention group and the control group with a p-value of 0.000 (&lt;0.05) and an average difference in p-value of</li> </ul>

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| 5. | The effect of ice pack gel on pain reduction of sheath removal in post-cardiac catheterization patients (Prasetya & Handian, 2023)           | To measure the effect of cold compresses with ice gel on reducing pain during removal of the femoral artery sheath in patients after cardiac catheterization. This research uses a quasi-experimental study design. | <p>Apply an ice gel compress immediately after removing the femoral sheath for 20 minutes. The research results show:</p> <ul style="list-style-type: none"> <li>▪ The mean patient pain score during the femoral artery sheath removal procedure after cardiac catheterization in the pre-test control group was <math>4.75 \pm 0.77</math>, then the post-test score after 4 hours decreased to <math>2.31 \pm 0.60</math>. Meanwhile, in the ice pack gel group, the pain level in the pre-test was <math>4.63 \pm 1.02</math> and decreased quickly to <math>1.63 \pm 0.81</math> in the post-test. The Wilcoxon test result for both groups was <math>p &lt; 0.001</math>. So it can be concluded that there is a difference in the level of pain during the femoral artery sheath removal procedure after cardiac catheterization before and after treatment in the control and intervention groups.</li> <li>▪ There was a decrease in the mean pain score in the intervention group which was higher than in the control group. This means that applying an ice gel compress is effective in reducing pain more quickly than standard protocols. In conclusion, there is a difference between ice pack gel and standard protocol in reducing pain in patients during the femoral artery sheath removal procedure after cardiac catheterization (<math>p &lt; 0.001</math>).</li> </ul> |
| 6. | The Effect of Sandbag and Ice Bag on the Pain After Percutaneous Coronary Intervention: A Randomized Clinical Trial (Valikhani et al., 2023) | To investigate the effect of the combined use of sand bags and ice bags in reducing pain in patients after percutaneous coronary intervention (PCI). Research method using RCT.                                     | <p>After the bleeding stops after the femoral sheath is removed, a compressive dressing is applied in place of a transparent bandage and an ice bag with a cloth cover (weighing less than 100 g) and a 3 kg sandbag is placed on top for 15 minutes. After 15 minutes, the ice bag was carefully removed, and the remaining sand bag was placed at the location of the femoral artery for 45 minutes. This cycle is repeated 4 times (total 4 hours). After 4 hours the sandbag is removed and patient is allowed to move his legs. Research results show:</p> <ul style="list-style-type: none"> <li>▪ The mean pain level in the intervention group was significantly lower than the control group at 3 hours after femoral sheath removal (<math>P &lt; 0.001</math>).</li> <li>▪ The results of the Friedman test showed that there was a significant difference in pain intensity at various measurement times in the two groups (<math>P &lt; 0.001</math>).</li> <li>▪ Post hoc tests showed significant differences in the intervention group between the start of femoral sheath removal and 3, 6, and 12 hours</li> </ul>   |
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7.	The effect of the local cold application on low back pain and vascular complications of patients undergoing coronary angiography (Ebrahimi-Shalmani et al., 2020)	To determine the effect of applying a cold compress to the femoral artery sheath area on low back pain and vascular complications in patients undergoing transfemoral coronary angiography. Research method using RCT.	After the femoral sheath is removed and hemostasis is controlled and the dressing is applied, then a cold pack is given with dimensions similar to a sandbag (18 × 14 cm) with a flexible structure that can shape the body. A cold compress is placed on the femoral artery area 4 times, each time for 20 minutes. at 10 minutes intervals for a period of 2 hours. The cold pack temperature is in the range of 15-18 °C which can be maintained for 30 minutes. The results of the study showed that in both the control and intervention groups there was no significant difference in mean low back pain at the beginning of the pain score measurement, however the statistical results showed significant differences in pain scores at other measurement time points ( $P < 0.001$ ).
8.	A comparative study on the effect of acupressure and ice bag on the pain during removal of femoral artery sheath in angioplasty patients: a clinical trial study (Allahbakhshi et al., 2021)	To compare the effect of two methods of acupressure and ice compresses on pain during arterial sheath removal in patients undergoing angioplasty/PCI. Research method using RCT.	<p>The intervention given to the ice compress group was that 15 minutes before removing the femoral sheath, the nurse placed an ice compress measuring 10 x 15 cm with a temperature of 0 to 2 degrees Celsius at the location of the femoral artery sheath in the patient's inguinal area.</p> <p>Next, after 15 minutes, the ice bag was removed and the femoral sheath was removed. In the acupressure group, acupressure massage was given to 4 points on the palms for 20 minutes before removing the femoral artery sheath. The research results show:</p> <ul style="list-style-type: none"> <li>▪ The mean pain scores in the ice compress and acupressure groups were <math>1.6 \pm 1.6</math> and <math>2.4 \pm 1.4</math>, respectively, and in the control group were <math>4.03 \pm 1.27</math>.</li> <li>▪ After femoral artery sheath removal, there was a significant difference in pain scores between the three groups (<math>P = 0.0001</math>).</li> <li>▪ It was found that the pain score in the ice bag group was lower although it did not show a significant difference with the acupuncture group (<math>P = 0.065</math>).</li> <li>▪ Both intervention methods, ice compresses and acupressure, are effective in controlling pain.</li> </ul>
9.	The Effect of Cold Sand Pack on Percutaneous Coronary Intervention-Induced Vascular Complications and Pain: A Randomized Controlled Trial (Pamuk & Özkaraman, 2024)	To evaluate the effect of using cold sand packs on the femoral area to prevent bleeding, hematoma, ecchymosis, and pain in patients undergoing PCI via the femoral artery. Research method using RCT.	After femoral sheath had been removed by doctor & bleeding had been successfully stopped, intervention group cold sand bag was placed on patient's femoral artery area at temperature of 18-20°C for 20 minutes, then at an average temperature of 24.1°C for 3 hours 40 minutes. Meanwhile, in control group, sand bags used at an average temperature of 24.1°C were placed on patient's femoral artery area for 4 hours. Results showed that VAS pain levels were known to be lower in patients in intervention group than in patients in control group at all assessment time periods ( $p < 0.001$ ) and magnitude of effect was known to be greater in first five hours ( $d > 0.8$ ).

Table 6. Characteristics Overview of Respondents

Article	Group	Characteristics			
		Number of respondents	Age (Mean)	Sex	
				Male	Female
Sokhanvar et al., 2023	Intervention	30	58,5	24	6
	Control	30	56,7	23	7
Kareem & Hamza, 2023	Intervention	45	NA	33	12
	Control	45	NA	28	17
Valikhani et al., 2023	Intervention	30	54,9	19	11
	Control	30	56,8	18	12
Ebrahimi-shalmani et al., 2020	Intervention	55	62,36	39	16
	Control	55	61,16	38	17
Wicaksono et al., 2020	Intervention	15	55,07	14	1
	Control	15	57,40	13	2
Allahbakhshi et al., 2021	Intervention 1	30	61,26	15	15
	Intervention 2	30	43,58	18	12
	Control	30	60,90	17	13
Pamuk & Özkaraman, 2024	Intervention	105	57,28	71	34
	Control	105	58,5	75	30
Mandal et al., 2022	Intervention	20	NA	18	2
	Control	20	NA	17	3
Kurt & Ka ıkçı, 2019	Intervention	100	NA	78	22
	Control	100	NA	79	21
Prasetya & Handian, 2023	Intervention	16	NA	NA	NA
	Control	16	NA	NA	NA
Total		922	57,26	637	253

## CONCLUSION

From literature studies that have been carried out in several studies, it is known that there are differences in carrying out cold compress application procedures, especially regarding the time, tools and procedures for administering the intervention. However, all showed the same results that the application of cold compresses was effective in significantly reducing pain during sheath removal procedures in post-transfemoral PCI patients. Meanwhile, research assessing the effectiveness of cold compresses in reducing the risk of vasovagal reflexes is still very rare, so it is hoped that further research will be able to better identify the effectiveness of cold compress intervention on the occurrence of vasovagal reflexes during femoral sheath removal procedures post-PCI. Research on differences in intervention effectiveness between the times cold compresses are given either before, during, or after the femoral sheath removal procedure is also needed to further strengthen evidence-based practice this intervention. Cold compresses are known to be a relatively easy and cheap intervention to apply, especially for patients after transfemoral PCI, and can be combined with other

non-pharmacological interventions to reduce the patient's pain level.

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