Effectiveness of Combined Sandbag and Ice Pack Application in Reducing Hematoma and Pain After Femoral Sheath Removal in Patients Undergoing Percutaneous Coronary Intervention: A Randomized Controlled Trial

Eka Tlaga Herawati[1], Cut Husna[2,*], Ardia Putra[3], Hilman Syarif[2], Adi Purnawarman[4]

[1]*Master of Nursing Student, Faculty of Nursing, Universitas Syiah Kuala, Darussalam, Banda Aceh, Indonesia.*
[2]*Department of Medical and Surgical Nursing, Faculty of Nursing, Universitas Syiah Kuala, Darussalam, Banda Aceh, Indonesia.*
[3]*Department of Nursing Management, Faculty of Nursing, Universitas Syiah Kuala, Darussalam, Banda Aceh, Indonesia.*
[4]*Department of Cardiology and Vascular Medicine, Zainoel Abidin Hospital, Banda Aceh, Indonesia.*
**corresponding authors: cuthusna@usk.ac.id*

Received January 30, 2026
Revised June 18, 2026
Accepted July 24, 2026
Available online August 17, 2026

Abstract

Aims: Hematoma and pain are common complications in patients undergoing percutaneous coronary intervention (PCI) using a femoral sheath. Nonpharmacological interventions, such as sandbags and ice packs, are commonly used to promote hemostasis. This study aimed to compare the effectiveness of using a sandbag and an ice pack in reducing hematoma and pain after femoral sheath removal in patients undergoing PCI.

Methods: A single-blind randomized controlled trial (RCT) was conducted to compare hematoma size and pain level in post-PCI patients with femoral sheath across three intervention groups: (1) combined sandbag and ice pack (n=20), (2) sandbag only (n=20), and (3) ice pack only (n=20). Participants were randomly allocated using a Random Number Generator. The ice pack intervention was applied for 20 min, whereas the sandbag intervention was applied for 2 h. This study was conducted in three coronary wards with 60 participants. Hematoma size and pain level were the primary outcome measures. Hematoma size was measured using a measuring tape in millimeters (mm), and pain was assessed using the Numeric Rating Scale (NRS). Data were analyzed using the Kruskal–Wallis and Friedman tests.

Results: The Kruskal–Wallis test showed no significant difference in hematoma size and pain scale at measurement 1 (0 min) and measurement 2 (20 min) among the three groups ($p>0.05$). However, significant differences were found at the 2 h assessment for hematoma size ($p=0.011$) and pain score ($p=0.002$), with large effect sizes ranging from 0.588 to 0.728. Post hoc analysis using the Mann–Whitney U test with Bonferroni correction showed that the combined sandbag and ice pack group had significantly greater reductions in hematoma size and pain than ice pack only group and the sandbag only group. No intervention-related discomfort or adverse responses were reported by the participants.

Conclusion: The results of this study indicate that significant differences between the intervention groups began to emerge at the 2-hour mark, with a large effect size. The combined sandbag and ice pack was the most effective intervention for reducing hematoma size and pain level, followed by the ice pack-only and sandbag-only groups. Therefore, the combined sandbag and ice pack is recommended as the preferred intervention for post-PCI patients with a femoral sheath.

Keywords: hematoma, ice pack, pain, post-percutaneous coronary intervention, sandbag

Introduction

The number of degenerative diseases, including vascular and heart disorders, continues to rise globally, including in Aceh Province, Indonesia (Martin et al., 2025; Survei Kesehatan Indonesia, 2023). According to World Health Organization (WHO) data, 32% of all deaths worldwide, or 17.9 million people, are caused by heart disease. Acute Coronary Syndrome (ACS) is the leading cause of death from heart disease, accounting for 85% or 15.2 million deaths (WHO, 2025). In Indonesia, the average prevalence of heart disease in 2023 reached 0.85% and remains a concern for the government among non-communicable diseases (Indonesian Health Survey, 2023). Data from a regional referral hospital in 2022 reported that the Cardiology Polyclinic had the highest number of visits, with 2,536 patients per year or an average of 121 visits per day (Mardhiyyah, 2022). Furthermore, the total number of cardiac patients treated at a regional referral hospital increased from 32,207 in 2023 to 32,966 in 2024 (Mardhiyyah, 2025). The most common type of heart disease was coronary heart disease (CHD).

Currently, PCI is the most widely used treatment for coronary heart disease worldwide (Byrne, Stone, Ormiston, & Kastrati, 2017; Ge, Wu, Zang, & Xie, 2023; Kang, Wang, & Wu, 2023; PERKI, 2024; Zhang & Qi, 2021). PCI is considered an effective primary treatment for patients with heart attacks because it causes less trauma, requires a shorter recovery time, and provides better healing results (Ge et al., 2023). Therefore, the use of PCI continues to increase globally, including Indonesia.

The most common complications after PCI are hematomas and pain (Çürük, 2017; Pamuk & Özkaraman, 2024; Sari, Arifin, & Fatimah, 2017; Sokhanvar, Tirgari, Forouzi, Salari, & Jahani, 2023; Valikhani, Mahdizadeh, Eshraghi, Mazlum, & Dehghani, 2020). In post-PCI patients, hematomas appear as swelling accompanied by discomfort (Kurt & Kaşıkçı, 2019). A preliminary observation at the Intensive Cardiology Care Unit (ICCU) of this regional referral hospital in January 2025 showed that 13 out of 28 post-PCI patients (46%) developed hematomas. At this regional referral hospital, the standard operating procedure (SOP) recommends using a sandbag for 6 hours after femoral sheath removal. However, field observations showed that this procedure was not optimally implemented because of patient discomfort during the 6-hour application. This situation makes the management of hematomas and pain less optimal.

Several studies have demonstrated that both sandbag application and ice packs effectively reduce hematoma while improving patient comfort. A 2.1 kg sandbag was associated with greater comfort in post-PCI patients than 2.3 kg and 2.5 kg sandbags (Kusumantoro, Armiyati, & Astuti, 2023). Reducing the application time of a 2.3 kg sandbag from six hours to two hours also improved comfort without increasing complication risk (Sinaga, Nurachmah, & Gayatri, 2022). Similarly, ice pack application effectively reduced hematoma and pain. Applying an ice pack for 20 min after sheath removal decreased pain at the femoral catheter insertion site (Bayındır, Çürük, & Oguzhan, 2017; Prasetya & Handian, 2023), while application for 20 min before and after sheath removal improved comfort and reduced hematoma size and pain (Mokadem & Ibraheem, 2016). Furthermore, a 30 min ice pack application was more effective than a 2.5 kg sandbag applied for 2 h in reducing hematoma and improving patient comfort (Syahri & Andriani, 2021).

Despite previous studies having demonstrated the benefits of sandbag and ice pack interventions in reducing hematoma and pain after femoral sheath removal, the available evidence remains inconclusive regarding their comparative effectiveness, optimal duration, and impact on patient comfort. Furthermore, most studies have evaluated these interventions separately, and evidence regarding the effectiveness of their combined use is limited. In this study, integrated the intervention duration and sandbag weight for blood control. The rationale for combining sandbag and ice pack interventions is based on complementary action mechanisms of both methods. Sandbags provide mechanical compression to prevent bleeding, and ice packs promote vasoconstriction and reduce pain. Therefore, the combination of these interventions may offer greater benefits than either intervention alone. This study has several important novelties. First, it evaluated a combined sandbag and ice pack intervention compared with sandbag-only and ice pack-only interventions. Second, it used a lighter sandbag (2.1 kg) than those commonly used in clinical practice. Third, it employs a shorter intervention duration of two hours compared with the conventional six hours protocol, aiming to improve patient comfort while maintaining effectiveness. Fourth, a standardized 20-minute ice pack application was used. Finally, hematoma size and pain level were assessed repeatedly at 0 min, 20 minutes, and 2 hours, providing a more comprehensive understanding of changes over time following femoral sheath removal.

This stepwise measurement approach was important as hemostasis and hematoma formation occur dynamically. In the initial minutes, the vasoconstriction and platelet aggregation phases occur, followed by fibrin formation and blood clot stabilization in the subsequent time period. Therefore, measurements taken at multiple time points provide a more accurate picture of the effectiveness of the intervention than a single measurement.

This study not only fills an existing research gap but also offers a new approach that is more efficient, convenient, and measurable for the management of post-PCI patients with a femoral sheath. Given the important role of nurses in providing nonpharmacological interventions and considering the results of preliminary studies and field observations, this study aimed to compare the effectiveness of using a sandbag and an ice pack in reducing hematoma and pain after femoral sheath removal in patients undergoing PCI.

Methods

Research design

This was a single-blind randomized controlled trial study to compare hematoma and pain in post-PCI patients with femoral sheath in three intervention groups at a regional referral hospital. The RCT was registered in the Australian New Zealand Clinical Trial Registry (ANZCTR) with the registration number ACTRN12625001448437. The participants were unaware of their group assignment and did not know the number of group variations.

Sample and randomization

The randomization and group allocation processes for this randomized controlled trial (Figure 1). A total of 384 patients underwent PCI during the study period. Of these, 127 underwent PCI via femoral access and 257 via radial access. Of the total 127 patients who underwent PCI via femoral access, only 60 met the inclusion and exclusion criteria (67 did not meet the inclusion criteria). There were no refusals because the researchers explained the informed consent form in detail and provided guidance from a cardiologist and a vascular specialist.

This study was performed on patients who met the sample selection criteria and were registered for PCI with a femoral sheath at the hospital between August 20, 2025, and December 10, 2025. G*Power analysis was used to determine the sample size. It was calculated in the analysis that 60 patients needed to be included in three groups, with 20 patients in each group, an effect size of 0.5, a power of 90%, and an alpha error of 0.05. Group 1 included patients who used both a sandbag and an ice pack, group 2 included patients who used only a sandbag, and group 3 included patients who used only an ice pack (Figure 2). Participants were randomly assigned to three groups using a block randomization system with a random number generator. The advantage of block randomization is that it ensures that the number of participants in each group remains balanced over time.

Group allocation was determined by assigning the first two numbers to Group 2, the next two numbers to Group 3, and the last two numbers to Group 1. The order of allocation was determined by randomization using the “Spin The Wheel” app. The entire randomization process was conducted before the study began to minimize any bias.

The inclusion criteria for the sample were as follows: patients aged between 18 and 70 years, post-PCI patients with femoral sheath, patients who experienced hematoma after femoral sheath removal, patients who reported pain after femoral sheath removal, patients without blood coagulation disorders based on laboratory results, patients who received a total heparin dose of ≤10,000 IU during PCI procedure, and patients who were in a calm psychological state according to the psychological assessment on the hospital’s integrated initial inpatient assessment form. The exclusion criteria were as follows: patients who received Integrilin therapy after PCI, patients who did not receive paracetamol or ibuprofen therapy, and patients who had a cold allergy (applicable to groups 1 and 3) based on the allergy history section of the same hospital assessment form.

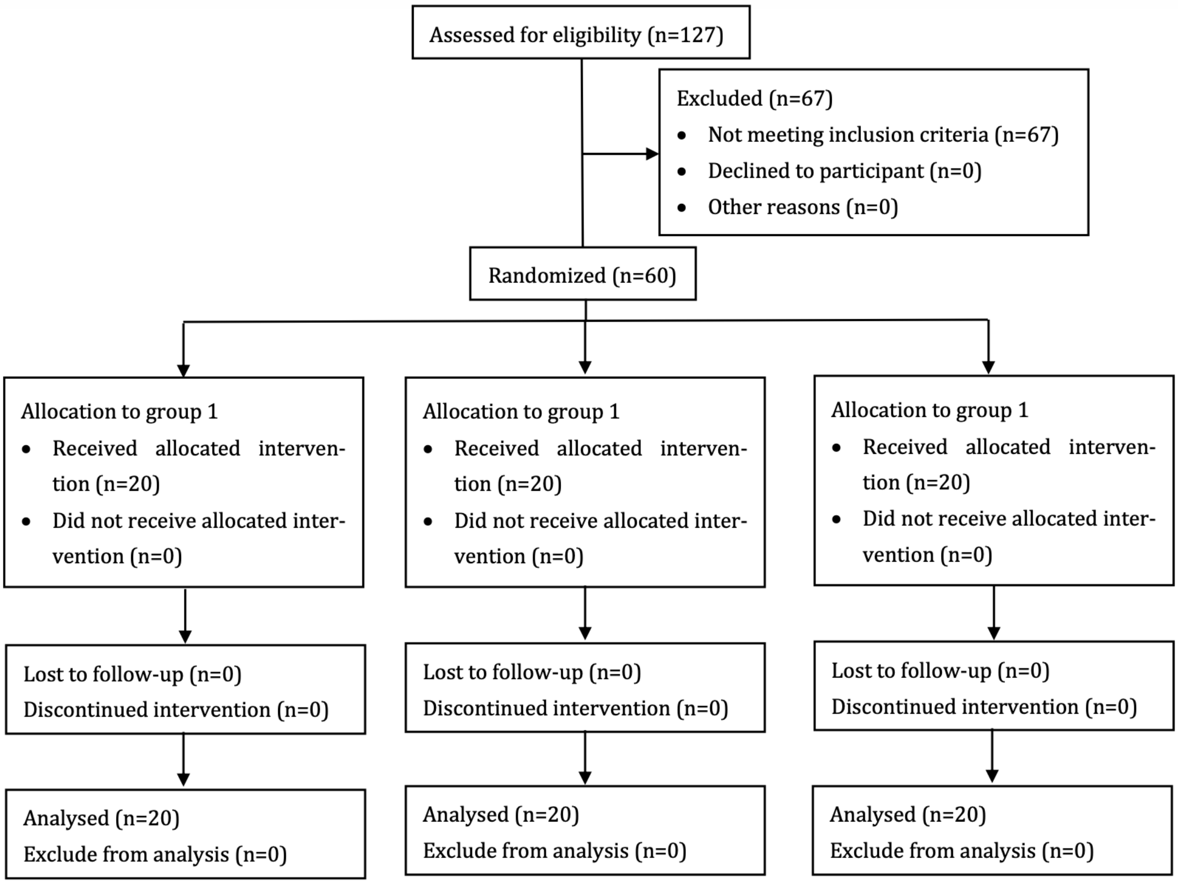

Figure 1. CONSORT flow diagram

Study procedure

Data collection will be assisted by six research assistants. The research assistant will first undergo training on the use of sandbags and ice packs and how to assess them to have a common perception and minimize bias. All enumerators were nurses who held a professional nursing degree and had worked as cardiology nurses for at least three years.

Post-PCI patients with a femoral sheath who were selected based on the study's inclusion and exclusion criteria were transferred from the CathLab to three coronary wards. The entire randomization process was conducted before the study began to minimize any bias. Therefore, the patients' interventions were already determined after they left the cath lab based on the randomization results. This was a single-blind RCT. Therefore, patients do not know which group they belong to or what the different groups are. Patients also do not meet each other; therefore, the likelihood of them encountering each other is very low.

The purpose of the study was explained, and informed consent was obtained from the respondents. If they agree to participate, they will be asked to sign a written informed consent form. The study will be terminated if a patient chooses to withdraw before the intervention is completed or if a complication involving massive bleeding occurs. Data collection began to fill in demographic data related to age, gender, education, occupation, marital status, PCI experience, and body mass index (weight and height), and looked at and checked the data in the medical records related to sheath size and coagulant therapy during the PCI procedure.

In group one, before performing the intervention, the research assistant measured the hematoma size and pain level for the first time. The first measurement was taken at 0 min after the femoral sheath or before the puncture site was covered with gauze. The research assistant then retrieved an ice pack from the medical refrigerator in each room. The ice pack was placed in a medical refrigerator at a temperature of 18-20°C for at least two hours before the procedure.

An ice pack was placed on top of two gauze dressings over the femoral sheath. This was performed to prevent hypothermia in the puncture area and to prevent water from the ice pack from entering the puncture wound. The research assistant then prepared a 2.1 kg sandbag that had been prepared in each room and placed it on top of the ice pack. The sandbag and ice pack were used simultaneously for 20 min.

After 20 min, the dressing was opened to take the second measurement of hematoma size and pain level. After the measurement was complete, the puncture area was covered again with gauze, and the ice pack was removed. Next, the puncture area was pressed using a sandbag for 1 h and 40 min or a total of 2 h. Ice packs that are no longer in use are cleaned with disinfectant and returned to the medical refrigerator for storage.

After two hours, the third measurement of hematoma size and pain level was performed, and the puncture area was covered again with gauze. The sandbag was cleaned with a disinfectant before being stored in the medical equipment cabinet. After 20 minutes, the dressing was opened to take the second measurement of hematoma and pain. After the measurement was complete, the puncture area was covered with gauze, and the ice pack was removed. Next, the puncture area was pressed using a sandbag for 1 hour and 40 minutes, or a total of two hours. The ice pack that was no longer in use was cleaned with disinfectant and returned to the medical refrigerator for storage. After two hours, the third measurement of hematoma and pain was taken, and the puncture area was covered again with gauze. Then, the sandbag was also cleaned with disinfectant before being stored in the medical equipment cabinet.

The same steps were followed for groups two and three. The difference was that group two only used a 2.1 kg sandbag for 2 h, and group three only used an ice pack for 20 minutes. More complete stages are listed in the standard operating procedure attachment. After collecting the data, the researchers and research assistants checked the completeness and accuracy of the questionnaire entries. After the data were collected, the research assistant thanked the respondents for their willingness to participate in the study.

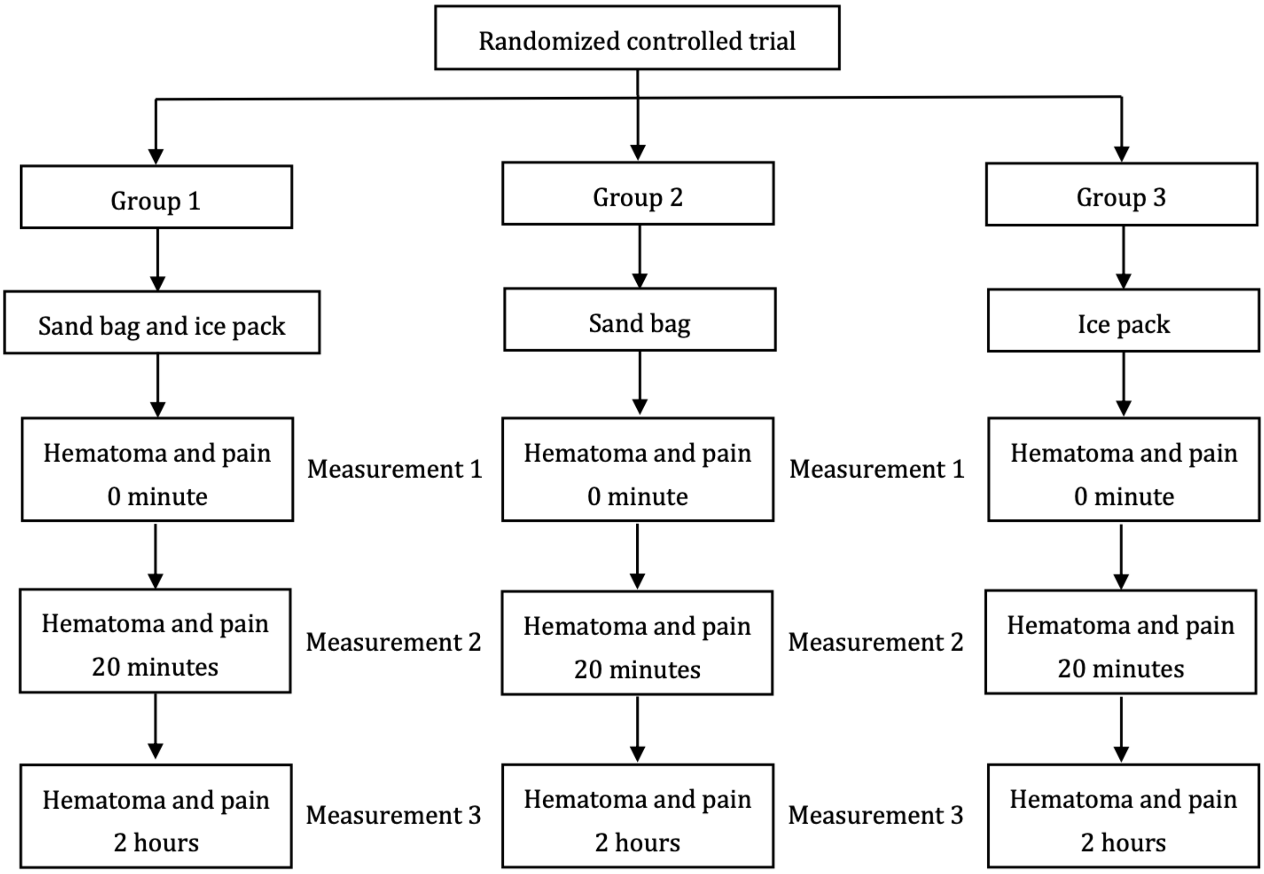

Figure 2. Intervention Groups Using RCT

Data collection

The instruments consisted of three parts: sociodemographic data, including age, gender, education, occupation, marital status, PCI experience, body mass index (BMI), sheath size, and use of anticoagulant therapy; measurement of hematoma diameter using a measuring tape in millimeters (mm); and assessment of pain level using the Numeric Rating Scale (NRS). The NRS is highly effective across various populations and can be used before and after the interventions are carried out (Downie et al., 1978; Nugent, Lovejoy, Shull, Dobscha, & Morasco, 2021).

A systematic review of 13 studies showed that the NRS instrument was valid and reliable, with Cronbach's alpha values ranging from 0.72 to 0.92 (Hrvatin & Puh, 2021). Additionally, Yani et al. (2024) tested the validity and reliability of the NRS, finding that the NRS is a valid questionnaire with a calculated r-value above 0.9, which is significantly higher than the critical value of 0.260. Furthermore, the intra-rater and inter-rater reliability of the NRS are very high, with Cronbach's alpha values above 0.9. The Cronbach's alpha value for pain in this study was 0.8.

Statistical analysis

Baseline characteristics were analyzed using one-way analysis of variance (ANOVA) and chi-square tests. The Friedman test was used to compare hematoma and pain at three time points within each group. The Kruskal–Wallis test was used to compare hematoma size and pain levels among the three intervention groups. Then, pairwise comparisons were performed using the Mann–Whitney U test with Bonferroni correction. Statistical analysis was performed using IBM SPSS Statistics version 31.0.0.0 (117).

Ethical considerations

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Health Research Ethics Committee of the General Hospital of Dr. Zainoel Abidin, Banda Aceh, Indonesia (ERC letter No. 238/ETIK-RSUDZA/2025 (protocol number: 25-07-245) on July 18th, 2025. Informed consent was obtained from all participants, and a single-blind randomized controlled trial was conducted.

Results

This study included several sociodemographic variables, such as age, sex, education, occupation, marital status, PCI experience, body mass index (BMI), sheath size, and use of anticoagulant therapy. The results of these characteristics are presented (Tables 1 and 2).

Table 1. Baseline Demographic and Clinical Characteristics of Post-PCI Patients with Femoral Sheath According to Study Groups (n = 60)

Variable	Category	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)	*p*-value
Age (year)	Mean ± SD	55.15 ± 6.98	56.85 ± 8.34	56.5 ± 5.84	0.730
Body Mass Index (kg/m^2)	Mean ± SD	27.07 ± 5.42	24.74 ± 2.86	25.92 ± 3.92	0.223
Sheath Size	Mean ± SD	6 ± 0	6 ± 0	6 ± 0	NA
Anticoagulant Therapy	Mean ± SD	6900 ± 1923	6675 ± 1541	6550 ± 1791	0.817
Gender	Female	9 (45)	7 (35)	9 (45)	0.760
	Male	11 (55)	13 (65)	11 (55)	
Education	ES / equivalent	2 (10)	1 (5)	1 (5)	0.981
	JHS / equivalent	4 (20)	4 (20)	5 (25)	
	SHS / equivalent	12 (60)	13 (65)	11 (55)	
	University / equivalent	2 (10)	2 (10)	3 (15)	
Occupation	Laborers/Farmers/Fishers	4 (20)	5 (25)	6 (30)	0.941
	Civil Servants/Army/Police	2 (10)	3 (15)	3 (15)	
	Entrepreneurs	6 (30)	7 (35)	6 (30)	
	Housewives	8 (40)	5 (25)	5 (25)	
Marital Status	Married	19 (95)	19 (95)	17 (85)	0.418
	Widower/Widow	1 (5)	1 (5)	3 (15)	
PCI Experience	Yes	7 (35)	8 (40)	8 (40)	0.932
	No	13 (65)	12 (60)	12 (60)	

Note: Continuous variables are expressed as mean ± SD and were compared using one-way ANOVA. Categorical variables are presented as n (%) and were compared using Pearson's chi-square test. NA = not applicable because all participants had the same sheath size (6 Fr).

The baseline demographic and clinical characteristics of the participants are presented in Table 1. No statistically significant differences were observed among Groups 1, 2, and 3 across all baseline variables (all p>0.05), indicating that the study groups were comparable before the intervention. The distributions of age (p=0.730), body mass index (BMI) (p=0.223), and anticoagulant therapy (p=0.817) were similar across the three groups. Femoral sheath size was identical in all participants (6 Fr); therefore, no statistical comparison was performed. Likewise, categorical variables, including sex (p=0.760), education level (p=0.981), occupation (p=0.941), marital status (p=0.418), and previous PCI experience (p=0.932), were evenly distributed among the groups. Overall, these findings demonstrate that the three groups were well balanced with respect to baseline demographic and clinical characteristics, supporting the validity of subsequent comparisons and suggesting that any observed differences in clinical outcomes were more likely attributable to the interventions rather than to pre-existing differences among participants.

Table 2. Analysis of Differences in Hematoma and Pain in Each Group in Post-PCI Patients with Femoral Sheath (n=60)

Variable	Category	Median (IQR)	Mean Rank	χ^2 (df)	p
Hematoma of Group 1	0 minutes	20 (10-70)	2.90	36.521 (2)	<0.001
	20 minutes	10 (0-41)	2.03		
	2 hours	0 (0-33)	1.08		
Hematoma of Group 2	0 minutes	20.5 (10-70)	2.80	33.091 (2)	<0.001
	20 minutes	17 (0-60)	2.05		
	2 hours	10 (0-40)	1.15		
Hematoma of Group 3	0 minutes	20 (10-80)	2.93	37.520 (2)	<0.001
	20 minutes	10 (0-50)	2.03		
	2 hours	5 (0-40)	1.05		
Pain of Group 1	0 minutes	4 (1-6)	2.95	37.520 (2)	<0.001
	20 minutes	2 (0-4)	1.98		
	2 hours	0 (0-2)	1.08		
Pain of Group 2	0 minutes	3.5 (1-5)	2.93	36.521 (2)	<0.001
	20 minutes	2.5 (1-3)	1.98		
	2 hours	1 (0-3)	1.10		
Pain of Group 3	0 minutes	3 (1-6)	3.00	38.316 (2)	<0.001
	20 minutes	2 (0-4)	1.90		
	2 hours	0 (0-2)	1.10		

Note: P-values were calculated using the Friedman test.

The Friedman test showed significant changes in hematoma size over time within all three study groups (all $p<0.001$) (Table 2). Descriptively, the median hematoma size and mean ranks progressively decreased from baseline to 20 minutes and 2 hours after the intervention in each group. A similar pattern was observed for pain scores, with significant reductions over time in all three groups (all $p<0.001$). The median pain scores and corresponding mean ranks consistently declined across the three assessment time points, indicating progressive improvement following the interventions.

The Kruskal–Wallis test showed no significant differences in hematoma size among the three groups at measurement 1 (0 min) ($H=0.228$, $df=2$, $p=0.892$) and measurement 2 (20 min) ($H=2.225$, $df=2$, $p=0.329$). However, a significant difference was observed at Measurement 3 (2 h) ($H=9.007$, $df=2$, $p=0.011$). Similarly, no significant differences in pain scores were found at measurement 1 (0 min) ($H=0.213$, $df=2$, $p=0.899$) and measurement 2 (20 min) ($H=0.963$, $df=2$, $p=0.618$), whereas a significant difference was observed at measurement 3 (2 h) ($H=12.702$, $df=2$, $p=0.002$). At the 2-hour assessment, Group 1 (combined sandbag and ice pack) demonstrated the lowest median hematoma size (0 mm; IQR 0–33) and pain score (0; IQR 0–2), as well as the lowest mean ranks for hematoma (23.28) and pain (23.90), indicating a greater reduction in both outcomes compared to Groups 2 and 3 (Table 3).

Table 3. The Comparison of Hematoma and Pain in Each Group of Post-PCI Patients with Femoral Sheath (n=60)

Variable	Category	Median (IQR)	Mean Rank	H (df)	p
Hematoma measurement 1 (0 minutes)	Group 1	20 (10-70)	30.20	0.228 (2)	0.892
	Group 2	20.5 (10-70)	31.93		
	Group 3	20 (10-80)	29.38		
Hematoma measurement 2 (20 minutes)	Group 1	10 (0-41)	28.48	2.225 (2)	0.329
	Group 2	17 (0-60)	35.10		
	Group 3	10 (0-50)	27.93		
Hematoma measurement 3 (2 hours)	Group 1	0 (0-33)	23.28	9.007 (2)	0.011
	Group 2	10 (0-40)	39.00		
	Group 3	5 (0-40)	29.23		
Pain measurement 1 (0 minutes)	Group 1	4 (1-6)	31.55	0.213 (2)	0.899
	Group 2	3.5 (1-5)	29.13		
	Group 3	3 (1-6)	30.83		
Pain measurement 2 (20 minutes)	Group 1	2 (0-4)	27.80	0.963 (2)	0.618
	Group 2	2.5(1-3)	33.00		
	Group 3	2 (0-4)	30.70		
Pain measurement 3 (2 hours)	Group 1	0 (0-2)	23.90	12.702(2)	0.002
	Group 2	1 (0-3)	40.55		
	Group 3	0 (0-2)	27.05		

Note: P-values were calculated using the Kruskal–Wallis test.

Table 4. Post Hoc Analysis of Paired Comparisons Using the Mann-Whitney Test with Bonferroni Correction

Variable	Group Comparison	Z value	Effect Size	*p-value*
Hematoma measurement 1 (0 minutes)	1 - 2	-0,275	0,061	0,783
	1 - 3	-0,110	0,024	0,913
	2 - 3	-0,507	0,113	0,612
Hematoma measurement 2 (20 minutes)	1 - 2	-1,227	0,274	0,220
	1 - 3	-0,099	0,022	0,921
	2 - 3	-1,329	0,297	0,184
Hematoma measurement 3 (2 hours)	1 - 2	-2,887	0,645	0,004
	1 - 3	-1,235	0,276	0,217
	2 - 3	-1,900	0,425	0,057
Pain measurement 1 (0 minutes)	1 - 2	-0,528	0,118	0,598
	1 - 3	-0,055	0,012	0,956
	2 - 3	-0,238	0,053	0,812
Pain measurement 2 (20 minutes)	1 - 2	-1,064	0,238	0,287
	1 - 3	-0,459	0,102	0,646
	2 - 3	-0,356	0,079	0,722
Pain measurement 3 (2 hours)	1 - 2	-3,255	0,728	0,001
	1 - 3	-0,724	0,161	0,469
	2 - 3	-2,629	0,588	0,009

Note: Bonferroni-adjusted significance level ($p < 0.017$)

Post hoc pairwise comparisons were performed using the Mann–Whitney U test with Bonferroni correction (adjusted significance level, $p<0.017$). At two hours, a significant difference in hematoma size was found only between Groups 1 and 2 ($p=0.004$; effect size=0.645), whereas no significant differences were observed between Groups 1 and 3 ($p=0.217$) or between Groups 2 and 3 ($p=0.057$). At two hours, pain scores were significantly different between Groups 1 and 2 ($p=0.001$; effect size=0.728) and between Groups 2 and 3 ($p=0.009$; effect size=0.588), but not between Groups 1 and 3 ($p=0.469$) (Table 4). These findings indicate that the combined sandbag and ice pack intervention was more effective than the ice pack-only and sandbag-only interventions in reducing hematoma size and pain following PCI with femoral sheath removal.

Discussion

This study examined the effectiveness of sandbag and ice pack application in reducing hematoma and pain after femoral sheath removal in patients undergoing PCI. Although transradial access is recommended because it has a lower risk of bleeding and vascular complications, transfemoral access is still widely used for complex coronary interventions, large-bore catheters, structural heart procedures, or when radial access is not feasible (Lawton et al., 2022; Naidu et al., 2021; Vrints et al., 2024). As a result, hematoma and pain after femoral sheath removal remain common complications that can delay mobilization, prolong hospitalization, increase healthcare costs, and reduce patient comfort. These challenges highlight the need for effective and practical nurse-led strategies to prevent access-site complications.

The present study demonstrated that all three interventions significantly reduced the hematoma size and pain over time. However, clinically meaningful differences between the intervention groups became apparent only at the two-hour assessment, with the combined sandbag and ice pack intervention producing the greatest clinical improvement. These findings suggest that the effectiveness of non-pharmacological interventions depends not only on the intervention itself but also on the physiological progression of vascular healing after femoral sheath removal. During the early phase following sheath removal, primary hemostasis is initiated through reflex vasoconstriction and platelet plug formation. At this stage, the physiological responses were relatively similar among the patients, explaining the absence of significant differences immediately after the intervention. As coagulation progresses, fibrin stabilization, clot retraction, and attenuation of the inflammatory response become more established, allowing differences between interventions to emerge more clearly approximately two hours after the procedure (Hall & Hall, 2021; Libby et al., 2022; Smeltzer & Bare, 2018).

The superior effectiveness of the combined intervention can be explained by the complementary physiological mechanisms of sandbag compression and ice packing. The mechanical compression provided by the sandbag reduces arterial blood leakage, supports platelet aggregation, and stabilizes fibrin clot formation, thereby preventing further blood extravasation into the surrounding tissue (Kern, Sorajja, & Lim, 2020; Sarabi, Farsi, Ghelich, Moradi, & Mousavi, 2023). In contrast, ice packs primarily induce local vasoconstriction, decrease tissue metabolism, suppress inflammatory mediator release, and slow peripheral nerve conduction, resulting in reduced edema and analgesic effects (Hall & Hall, 2021; Kurt & Kaşıkçı, 2019). When applied simultaneously, these interventions appear to produce a synergistic effect by targeting two key pathophysiological pathways: mechanical control of bleeding and modulation of inflammatory pain. This dual mechanism provides a plausible explanation for the greater reduction in hematoma size and pain observed in the combined intervention group.

While the sandbag-only and ice pack-only interventions also demonstrated significant improvements, each addressed only part of the underlying pathophysiological process. Sandbag compression effectively promotes hemostasis through sustained external pressure but has limited influence on inflammatory pain and may contribute to discomfort when applied for prolonged periods. Conversely, ice packs rapidly reduce pain and limit inflammatory edema through vasoconstriction and decreased nociceptor activity but do not provide continuous mechanical support for clot stabilization. These findings indicate that combining both interventions offers greater therapeutic benefits than either intervention alone, as it simultaneously enhances vascular hemostasis while attenuating inflammatory responses. Unlike previous studies that evaluated sandbags or ice packs separately (Bayındır et al., 2017; Çürük, 2017; Kurt & Kaşıkçı, 2019; Mandal et al., 2022; Nuraeni et al., 2023; Pamuk & Özkaraman, 2024; Sokhanvar et al., 2023), the present study directly compared the combined intervention with each single intervention. Furthermore, the use of a lighter 2.1-kg sandbag, shorter compression duration of two hours, and repeated assessments at baseline, 20 min, and two hours enabled a more comprehensive evaluation of early vascular healing while potentially improving patient comfort. These methodological innovations provide additional evidence to support the integration of combined non-pharmacological interventions into routine post-PCI nursing care.

From a nursing perspective, these findings have important clinical implications. Nurses play a pivotal role in monitoring vascular access sites, assessing hematomas and pain, and implementing evidence-based interventions following femoral sheath removal. Incorporating the combined application of a 2.1-kg sandbag and a 20-minute ice pack into post-PCI nursing protocols may reduce access-site complications while shortening compression time compared with conventional practices. Standardized reassessment of hematoma size and pain during the first two hours after sheath removal may further facilitate the early identification of complications, improve patient comfort, support earlier mobilization, and enhance the overall quality and efficiency of cardiovascular nursing care.

Overall, this study demonstrates that combining sandbag compression with ice pack application provides greater clinical benefits than either intervention alone by simultaneously promoting hemostasis and reducing inflammatory pain after femoral sheath removal. These findings support the incorporation of this combined intervention into evidence-based nursing protocols to reduce access site complications and optimize post-PCI patient care.

Limitations

This study had several limitations. The relatively small sample size may limit the generalizability of our findings. Although a single-blind design was implemented to minimize participant bias, the intervention providers were not blinded because of the nature of this intervention. Therefore, the possibility of performance bias cannot be completely ruled out. Finally, the short follow-up period did not allow for the evaluation of the long-term effects of the intervention.

Contribution to Global Nursing Practice

The findings of this study provide evidence supporting the use of combined ice pack and sandbag therapy as an effective non-pharmacological nursing intervention for reducing hematoma size and pain following femoral sheath removal after PCI. This evidence may support the development or refinement of standardized nursing protocols for post-PCI vascular access management, promoting more consistent, safe, and evidence-based nursing care. By demonstrating the effectiveness of a lighter sandbag combined with a shorter compression duration, this study offers a practical strategy that may improve patient comfort, reduce prolonged immobilization, and enhance the efficiency of nursing care without compromising patient safety. Although transradial access has become the preferred approach for PCI in many settings, femoral access remains essential for complex procedures and for patients in whom radial access is not feasible. Therefore, these findings may be applicable across diverse cardiovascular care settings, including tertiary hospitals and resource-limited healthcare facilities where femoral access continues to be widely used. Incorporating this evidence into clinical practice may improve the quality and consistency of post-PCI nursing care, strengthen patient safety, and reinforce the role of nurses in implementing evidence-based cardiovascular care.

Conclusion

This study demonstrated that the combined use of a sandbag and an ice pack, a sandbag alone, and an ice pack alone effectively reduced hematoma size and pain following femoral sheath removal after PCI. Clinically meaningful differences among the interventions became evident after two hours, with the combined intervention producing the greatest reduction in hematoma size and pain, followed by the ice pack alone and the sandbag alone. These findings suggest that combining a 2.1-kg sandbag for two hours with a 20-minute ice pack provides a simple, safe, affordable, and comfortable non-pharmacological nursing intervention for managing access-site complications after PCI. Incorporating this combined intervention into routine post-PCI nursing care may improve patient comfort and support evidence-based cardiovascular nursing practice.

Author Contribution

CH, AP, and ETH wrote the protocol and monitored data collection. ETH, HS, and AP contributed to the data analysis. CH and ETH performed the data analysis and wrote the initial manuscript. AP, CH, and AP contributed to the critical review of the manuscript. All authors have approved the final version of this article.

Conflict of Interest

All authors declare no conflicts of interest.

Acknowledgments

The authors are grateful to all the participants who willingly participated in this study. The authors also thank the research assistants who helped collect the data and contributed to the success of the study.

Funding

This study was funded and supported by an award granted by the Institute for Research and Community Services of Universitas Syiah Kuala, Banda Aceh, Indonesia, with contract number: 387/UN11.L1/PG. 01.03/14277-PTNBH/2025.

References

Bayındır, S. K., Çürük, G. N., & Oguzhan, A. (2017). Effect of ice bag application to femoral region on pain in patients undergoing percutaneous coronary intervention. *Pain Research and Management*, *2017*, 1–7. https://doi.org/10.1155/2017/6594782

Butman, S. (2015). *Complications of Percutaneous Coronary Interventions*. United States: Springer Science.

Byrne, R. A., Stone, G. W., Ormiston, J., & Kastrati, A. (2017). Coronary balloon angioplasty, stents, and scaffolds. *The Lancet*, *390*(10096), 781–792. https://doi.org/10.1016/S0140-6736(17)31927-X

Çürük, G. N. (2017). The effect of ice-bag applied to femoral region of individuals with percutaneous coronary intervention on local vascular complications and low back-pain. *IOSR Journal of Nursing and Health Science*, *06*(01), 136–144. https://doi.org/10.9790/1959-060105136144

Downie, W. W., Leatham, P. A., Rhind, V. M., Wright, V., Branco, J. A., & Anderson, J. A. (1978). Studies with pain rating scales. *Annals of the Rheumatic Diseases*, *37*(4), 378–381. https://doi.org/10.1136/ard.37.4.378

Ge, X., Wu, H., Zang, Z., & Xie, J. (2023). Application of checklist-based nursing care process in patients undergoing intervention for coronary chronic total occlusions: a quasi-randomized study. *BMC Cardiovascular Disorders*, *23*(591), 1–11. https://doi.org/10.1186/s12872-023-03627-8

Hall, J. E., & Hall, M. E. (2021). *Guyton and Hall textbook of medical physiology*. Philadelphia: Elsevier.

Kang, L., Wang, M., & Wu, S. (2023). Construction of nursing-sensitive quality indicator system for cardiac rehabilitation of patients undergoing percutaneous coronary intervention based on structure-process-outcome model. *BMC Nursing*, *22*(457), 1–7. https://doi.org/10.1186/s12912-023-01618-w

Kern, M. J., Sorajja, Paul., & Lim, M. J. . (2020). *Kern's cardiac catheterization handbook*. Philadelphia: Elsevier.

Kurt, Y., & Kaşıkçı, M. (2019). The effect of the application of cold on hematoma, ecchymosis, and pain at the catheter site in patients undergoing percutaneous coronary intervention. *International Journal of Nursing Sciences*, *6*(4), 378–384. https://doi.org/10.1016/j.ijnss.2019.09.005

Kusumantoro, A., Armiyati, Y., & Astuti, R. (2023). Pengaruh penggunaan bantal pasir terhadap keluhan ketidaknyamanan pasien pasca percutaneous coronaryangiography (PCA) di Instalasi Jantung dan Pembuluh Darah RSUP dr. Kariadi Semarang. *Fikkes Jurnal Keperawatan*, 1–14.

Lawton, J. S., Tamis-Holland, J. E., Bangalore, S., Bates, E. R., Beckie, T. M., Bischoff, J. M., … Zwischenberger, B. A. (2022). 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the american college of cardiology/american heart association joint committee on clinical practice guidelines. *Circulation*, *145*(3), E18–E114. https://doi.org/10.1161/CIR.0000000000001038

Libby, P., Bonow, R., Mann, D., Tomaselli, G., Bhatt, D., & Solomon, S. (2022). *Braunwald's Heart Disease* (12th ed., Vol. 1st; E. Braundwald, Ed.). Philadephia: Elsevier.

Mandal, S., Joseph, A., Razack, A., Pattanayak, D., Singh, P., Vidya, J., & Manisha. (2022). A study to compare the effect on application of sandbags after percutaneous coronary intervention (coronary angioplasty) versus the effect of simultaneous sandbag-ice pack alternatively after percutaneous coronary intervention at HCG Hubli Suchirayu Hospital. *Global Research Review in Business and Economics*, *8*(6). https://doi.org/10.56805/grrbe

Mardhiyyah, M. (2022). *Kunjungan Poliklinik Jantung 2022*. Banda Aceh.

Mardhiyyah, M. (2025). *Jumlah Pasien Jantung*. Banda Aceh.

Martin, S. S., Aday, A. W., Allen, N. B., Almarzooq, Z. I., Anderson, C. A. M., Arora, P., … Palaniappan, L. P. (2025). 2025 Heart disease and stroke statistics: A report of US and global data from the American Heart Association. *Circulation*, *151*(8). https://doi.org/10.1161/CIR.0000000000001303

Mokadem, N. EL, & Ibraheem, S. (2016). The effectiveness of using ice application on vascular access site complication after cardiac catheterization. *Journal of Nursing and Health Science*, *5*(1), 8–16. https://doi.org/10.9790/1959-05140816

Naidu, S. S., Abbott, J. D., Bagai, J., Blankenship, J., Garcia, S., Iqbal, S. N., … Kolansky, D. M. (2021). SCAI expert consensus update on best practices in the cardiac catheterization laboratory. *Catheterization and Cardiovascular Interventions*, *98*(2), 255–276. https://doi.org/10.1002/ccd.29744

Nugent, S. M., Lovejoy, T. I., Shull, S., Dobscha, S. K., & Morasco, B. J. (2021). Associations of pain numeric rating scale scores collected during usual care with research administered patient reported pain outcomes. *Pain Medicine*, *22*(10), 2235–2241. https://doi.org/10.1093/pm/pnab110

Nuraeni, A., Arrafi, A. R., Rahmah, A., Rohaeti, E., Adzillah, F. L. N., Arafah, H. N., … Mirwanti, R. (2023). Potensi kompres dingin terhadap pencegahan hematoma pada pasien pasca percutaneous coronary intervention (PCI): Scoping review. *Malahayati Nursing Journal*, *5*(7), 2185–2200. https://doi.org/10.33024/mnj.v5i7.9996

Pamuk, G. D., & Özkaraman, A. (2024). The effect of cold sand pack on percutaneous coronary intervention-induced vascular complications and pain: A randomized controlled trial. *Florence Nightingale Journal of Nursing*, *32*(1), 58–67. https://doi.org/10.5152/FNJN.2024.23074

PERKI. (2024). Pedoman Tata Laksana Sindrom Koroner Akut. In *Perhimpunan Dokter Spesialis Kardiovaskular Indonesia (PERKI)* (5th ed.). Jakarta: PERKI. https://doi.org/10.5694/j.1326-5377.2007.tb01292.x

Prasetya, A., & Handian, F. I. (2023). The effect of ice gel pack on pain reduction of sheath removal in post-cardiac catheterization patients. *The Journal of Palembang Nursing Studies*, *2*(1), 67–74. https://doi.org/10.55048/jpns.v2i1.79

Sarabi, H. N., Farsi, Z., Ghelich, Y., Moradi, B., & Mousavi, S. H. (2023). Comparison of the effectiveness of the femostop device and sandbag pressure on hemostasis during sheath removal and reducing puncture site complications following transfemoral coronary angiography: A randomized controlled trial. *Jundishapur Journal of Chronic Disease Care*, *12*(4). https://doi.org/10.5812/jjcdc-139002

Sari, E. A., Arifin, M. Z., & Fatimah, S. (2017). Perbandingan hematoma pasca kateterisasi jantung berdasarkan penekanan bantal pasir dan cold pack. *Jurnal Pendidikan Keperawatan Indonesia*, *3*(2), 100–114. https://doi.org/10.17509/jpki.v3i2.9414

Sinaga, J., Nurachmah, E., & Gayatri, D. (2022). Penekanan bantal pasir efektif untuk klien pasca kateterisasi jantung dengan komplikasi: Randomized controlled trial. *Jurnal Keperawatan Indonesia*, *15*(3). https://doi.org/10.7454/jki.v15i3.24

Smeltzer, S. C., & Bare, B. G. (2018). *Brunner and Suddarth's Textbook of Medical Surgical Nursing*. Jakarta: Penerbit Buku Kedokteran EGC.

Sokhanvar, S., Tirgari, B., Forouzi, M. A., Salari, M., & Jahani, Y. (2023). Effect of ice bag application to femoral region on pain and vital signs in patients with acute myocardial infarction undergoing percutaneous coronary intervention: A randomized controlled trial. *The Open Nursing Journal*, *17*(1). https://doi.org/10.2174/18744346-v17-e230113-2022-133

Soylu, A., Şahin, A. T., Kan, H., Sarı, H., & Tatar, S. (2024). Effects of sandbag free follow up after manual compression in patients who underwent transfemoral access for percutaneous intervention. *Turk Kardiyoloji Dernegi Arsivi*, *52*(6), 394–399. https://doi.org/10.5543/tkda.2024.59987

Survei Kesehatan Indonesia. (2023). Survei Kesehatan Indonesia (SKI) 2023. In *Kementerian Kesehatan*. Jakarta: Kementerian Kesehatan.

Syahri, A., & Andriani, R. (2021). Perbandingan penggunaan bantal pasir dan cold pack dalam mencegah komplikasi hematoma pada pasien pasca cardiac catheterization di cathlab rumah sakit umum pusat H. Adam Malik Medan. *Biology Education, Science & Technology*, 195–202. https://doi.org/https://doi.org/10.30743/best.v4i2.4492

Valikhani, M., Mahdizadeh, S. M., Eshraghi, A., Mazlum, S. R., & Dehghani, J. (2020). The effect of simultaneous sand-ice bag application on hemorrhage and hematoma after percutaneous coronary intervention: A randomized clinical trial. *Journal of Caring Sciences*, *9*(4), 188–194. https://doi.org/10.34172/jcs.2020.029

Vrints, C., Andreotti, F., Koskinas, K. C., Rossello, X., Adamo, M., Ainslie, J., … Rossi, A. (2024). 2024 ESC guidelines for the management of chronic coronary syndromes. *European Heart Journal*, 1–123. https://doi.org/10.1093/eurheartj/ehae177

WHO. (2025). Cardiovascular Diseases (CVDs). Retrieved March 19, 2025, from World Health Organization website: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)?gad_source=1&gclid=Cj0KCQjw_sq2BhCUARIsAIVqmQtPFg9LQPMxhCdnbd4ZMvg25u0xYXpHzoj-kMOhoqNY77FJl6Mw_uMaAr40EALw_wcB

Zhang, T., & Qi, X. (2021). Greater nursing role for enhanced post-percutaneous coronary intervention management. *International Journal of General Medicine*, *14*(7), 7115–7120. https://doi.org/10.2147/IJGM.S337385