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Effectiveness of the Benson Relaxation Technique in Reducing Pain During Femoral Artery Sheath Removal Following Percutaneous Coronary Intervention

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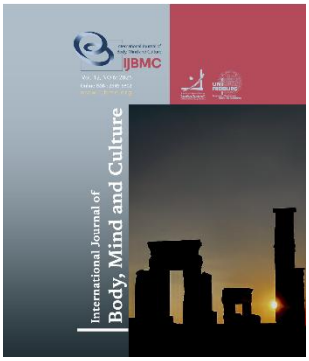

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ABSTRACT

Objective: This study aimed to evaluate the effectiveness of the Benson Relaxation Technique (BRT) in reducing pain during femoral artery sheath removal after percutaneous coronary intervention (PCI).

Methods and Materials: A randomized controlled trial was conducted at three cardiac centers in Iraq. A total of 58 patients undergoing therapeutic PCI were randomly assigned into two groups: intervention (n=27) and control (n=31). The intervention group received BRT for 10 minutes before and after sheath removal. Pain was assessed using the Visual Analogue Scale (VAS) immediately after the procedure. Demographic data and clinical variables were collected. Data were analyzed using SPSS v26 and non-parametric tests (Mann-Whitney U, Kruskal-Wallis, and Spearman correlation).

Findings: The mean VAS score in the control group was 61.13±12.06 before sheath removal and 50.10±10.55 after. In contrast, the BRT group reported significantly lower pain scores: 36.48±11.80 and 28.81±8.20, respectively ($p<0.001$). No significant differences in pain scores were found with regard to BMI, smoking status, chronic disease, or previous PCI. Age showed a negative correlation with pain levels ($p<0.05$), and occupation had a significant influence.

Conclusion: Benson Relaxation Technique is an effective, non-pharmacological, and low-cost method for reducing pain during femoral sheath removal in PCI patients. Its implementation in nursing care can enhance patient comfort without adverse effects.

Keywords: Relaxation, Pain Management, Coronary artery disease.

Introduction

Cardiovascular diseases(CVDs) refer to many heart and circulatory disorders (Ahmad, 2020; Ike & Onyema, 2020). Countries with middle and low incomes constitute 90% of fatalities due to CVDs (Gaziano et al., 2020; Ndejjo et al., 2021). The predominant form of CVDs is Coronary Artery Disease (CAD), also known as Ischemic Heart Disease (Al-Mussawi & Al-Jubouri, 2024; Valikhani et al., 2020). CAD continues to be a significant contributor to morbidity and mortality in numerous countries (Abbas & Hassen, 2024; Amini et al., 2021; Salman & Salman, 2024; Vaduganathan et al., 2022). Ischemic heart disease (IHD) constitutes a significant public health hazard, with recent studies projecting its global increase (Al-zuhairy & Al-Jubouri, 2024; Shu et al., 2024). The 2019 Global Burden of Disease, Injuries, and Risk Factors Study estimated 197 million cases of IHD (Abbas & Hassen, 2024). In 2019, IHD resulted in 182 million disability-adjusted life years and 9.14 million fatalities in China. IHD was the predominant cause of mortality in Central Europe, Central Asia, high-income nations, North Africa, and the

Middle East from 1990 to 2021 (Naghavi et al., 2024). CAD may be increasing among Iraqi adolescents aged 15 to 17. The expenses associated with IHD encompass hospital admissions, therapeutic interventions, revascularization procedures, outpatient consultations, emergency care, and prescribed medications (Gheorghe et al., 2018; Khan et al., 2019).

Angiography is the definitive method for diagnosing CAD and is frequently employed for its evaluation. IHD must be treated with invasive and surgical procedures, such as percutaneous coronary intervention (PCI) and coronary artery bypass grafting (Sabri & Hassan, 2023; World Health Organization, 2021a). A prevalent intervention for managing IHD is PCI. Transfemoral access has been the standard way to do PCI for a long time because the larger artery makes it easier to cannulate, manipulate, and deploy mechanical assist devices at the same time, and the door-to-balloon times are shorter (Changal et al., 2021).

Post-PCI, patients often report discomfort originating from multiple sources, including headache, back pain, and pain at the puncture site (Paganin et al., 2018). Furthermore, PCI patients may endure discomfort upon the removal of the arterial sheath. Furthermore, exerting pressure at the catheter insertion site may induce pain (Nair et al., 2020). Regular method for stopping bleeding after arterial sheath extraction involves applying pressure to the femoral site by hand. This takes about 20 minutes to stop the bleeding (Ali et al., 2020). The patient experienced pain during the sheath removal procedure, increasing the risk of a significant vascular incident (Heidaranlu et al., 2021). The primary responsibilities of healthcare providers, especially nurses, encompass the prevention and mitigation of postoperative pain (Small & Laycock, 2020). Consequently, it is the ethical and professional obligation of nurses to ensure their patients receive adequate pain relief. Pain management practices encompass actions that nurses should undertake to alleviate patient discomfort. This involves assessing the patients' pain, implementing appropriate nursing interventions to alleviate their discomfort, and subsequently reassessing the patients' pain following the interventions (Zeleke et al., 2021). Medications such as lidocaine infiltration or morphine sulfate can mitigate the pain associated with femoral catheter removal (Bayindir et al., 2017). Numerous pharmaceutical options exist for postoperative pain; however, they are suboptimal due to adverse effects such as hemorrhage, renal impairment, and respiratory depression (Alhassani et al., 2021; Bayindir et al., 2017). Numerous alternatives to pharmaceutical treatment are available, and they are more cost-effective, less invasive, and less hazardous (34, 35). These approaches' focus on the psychological, emotional, and social aspects of pain provides them with an advantage over conventional pharmacological methods. It enhances feelings of competence, diminishes pain severity, improves quality of life, decreases reliance on pain medication, and lowers costs (35, 36).A variety of non-pharmacological methods are available for pain management, including positioning, massage, temperature therapy, acupuncture, TENS, progressive muscle relaxation, and thermal therapy. Benson's Relaxation Technique (BRT), developed by Herbert Benson in 1970 as a simple method for reducing tension, is an additional nonpharmacological approach. This strategy positively impacted the reduction of pain levels in patients undergoing cardiac catheterization and hemodialysis; furthermore, it may also be effective in diminishing pain intensity (Molazem et al., 2021). The BRT functions by reducing sympathetic activity. It assists individuals in enhancing their emotional state, alleviating pain-induced muscle tension, and restoring their sense of well-being (Ebrahimloee et al., 2022). There is a notable lack of research specifically looking at how the BRT affects the pain of removing the sheath after PCI, even though it is known that different relaxation techniques can help ease procedural pain. While some studies have examined general pain management strategies in this context, they often overlook the unique benefits of the Benson Relaxation Technique. This gap in the literature underscores the necessity for targeted research on its efficacy and application in clinical practice, limiting our understanding of its potential to alleviate pain and anxiety in patients undergoing sheath removal. The main goal of this study is to fill in this gap by conducting a clinical trial to see how the BRT can help ease pain during the removal of the arterial femoral sheath after PCI. The question that was looked into was whether the Benson relaxation technique, compared to standard care, lessened the pain of removing the femoral artery sheath in patients who had recently had PCI.

Methods and Materials

Research design

The study is a multicenter randomized controlled trial. The researcher can use this design to find the best cause-and-effect relationship between the independent variable (the Benson relaxation technique) and the dependent variable (pain). They can also see how the BRT affects pain after removing the femoral artery sheath and figure out which intervention works best.

Setting; -

The study took place at three cardiac centers. Imam Hassan Al Mujtaba Cardiac Surgery Centre in Karbala, which is a government teaching special center for open-heart surgery and cardiac catheterization, Karbala center of cardiac surgeries and catheterization interventions, and Ibn Alnafees Teaching Hospital in Baghdad.

Sample and sampling

Study sample collected from patient going to femoral sheath removal after PCI.

Figure 1

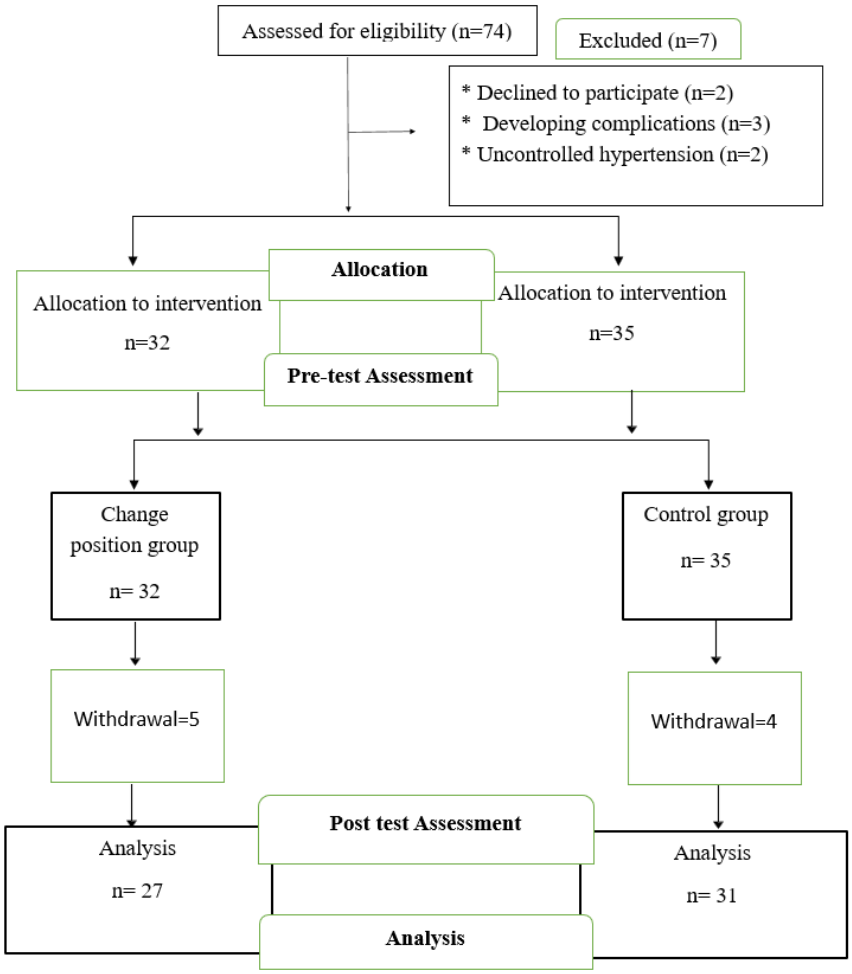
study flow diagram

Inclusion criteria

A patient who is going to remove the femoral sheath after therapeutic PCI, able to speak and understand Arabic, over 18 years of age. **Exclusion criteria**: -The patient underwent successful PCI without any complications requiring cardiopulmonary resuscitation, such as a pulse rate below 60, a hearing defect, a visual problem, a decreased level of consciousness, diabetic peripheral neuropathy, drug addiction, and hepatitis C and B.

Sampling method

The procedure involves a simple random sampling of patients undergoing therapeutic PCI, during which the sheath is removed. The envelope should contain two colors: white for the intervention and black for the control. **Minimum sample size:** -26 for each group, anticipated effect size (Cohen's d) 0.8, which is considered a large effect size, desired statistical power level (0.8), and probability level 0.05. And because of the randomization process, the total sample size was 63 for the BRT and the control group; 5 patients are not analysed as in Figure 1.



Instrumentation

Demographic and clinical data: -first section contains the participant's age, chronic disease, previous PCI, smoking, job and BMI. The second section is **Visual Analogue Scale (VAS):** We use this scale to evaluate the intensity of pain individuals experience during the sheath removal process. Hayes and Patterson used the first one in 1921 (40). The research literature frequently uses VAS, demonstrating its importance in determining the severity of pain. Numerous studies have demonstrated its validity and reliability in assessing pain severity (41–43). The reliability of the VAS was 0.97 (44).The VAS evaluates pain on a range of 1–100, classifying it as "none" (0–4 mm), "mild" (5–44 mm), "moderate" (45–74 mm), or "severe" (75–100 mm). We use a ruler to measure the distance between the anchor (0 mm) and the client's mark on VAS (40).

Data collection

The researcher obtains consent from all participants to gather the research data. The researcher engages with the study participants who were admitted to Cardiac Surgery Centers to obtain their consent for participation and elucidate the study's objectives. The study started in September 2024, with data collection initiating on November 17, 2024. The collection began on November 17, 2024. The patients scheduled to have the femoral sheath removed post-PCI are randomly assigned to two groups: the BRT group and the control group. The researcher employed the VAS with all patients to evaluate pain levels during sheath removal following the completion of study procedures via a self-report method. In the Benson relaxation group, we instructed the patients in the following technique: Adopt a comfortable position and engage in contemplation in silence. Close your eyes. Systematically relax all your muscles, starting

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from your feet and moving upward to your face. and maintain their relaxation. Inhale through your nostrils; maintain consciousness of your respiration. Softly exhale through your mouth while articulating a soothing word, then return to your regular breathing pattern. Repeat the procedure for 10 to 20 minutes; endeavor to fully relax; subsequently, open your eyes gradually and maintain the same position for several minutes. Do not concern yourself with attaining a profound state of relaxation; allow it to manifest at its own tempo. When intrusive thoughts arise, endeavor to disregard them by refraining from ruminating on them. This The technique is executed for 10 minutes prior to the commencement of sheath removal and for an additional 10 minutes following the initial sheath removal.

Data analyzation

The data was analysed utilizing version 26 of the Statistical Package for the Social Sciences (SPSS).

Findings and Results

Fifty-eight patients who were undergoing sheath removal gave their consent to participate in this study. Based on the randomization that has been mentioned in the methods, the study sample was divided into two groups: 31 as the control group and 27 as the intervention group. Regarding Table 1 of demographic data information, the mean age of the control group was 56.1 with a 7.9 SD; for the intervention group, it was 61.9 with a 7.5 SD, and the total mean age was 59 with a 7.9 SD. Also, the contingency coefficient was 0.5, and sig was 0.9, which means the data is homogenous.

Regarding occupation, the highest percentage was 38.7% for earners of the control group (35.5%), 12.9% and 12.9% for employed, retired, and unemployed, respectively, and 37% were retired for the intervention group (14.8%, 25.9%, and 22.2% for employed, earner, and unemployed, respectively). The entire sample size (32.8%) consisted of earners. and 25.9, 24.1, and 17.2 are employed, retired, and unemployed, respectively. The contingency coefficient was 0.3, and the significance was 0.06, which means the data is homogeneous.

In the control group, subjects are cigarette smokers (32.3%), 9.7% are only non-smokers, 16.1% are hookah smokers, and 22.6% are both types of smokers; lastly, 19.4% are previously smokers. Regarding the intervention group, most of them were previously smokers (33.3%), and 11.1%, 25.9%, 14.8%, and 14.8% were non-smokers, cigarette smokers, hookah smokers, and both types of smokers, respectively. Cigarette smokers make up the majority of the total sample size (29.3%), while non-smokers, hookah smokers, both types of smokers, and previous smokers make up 10.9%, 15.5%, 19%, and 25.9%, respectively. According to the contingency coefficient, it was 0.173, and sig was 0.774, which means the data is homogeneous.

In the control group, most subjects are cigarette smokers (32.3%), 9.7% are only non-smokers, 16.1% are hookah smokers, and 22.6% are both types of smokers; lastly, 19.4% are previously smokers. Regarding the intervention group, most of them were previously smokers (33.3%), and 11.1%, 25.9%, 14.8%, and 14.8% were non-smokers, cigarette smokers, and hookah smokers, respectively. The majority of the total sample size (29.3%) consists of cigarette smokers, while 10.9%, 15.5%, 19%, and 25.9% are non-smokers. The sample also includes hookah smokers, both types of smokers, and previous smokers. According to the contingency coefficient, it was 0.173, and sig was 0.774. which means the data is homogenous.

The history of previous PCI shows 12.9% have done PCI. previously in the control group and 29.6% in the intervention group; in total, 20.7% have had previous PCI from the total sample size. The contingency coefficient was 0.202, and sig was 0.117, which means the data is homogenous.

The mean of BMI for the control group was 26.13, which is considered pre-obesity, and the minimum BMI was 21.20, and the maximum BMI was 32.11. In the intervention group, the mean BMI was 27.66, with a standard deviation of 2.76, a minimum BMI of 20.76, and a maximum BMI of 33.56. The total sample size was 26.66, with a standard deviation of 2.88, indicating pre-obesity, a minimum BMI of 20.75, and a maximum BMI of 33.56. Lastly, the contingency coefficient was 0.603, and sig was 0.859, which means the data is homogenous.

According to Pain One, the mean was 61.13, with a 12.06 score. The SD for the control group was the minimum pain of 28, and 81 was the maximum. 36.48 with an 11.801 SD pain level for the intervention group, and the minimum pain was 15 and maximum pain was 61, and the total mean was 46.96 with a 14.859 SD, and the minimum pain was 15 and maximum pain was 81,

the cc 0.692 was and its sig 0.063. The control group's mean pain was 50.10 with a 10.549 SD, with 25 being the least painful and 71 being the most painful. The intervention group's mean pain was 28.81 with an 8.200 SD, with 12 being the least painful and 42 being the most painful. The total mean pain for both groups was 37.52 with a 12.524 SD, with 12 being the least painful and 71 being the most painful. The cc was 0.651, and the sig was 0.100. in Table 2, according to Kolmogorov-Smirnov. Both pain 1 and pain 2 were non-normal distributions at level 0.05. At a 0.00 p-value, Table 3 shows that there are significant differences between the control group and the Benson relaxation group in both pain 1 and pain 2. This means that the BBRT can lower the level of pain. Regarding Table 4, the result shows that there is a significant negative correlation between age and pain1 and pain2. According to BMI, the results show there are no significant correlations with pain1 or pain. Finally, Table 5 shows that there were significant differences between pain1 and pain2 when it came to occupation. However, there were no differences when it came to smoking, previous PCI, or chronic diseases.

Table 1

distribution of demographic data for each group of study.

Variable	Groups	Control		Benson relaxation technique		Total		Cc	Sig
Age	Mean	56.10		61.93		59.00		.531	.694
	SD	7.922		7.519		7.997			
	Min	39		47		39			
	Max	70		72		72			
Occupation	Groups	F	%	F	%	Total	%		
	Employed	11	35.5%	4	14.8%	15	25.9		
	Earner	12	38.7%	7	25.9%	19	32.8		
	Retired	4	12.9%	10	37.0%	14	24.1		
	Unemployed	4	12.9%	6	22.2%	10	17.2		
	Total	31	100%	27	100%	58	100.0	.335	.063
Chronic disease	No	5	16.1%	4	14.8%	9	15.5		
	HTN	15	48.4%	11	40.7%	26	44.8		
	DM	7	22.6%	4	14.8%	11	19.0		
	Both	4	12.9%	8	29.6%	12	20.7		
	Total	31	100%	27	100%	58	100.0	.208	.455
Smoking	No smoking	3	9.7	3	11.1	11	10.3		
	Cigarette	10	32.3	7	25.9	34	29.3		
	Hoka	5	16.1	4	14.8	14	15.5		
	Both	7	22.6	4	14.8	20	19.0		
	Previously smoker	6	19.4	9	33.3	34	25.9		
	Total	31	100.0	27	100.0	113	100.0	.173	.774
Previous PCI	Yes	4	12.9	8	29.6	12	20.7		
	No	27	87.1	19	70.4	46	79.3		
	Total	31	100.0	27	100.0	58	100.0	.202	.117
BMI	Mean	26.12		27.28		26.66		.603	.859
	SD	2.92		2.76		2.88			
	Min	21.20		20.76		20.75			
	Max	32.11		33.56		33.56			
Pain1	Mean	61.13		36.48		46.96		.692	.063
	SD	12.069		11.801		14.859			
	Min	28		15		15			
	Max	81		61		81			
Pain2	Mean	50.10		28.81		37.52		.651	.100
	SD	10.549		8.200		12.524			
	Min	25		12		12			
	Max	71		42		71			

Min=minimum. Max=maximum. SD= stander deviation. F=frequency. %=percentage. Cc= contingency coefficient. Sig= significant

Table 2

test of normality for data distribution

Statistic	Statistics	Df	Sig
Pain1	.101	58	.200
Pain2	.120	58	.036

Df= degree of freedom, sig= significant

Table 3

differences between control and intervention group of level of pain1 and pain 2 according to Mann-Whitney test

Pain1	Group	Mean rank	Mann-Whitney	Sig
	Control	40.89		
	Benson relaxation technique	16.43	65.500	0.000
Pain2	Group	Mean rank	Mann-Whitney	Sig
	Control	41.45		
	Benson relaxation technique	15.78	48.000	0.000

Sig= significant

Table 4

Spearman correlations between age, BMI s with pain 1, pain2

Age	Pain1	Pain2
Correlation Coefficient	-.359	-.269
Sig	.006	.041
BMI	Pain1	Pain2
Correlation Coefficient	-.254	-.182
Sig	.055	.173
N	58	58

Sig= significant, n= number of participants

Table 5

differences between pain1, pain2 and chronic disease, occupation and smoking.

Occupation	Pain1	Pain2
Kruskal-Wallis H	10.515	8.542
Df	3	3
Asymp. Sig.	.015	.036
Chronic Disease	Pain1	Pain2
Kruskal-Wallis H	.693	1.015
Df	3	3
Asymp. Sig.	.875	.798
Smoking	Pain1	Pain2
Kruskal-Wallis H	6.663	3.598
Df	4	4
Asymp. Sig.	.155	.463
Previous PCI	Pain1	Pain2
Kruskal-Wallis H	2.602	1.306

Df	1	1
Asymp. Sig.	.107	.253

Df= degree of freedom, sig= significant

Discussion and Conclusion

According to study statistics, the majority of the sample size was at the end of the fifth decade of their ages; according to the literature, aging is considered a major risk factor for IHD risk (18). There is a significant negative correlation between age and pain1 and pain2. This means that as people got older, their pain got worse and vice versa. Other studies have found that there are no statistical differences between age and pain (Heidaranlu et al., 2021; Kurt & Kaşıkçı, 2019).One possible explanation for these findings is that somatosensory declines tend to make individuals more susceptible to injury, implying age-related decreases in pain sensitivity (Zhi et al., 2024). Research studies suggest that pain threshold may increase with aging or interpret pain differently than younger individuals (Mullins et al., 2022).

One third of the sample was a freelancer. The results indicate that there are significant differences in pain levels depending on the occupation. The World Health Organization (WHO) has revealed that working long hours may increase the risk of IHD (World Health Organization, 2021b). According to the WHO, freelancers may encounter unique stressors related to their work, including irregular hours, a lack of job security, and varying workloads, all of which can contribute to physical discomfort or pain.

Based on the smoking status of the samples, the majority of them are smokers, with only 10% being non-smokers. Smoking is considered a significant modifiable risk factor for CVD, leading to over 8 million deaths worldwide annually, primarily from IHD. However, study statistics indicate that smoking has no effect on pain. People and animals may feel less pain when nicotine is present because it blocks nAChR, changes the descending pain-inhibitory pathway, and activates the opioid and neuroendocrine systems (Bastian et al., 2015). Epidemiological studies suggest that chronic tobacco use, despite its potential analgesic effect, may increase the risk of persistent pain. A study of patients with subacute low back pain found that smoking was associated with pain persistence one year after onset (Petre et al., 2015). Although most studies show a positive correlation between smoking and pain, many lack high-quality methods and do not include an adjusted analysis. Smoking is associated with demographic and socioeconomic factors, which also link to chronic pain (Khan et al., 2019).

The majority of the sample size did not have a previous PCI, and the results showed no difference in pain intensity. The prevalence of chronic access site pain is 3.7%. The main predictive factors for A-S pain chronicity are diabetes, hematoma, and persistent pain. The intensity of pain during the 48-hour period following PCI is also a significant predictor.

Upon examining the BMI of the study sample, it was found that the majority of the subjects were pre-obese, which is a well-established independent risk factor for developing CVDs and premature death. The result of the BMI correlation revealed there is no significant correlation between pain and BMI; this finding is consistent with studies (Jakobsen et al., 2022; Pamuk & Özkaraman, 2024; Wicaksono & Djamil, 2020). Other study findings reported that patients with a low BMI experienced more pain during prostate biopsy (Soysal & Çelebi, 2024). These results indicate that the intensity of pain was not affected by the BMI, and they did not interfere with the pain-relieving techniques.

The intervention group had milder pain than the control group, which means there was a significant difference between the two groups. These results show that the BRT is an effective way to reduce pain after femoral artery sheath removal. These results are similar to those of other studies that have shown that BRT can reduce pain after surgery and other procedures (Desreza et al., 2024; Raipure & Patil, 2023; Titi et al., 2021). Personal belief inspired the creation of BRT, a deep breathing technique that shifts the focus of pain. Reciting spiritual sentences that provide calm can strengthen this relaxation and increase endogenous analgesics (Kaparang et al., 2022).

The result revealed there are no differences between chronic disease, smoking, and a previous PCI with two periods of pain measurement. These results suggest that the intensity of pain remained unaffected. These

demographic data did not interfere with the pain-relieving techniques. This result is consistent with studies (Al-Mussawi & Al-Jubouri, 2024; Niknam Sarabi et al., 2021), which revealed that previous PCI did not affect pain intensity. Another study also found no differences in pain intensity between smoking and chronic disease (Jakobsen et al., 2022).

Femoral Artery sheath removal can cause mild to severe pain in patients after PCI. Although patients' perceptions of this pain can vary, it is crucial for nurses to assess and manage it effectively. There are several methods to reduce this pain, such as applying ice, sandbags, and aromatherapy. This study explores the effectiveness of BRT in alleviating pain associated with sheath removal. The results suggest that this method may be an effective way to reduce the intensity of pain. The current study has advantages. Firstly, the study took place across three cardiac centers of different sizes. Second, a single nurse performed the sheath removal for all study participants to minimize potential bias on the VAS score. Third, the random allocation of the sample enhances the generalizability of the results. However, the present The study is not without limitations.

One disadvantage of simple randomization is that participants may not be allocated equally into groups, potentially reducing the power of this clinical trial by 5%. (58) Another limitation is difficulty in applying blinding, as participants were aware of the applied interventions, which was beyond the researchers' control; lastly, the participant was only male.

Nursing is a profession that applies evidence-based practice to solve patients' problems. The BRT can reduce pain during arterial sheath removal. In terms of time and cost, BRT is a fast and less expensive way of reducing pain during sheath removal. Nurses can teach patients this method during sheath removal to aid in pain reduction. We recommend further research to evaluate the combination of non-pharmacological and pharmacological therapies and compare their respective outcomes. Moreover, the application of pain-relieving techniques on a large sample size is also recommended.

Acknowledgments

We recognize the assistance and Institutional Review Board approval from the College of Nursing at the University of Baghdad. The authors express gratitude to the cardiac centre administrators for providing approval letters for data collection.

Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The scientific committee in adult nursing The department initially evaluated the proposal, subsequently followed by the college council. The Nursing program at the University of Baghdad provided the necessary agreement. The Institutional Review Board (IRB) at the College of Nursing, University of Baghdad, has received the study protocol. This study was conducted in compliance with the Declaration of Helsinki, with the protocol submitted to the Iranian Registry of Clinical Trials (IRCT20240309061232N1), registered on 2024-11-16, 1403/08/26, and subsequently implemented at the Centre for Training and Developing Staff of the Health Ministry in Iraq. The researcher secures the participants' verbal consent for participation in this study. All information, including name, occupation, and residence, will remain confidential.

Transparency of Data

In accordance with the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

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Authors' Contributions

All authors equally contribute to this study.

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