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The effect of ice pack gel on pain reduction of sheath removal in post-cardiac catheterization patients

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ABSTRACT

Background: Cardiac catheterization is a minimally invasive intervention that can cause complications of vascular access after compression of the femoral artery or sheath removal. Cold pack gel is a non-pharmacological therapy given after sheat removal to reduce pain.
Objective:This study aimed to measure the effect of ice pack gel on pain reduction in arterial sheath removal post-cardiac catheterization patients.
Methods: This interventional clinical study with control and group treatment was conducted in the cardiology room of Saiful Anwar Hospital Malang, Indonesia. The respondents (n=32) were divided into two groups in pre and post-test control group design. Group A receives pressure bandages as a standard protocol (control groups) while group B, ice-packed gel. Pain scale measured by Visual Analog Scale (VAS) by 1-10.
Results: The Mann-Whitney test in two groups shows that there are differences in scores of pain reduction. The pain reduction difference in the treatment group (ice pack gel) was higher than the control ones ($p < 0.001$). The cold temperature of the cold-packed gel decreased the peripheral free nerve ending conductivity, furthermore, it made sensitivity stimulus or pain impulses slowed down then reduced the perception of pain.
Conclusions: The intervention of ice-packed gel is more effective than the standard protocols to reduce the pain in the removal sheath post cardiac catheterization.

Keywords: ice-packed gel; sheath removal; pain; cardiac catheterization

INTRODUCTION

Cardiac catheterization and percutaneous interventions are minimal invasive causes of vascular access complications or vascular injury. The compression or pressure manually done above the femoral arteries caused pain. This intervention provides to achieve homeostasis condition by spending 10-20 minutes in time after removing the catheter sheath immediately called removal sheath (Lombardo & van den Berg, 2010). The homeostasis protocol is divided into the removal of the sheath of venous and arterial femoral; the venous sheath removal (VSR) and arterial sheath removal (ASR). It causes major

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- *Non pharmacological intervention such as ice-packed gel can be an arternative to reduce pain*
- *Nurse can use this intervention to reduce patient pain during PCI*

and minor complications (Bhatty et al., 2011) starting from bleeding, death risk, AV fistula, and pseudoaneurysm (Bhatty et al., 2011) while the major complication after removal of sheath intervention could be higher at 64% (Lombardo & van den Berg, 2010).

According to the World Health Organization, vascular and cardiac diseases result in 17 million people dying. In Indonesia, in 2020 reported 11.592.990 people suffered from cardiac disease. Furthermore, it gives financial burdens to the country up to 8.3 trillion rupiahs in 2020 (Beyer et al., 2006). Preliminary research was conducted in the cardiac catheterization laboratory room of Saiful Anwar Hospital of Indonesia, at least 782 cardiac catheterizations were done during 2020-2021. That numbers consist of 45,5% coronary intervention; 9% electrophysiology; 1.7% peripheral vascular; 6,33% congenital intervention and 1.75% others. The observation and interview data held on February 2021 in 15 cardiac catheterization inpatients after the ASR intervention showed that they feel a painful sensation and were uncomfortable with the puncture marks of catheter sheath injection which is a rating from 4 of non-complication to 8 on a scale which complicated such as multiple puncture hematoma. Regularly, the hospital solved this problem by giving bandage intervention standards in surface areas.

Cardiac catheterization is done by entering the small hose catheter into the arterial or venous and then reaching the coronary blood vessels or another system organ helped by an X-ray. The procedures were done to know the potential of coronary arterial, either cardiac structure or therapeutic intervention needed by patients such as diagnostic coronary angiography (DCA), percutaneous transluminal coronary angioplasty (PTCA), percutaneous coronary intervention (PCI) (Association, 2018).

Cardiac catheterization and percutaneous intervention could cause complications in vascular access. This condition more often happens in the femoral than radial access. The vascular wound in the femoral arterial provided pain mediators i.e leukotrienes, prostaglandin E2, and histamines then stimulated nociceptors. Similarly, bradykinin and serotonin are activated by wounds and cause pain sensations (Bahrudin, 2018).

Management of pain reduction and hematoma in the cardiac catheterization room at RSUD Dr. Saiful Anwar was performed with elastic bandage pressure on the area where the catheter was removed. This bandage pressure has become the standard operating procedure for pain management for both VSR and ASR at RSUD Dr. Saiful Anwar. The use of bandage pressure is based on the patient's strong pain experience, so the use of alternative pain management needs to be pursued. Despite Based on this, researchers want to innovate non-pharmacological pain management that can be done to reduce pain in aff sheath patients by cold pack compresses.

During the last decades, pain management was treated by pharmacology or a non-pharmacology approach. One non-pharmacological approach for ASR management is by cold pack (Kristiyan et al., 2019). In early research by Bayindir in 2017, cold packs for 20 minutes were effective in reducing pain post-PCI (Bayındır et al., 2017). This research uses cold pack gel as a piece of compressed equipment. Besides the flexibility, it also has bandage management on arterial access after the ASR intervention. Generally, this instrument has a stable temperature of -90 to -130 Celcius and the endurance to absorb or save cold temperature from the freezer or cold storage. Gel usage at cold temperatures has the benefit to minimize tissue destruction after cardiac catheterization and affected the body surfaces in pain reduction, muscle relaxation, blood vessels change, and connective tissue effect. The temperature causes arterial and venous vasoconstriction to stimulate the smooth muscle in blood vessel layers. Furthermore, vasoconstriction prevents bleeding and tissue hematoma (Wicaksono et al., 2020). Ice pack gel was chosen for this research because of its simplicity, inexpensiveness, comfort, and non-invasive nursing management. This study aimed to measure the effect of ice pack gel on pain reduction in arterial sheath removal post-cardiac catheterization patients.

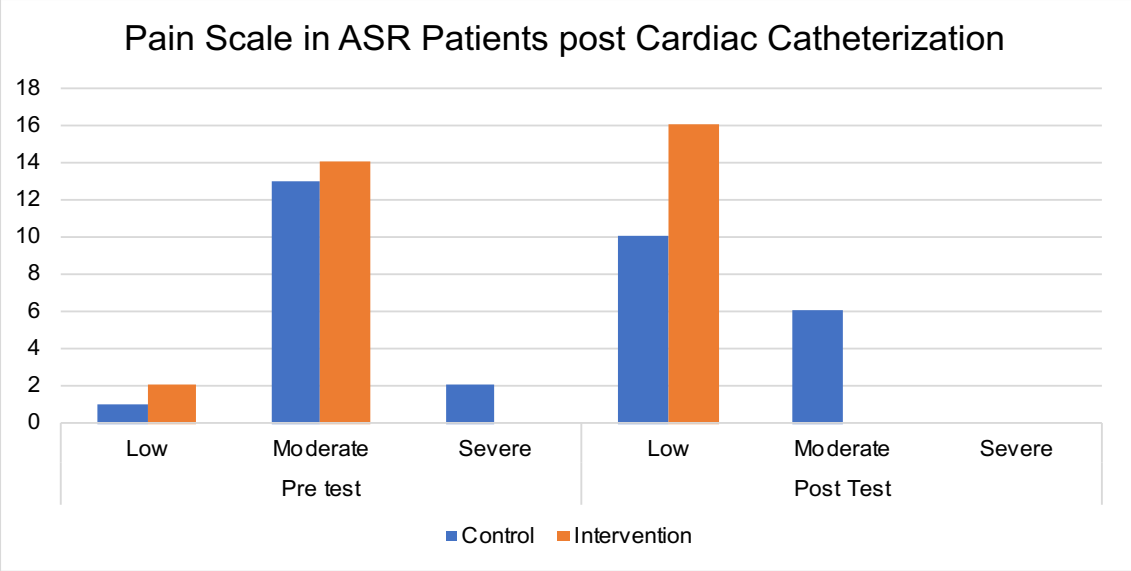

Figure 1. Pain scale in ASR post cardiac catheterization

METHODS

Design

A quasi-experimental study design was used in this study.

Sample and Setting

This interventional clinical study was conducted in the Cardiac Catheterization Room, Cardiology Department of Saiful Anwar Hospital, Malang, Indonesia. The time setting was from November—December 2021. As many as 32 respondents were selected by purposive sampling technique. Respondents have been divided into two groups. The group was divided randomly after the patient underwent catheterization. The treatment group is intervened with ice pack gel (n=16) and the control group (n=16) by standardized treatment in the hospital with bandage pressure. Inclusion criteria : (1) Cardiac catheterization with access via the femoral artery (2) Experience pain after aff sheath procedure by Numeric Rate Scale (3) Age 21 – 60 years (4) Cardiac catheterization without general anesthesia or sedation (5) During catheter sheath removal not receiving pharmacological analgesia. Exclusion Criteria : (1) Post-cardiac catheterization patients with major complications of pseudoaneurysm, arteriovenous (AV) fistula, hematoma requiring transfusion, and retroperitoneal bleeding and experiencing cardiac arrhythmia disorders (2) Patients with IABP (Intra Aortic Ballon Pump) procedures who require post-cardiac catheterization observation.

Study Procedure

A first group is a control group that uses the standard protocol in the hospital by using the bandage pressure intervention in ASR post-cardiac catheterization. It applicated immediately after the ASR protocol and was observed for 4 hours. The second group is the treatment group, given ice-packed gel immediately after the ASR protocol and observed for 20 minutes. Pain scale scores were measured twice. The first is a pre-test directly when ASR intervention is done before ice pack gel and bandage application; the second is a post-test 20 minutes after the treatment of ice pack gel and 4 hours after standardized ones.

Statistical Analysis

Pain reduction was analyzed by the Wilcoxon and Mann-Whitney tests ($p < 0.05$ and 95% confidence interval) using SPSS 16 for windows.

Ethical Approval

This study was approved by the health research ethics committee of Saiful Anwar Hospital, Number: 400/204/K.3/302/2021.

RESULTS

All 32 patients following the study. The respondent characteristic of this research shows in table 1. It is divided into three groups: age, work, and education. The first aspect in

Table 1. Characteristics of respondents (n=32)

Characersitics	Intervention	Control	n (32)	(%)
Age (Year)				
20-30	2	1	3	9.4
31-40	4	2	6	18.5
41-50	3	2	5	15.5
>50	7	11	18	56.0
Work				
Farmers	1	0	1	3.1
Private Sector	11	11	22	68.8
Housewife	1	1	2	6.2
Students	2	1	3	9.4
Public Sector	1	1	2	6.2
Education				
Secondary School	0	2	2	6.2
High School	9	11	20	62.5
Graduate	7	3	10	31.3

Table 2. Statistical result

Wilcoxon Test		
Group	Mean±SD	P Value
Control		
Pre	4.75 ± 0.77	< 0.001
Post	2.31 ± 0.60	
Treatment		
Pre	4.63 ± 1.02	< 0.001
Post	1.63 ± 0.81	
Mann-Whitney Test		
∆ Mean pre-post control vs treatment group		< 0.001

the age group, >50 years is the highest number (56%) and the opposite age group at 20-30 years is the lowest. Most of them work in the private sector (68.8%) while only 3,1% are farmers. The educational grade, the highest is graduate from high school (62.5%), graduate (31.3%), and the last followed by secondary school (6.2%) (Table 1).

Information in the bar chart (Figure 1) shows pain scale measurement in ASR intervention patients after cardiac catheterization. The use of diagrams makes it easy to observe direct comparisons between the control group and the treatment group before and after an intervention. In general, there are few differences in the scale of pain in pre and post-test. In the pre-test, both in the control and intervention groups the pain scale varies in low, moderate, and severe. While the post-test shows the two areas of pain scale into low and moderate, no one is severe.

In the pre-test, the pain scale of the patient who used the standard protocols by pressure bandage was spread in three areas of low, moderate, and severe level pain. The pain dominated on the moderate scale as the highest (13/81,25%) underneath followed by severe (2/12,5%) then low scale (1/6,25%). At the same time in the intervention group with ice-packed gel patients experienced a moderate scale of pain, with the highest number (14/87,5%) and a small number low (2/12,5%). Furthermore, during the post-test as represented in figure 2, the spreading areas

of a pain level of bandage treatment were more varied than in the treatment group. The standardized treatment was divided into two pain levels; low and moderate, but in an ice pack gel group all of the pain levels become low overall.

Table 2 shows the differences in scores of pain levels in both groups before and after treatment. The average ice-pack gel differences score is higher than the control group. The mean score in ASR patients post cardiac catheterization in the control groups pre-test is 4.75 ± 0.77 then in the post after 4 hours of treatment decreased to 2.31±0.60. Whereas in ice pack gel groups, pain levels in the pre-test are 4.63±1.02 and decrease rapidly to 1.63±0.81 in the post-test. The Wilcoxon test of both groups is $p < 0.001$. It is concluded that there is a difference in pain levels in ASR patients before and after the treatment in the control and intervention groups.

Furthermore, to make sure which group is more significant in the two groups, a difference score test was conducted between the control and ice pack gel groups using the Mann-Whitney test. Table 4 indicates that the declining average of the intervention group is higher than the control ones. It means the ice pack gel is adequate to reduce pain faster than the standard protocol. To summarize, there were differences between ice pack gel and standard protocol in reducing pain in ASR patients post cardiac catheterization ($p < 0.001$).

DISCUSSION

Cardiac catheterization is a non-invasive procedure in which asymptomatic cardiac disease patients need hospital treatment in diagnostic and percutaneous intervention. However, when the procedure was held it can be a major cause of stress, anxiety, and uncomfortable for the patients. Uncertainty feelings will develop pain sensations due to intervention and the ASR after cardiac catheterization (Bashore et al., 2012).

This research is in line with the other, that the manual compression by a sand pillow on the femoral artery after the ASR procedure can reduce the vascular complication after cardiac catheterization (Manik, 2015). The disruption or vascular injury on the femoral artery release histamine, serotonin, bradykinin, and prostaglandin called pain mediators. This will stimulate pain receptors located in the peripheral free nerve ending, blood vessels membrane, and other tissues then appear as pain. The release of pain mediators also stimulated the sympathetic nerves and vasoconstriction happened. Furthermore, the muscle density would increase and cause muscle spasms, decrease blood flow, and increases the muscle metabolic rate thus developing impulse transfer and causing pain perception (Mutlu & Yılmaz, 2020).

The decrease of pain in the controls group during the pre and post-test was caused by the prolonged time of pressure by the elastic bandage on the femoral artery. According to the standard protocol of cardiac room inpatients, the bandage pressure must do at least 4 hours after taking the ASR protocols. This procedure aims to stop the bleeding in the femoral artery, develop blood clots, and maintain the homeostasis of blood vessels. Bandage and pressure are a way to stimulate hematoma, another condition that causes pain sensation or vascular damage which is uncomfortable for patients, whereas immobilization will prevent the bleeding.

In another research; firstly, sand pillow intervention or manual pressure after the ASR procedure is effective in reducing vascular complications (Manik, 2015). Secondly, the comparison between sand pillow compression and cold-pack ice to prevent hematoma after cardiac catheterization shows that there is a significant difference in blood vessel vasoconstriction incidents. The cold-packed ice is more effective than a sand pillow to decrease the hematoma complication (Syahri & Andriani, 2021)

In the intervention groups, the levels of pain majority are mild and the view patients is low during the pre-test, whereas in the post-test all respondents changed to a low level. There is a difference in pain level reduction in post-ASR cardiac catheterization procedures by cold-packed ice.

Ice gel is effective to reduce pain after the PCI procedure (Wicaksono et al., 2020). In a few years, research has developed to expand cold pack gel as a replacement for dry ice or ice. Cold pack gel has many transcendences compared to regular ice. This material is reusable and becomes an alternative option besides ice or dry ice. People also can freeze it in the freezer. It is beneficial as long as the package didn't break. The endurance of ice-packed gel achieves 12 hours maximum depending on the material as a substitution compound to the container.

The low-temperature method will inhibit the acceleration of the nerve's signal related to pain to the brain access. According to the gate theories, ice has a role as a nociceptor related to hurt feelings. It collected both perceptions of mechanical and chemical impulses, including wounds or hurt by closing the 'gates' sensation to the central nervous system. This study proved that cold compressing the ice-packed gel is possibly done as a non-invasive and non-pharmacologic intervention in nursing, especially in pain management of removal sheath in post-cardiac catheterization. The other research which is supported this finding is that ice compression gives a positive impact on the physiologic aspect in increasing vasoconstriction, and decreasing capillary permeability. The other way is by influencing the metabolic mechanism, muscle relaxation, inhibiting the bacterial growth, non-inflammatory agents, relieving pain by shaking the pain sensory or developing the numb tissue, slowing down pain impulse, increasing pain threshold, and giving temporary local anesthesia (Bayındır et al., 2017).

In our opinion, the decrease of pain in the intervention groups between pre and post-test is influenced by cold-pack gel. The 20 minutes give a positive effect on the patients, but if the intervention is prolonged, it would give many symptoms such as paresthesia, redness, itchy sensation, soreness and even changing the skin color. The cold-packed gel also prevents the hematoma process. This result is in line with other research that an ice-cold pack is effective to avoid the hematoma complication in post-cardiac catheterization (Syahri & Andriani, 2021). The cold temperature in cold-packed gel prevented the blood flow and capillary permeability by increasing the arteriole vasoconstriction and then lessening the bleeding, inflammation, and pain.

There is a difference in the deviation score of the pain scale in ASR patients post cardiac catheterization in control and intervention groups. The decrease in score differences of pain in ASR post cardiac catheterization in the intervention group is higher than in the control groups. It means the ice-packed gel can reduce the pain faster than the pressure bandage as the standard protocol. It is in line with previous research, that cold-packed is effective to reduce pain in the removal of the femoral sheath in percutaneous coronary intervention (PCI) (Wicaksono et al., 2020).

In addition to pharmacologically pain management, currently also being developed non-pharmacological treatment. Examples are distractions, relaxation hypnosis, or Transcutaneous Electrical Nerve Stimulation (TENS) technique. This method is used to organize various conditions of pain. It has specific characteristics; non-invasive, non-systemic side effects, simple, safe, cost-effective, and available for self-monitoring (Rizqi, 2018).

Many references state that ice is effective to reduce pain. The effectiveness of cold compress with various methods has been studied and applicated in medical sciences or other fields. The application of cold compress and manual bandage on the femoral artery gave a good effect in decreasing vascular complicated symptoms such as hematoma, and ecchymosis and releasing pain reduction in patients with coronary percutaneous intervention (Shofyan Baidhowy et al., 2021). Cold application is effective to reduce pain in subcutaneous heparin injection (Inangil & Şendir, 2020). Cold compress decreases pain sensation because it inhibits the nerve's response transfer to the central nervous system (Bahrudin, 2018). The pain in the patient's post-PCI procedure causes vasovagal incidents or other complications, furthermore, this should be handled. Uncontrolled vasovagal reactions cause irreversible shock and even death. The anxiety and prolonged treatment times caused by pain and unexpected hospital costs occurred (Bayındır et al., 2017).

According to the gate control theory, cold acts as nociceptors that are collected mechanical and chemical stimulation perceptions including pain by closing the gate system of sensation to the central nervous system (Ropero Peláez & Taniguchi, 2016). In line with this, the ice-packed gel compress in pain stimulation decreases the hurt feeling. Other research mentions that pain works in the peripheral nervous system by protecting the nerve transmission acceleration. Furthermore, it would increase pain threshold and pain tolerance along the same nerve. Another one said that cold application and pharmacological intervention decrease the side effect, improve the outcome, and reduce the hospital time treatment (Mutlu & Yılmaz, 2020). Furthermore, ice application together with a pharmacological agent can effectively be used in reducing pain.

In this research, the decrease in pain scores in the intervention groups gives a huge number and is faster than in the control

groups in terms of time. The comparison of pain inhibition mechanisms in the control and intervention groups shows that the ice-packed gel intervention in 20 minutes has less time compared to the bandage pressure (4 hours). It happened because the acceleration of the nerve conjunction of the gate control mechanism in the ice-packed gel groups was faster and shorter than in another group. The regular bandage needs more time to reduce the pain. Besides that, the ice-packed gel can reduce pain and prevent the vasovagal reflex.

The catheter size which is used may contribute to complications of vascular injury. The higher the number of the sheath, the more visible it contributes to an incident of bleeding or hematoma during the deliverance of the ASR. Pain as a symptom of hematoma was present and cold application using ice-packed gel is appropriate during this time.

Age may contribute to pain perception in this study. The observational data in this research represent that the perception of pain in older age is getting more biased. This condition is probably affected by the aging factor. Many elderly people generally have pathological symptoms following the pain sensation in the past. Then it would describe that pain sensation in old people is lower than in younger ones.

Pain causes anxiety problems. It would affect the time of treatment in the hospital, burden condition to the health care provider, and increases the cost of therapy. To sum up it is important to consider the use of ice-packed gel to reduce pain as a non-pharmacological approach.

CONCLUSION

The result suggested that the application of ice-packed gel as pain management in the removal of sheath post cardiac catheterization has a potential role in reducing pain. However, future research with larger sample sizes and observing the complications of the ice-packed gel application is recommended in post-cardiac catheterization patients.

Declaration of Interest

The authors have no conflict of interest to declare.

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Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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