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Efficacy of Valsalva Maneuver on Pain and Vasovagal Response during Removal Femoral Sheath Post Percutaneous Coronary Intervention

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ABSTRACT
Background: The obstructed coronary artery can be re vascularized through a minimally invasive procedure called the percutaneous coronary Intervention (P.C.I). Many complications might occur through the femoral sheaths was removed such as pain and vasovagal response, that may induce morbidity and mortality.
Study Aim: To evaluate the efficacy of Valsalva maneuver on pain and vasovagal response during removal femoral sheath post PCI.
Methods:A quasi experimental design, was performed at the AL-Najaf Center for Cardiac Surgery and Cardiac Catheterization in Al-Najaf AL Ashraf city between (16th October to 1st December 2024). A non-probability (purposive sample) of (128) patients after elective PCI.
Result: The current result indicated that there is a significant reduction in pain and vasovagal response during the removal of the femoral sheath.
Conclusion: The Valsalva maneuver was effective in relieving complications during removal femoral sheath.
Recommends: Accepting into consideration the finding of the current should use pharmacological methods such as Valsalva maneuver to relieve pain intensityand prevent vasovagal response.

Keywords: femoral sheath, pain, percutaneous coronary Intervention, vasovagal response, Valsalvamaneuver.

INTRODUCTION

Coronary artery disease (CAD) is a complex condition that affects one or more of the arteries surrounding the heart muscle, resulting in impaired or blocked blood flow[1]. It is one of the most prevalent cardiovascular diseases in developed nations and continues to be a Principal cause of morbidity and mortality[2].
CAD is the most common cause of fatalities worldwide, contributing to 17.8 million deaths every year, or over 610,000 fatalities [3]. CAD, which is also known as coronary heart disease (CHD), ischemic heart disease (IHD), and atherosclerotic heart disease, is the most common type of cardiac disease[4]. Additionally, according to the Iraqi Ministry of Health (MOH), CHD is a common condition that can cause sudden cardiac death or hemodynamic impairment[5.]
Atherosclerosis is the most significant cause of CAD, that defined by a chronic, associated with aging,excessive accumulation of lipids in the artery walls. This causes limited blood flow and raises the risk of the heart attacks[6].
Percutaneous coronary intervention (PCI) is used to manage coronary artery disease and improve the quality of life for those who are affected using a minimally invasive procedure a stent is implanted into the blocked artery. Therefore, PCI enhances blood flow and preserves arterial patency, Thus PCI not only removes the blockage but makes a Significant contribution to enhancing patient outcomes[7].
Universally, millions of people have percutaneous coronary intervention every year, and the majority of them are treated with 1 or more drug-eluting stents[8.] In China ,1.04 million PCI procedures were performed in 2019, thereby the number of cardiac stents implanted was the highest in the world[9].The most prevalent approach in the United States is femoral access, which involves introducing a catheter into the femoral artery in the thigh to reach the heart and arteries[10].
Trans femoral access (TFA) was the preferred choice for percutaneous treatments because of the huge size of

the femoral artery, which allows for bigger catheters and sheaths. Notably, it has been the most common option for PCI in STEMI cases for many decades, enabling quick artery access and the ability to provide temporary pacemaker and circulatory support when needed[11]. However, Patients conducting PCI procedures through the femoral artery access site experience life-threatening complications in the range of 2-6% [12.]

After a trans femoral PCI interventions, the artery sheath is usually removed 4–6 hours later. Nevertheless, a most patients suffer from pain while the sheath is remove[13]. Pain is understood as an unpleasant sensory and emotional experience associated with prospective or actual tissue damage[14].

The vasovagal response (VVR) is a serious condition characterized by a drop in blood pressure and heart rate characterized by light-headedness, blurred vision,sweating facial pallor, nausea and pupillary dilation [15]

VVR can be induced by pain, damage to tissues, and extreme emotional conditions during non-invasive interventional procedure. Additionally, this condition might result in serious complications such as profound bradycardia and hypotension[16].

In response to their vital role in preventing vascular complications, nurses must understand and implement nursing strategies and interventions. As a result, this can greatly aid in lowering PCI complications[17].

Sedatives, local anesthetics, and analgesics are frequently used to help with pain relief during removing arterial sheath. Moreover, nerve blocks can be utilized by numbing the affected region[18].

Many pharmacological and non-pharmacological methods have been used to relieve pain, as the Valsalva maneuver (VM) is a non-pharmacological method that can be used to reduce pain by exhaling against a closed airway. Moreover, VM decreases the severity of pain by increasing the pressure in the chest cavity, which causes analgesic effects of thevagus nerve stimulation. Therefore, relieves pain [19]

In general, there have been no studies focusing on the Valsalva maneuver during removal sheath post PCI in Iraq. As a consequence, an effective Valsalva maneuver can result in relief painfor this reason, this study aimed to implement theValsalva maneuver during removing the arterial sheath in patients after PCI

Aim of the study

To evaluate the efficacy of Valsalva maneuver on pain and vasovagal response during removal femoral sheath post PCI

METHODOLOGY

The Design of the Study

To achieve the aims of this study, a quasi-experimental design (the control group was nonequivalent) was conducted on patients separated into two groups (experimental and control).

The Setting of the Study

The study was conducted at CCU unit in Al-Najaf Al-Ashraf City/ Al-Najaf Center for Cardiac Surgery and Cardiac Catheterization from 16th October 2024 to 1st December 2024.

The Study Sample and Sampling Technique

128 patients are participating in this study, undergoing elective percutaneous coronary intervention. The sample size was calculated by using G power analysis at the power 80% and the confidence level 95%

The study sample selected through the non-probability technique (purposive sample) Was allocated into two groups, each group was (64) patients. This study sample was selected based on scientific and methodological reasons and medical recommendations were also taken into consideration. Patients who do not meet the criteria are excluded from the study. The experimental group has been submitted to the Valsalva maneuver by blowing in the plastic tube under the pressure 20-40 mmHg to prevent further complication. The other group has not been submitted to Valsalva maneuver by the researcher, which is considered a control group. The inclusion criteria as follows: a. Patient who underwent elective PCI with femoral access b. A Patient who accepted to participate in the study C. Adult (18-75) years and both sexes d. patient alert, conscious and able to communicate verbally because this study used a numeric pain scale to determine pain level during femoral sheath removal Patients with no history of pain and use analgesic f. Sheath size 6 F and 7F c. Exclusion criteria a. Patients experience hemodynamic instability while or after PCI b. Patients who suffer from diabetic neuropathy c. Patients who have glaucoma and have recent eye surgery ; this is due to the maneuver increased intraocular pressure d. Patients who failed to hold their breath for 10 seconds and suffer from respiratory disorders.

Ethical Considerations

The ethical agreement sheet was implemented according to the National Research Ethics Committee's (NREC) guidelines for human study of the university of Kufa , Collage of Medicine, The reference number is 47 , dated 30/9/2024 .At Al-Najaf Cardiac Center for Cardiac Surgery and Cardiac Catheterization , before starting the data collection process, in the first interview with the subject the researcher introduced himself ,explaining

aims and benefits of the study , confirms the patients confidentiality and the freedom to withdraw from the current research at any time without any consequence

The Study Instrument

Part I: Socio-demographic Data

The first part of the questionnaire involved the socio-demographic part obtained from the patient post -PCI by using the interviews. This part includes (5) items such as : age , sex , marital status , level of education and occupational status .

Part II: Clinical characteristics

The second section of the assessment tool consists of (7) items, which include:Smoking, Body mass index (BMI), Past medical history, Duration of present intra -cardiac catheterization (min), catheter size, Duration of femoral sheath in site (min) and index procedure.

Part III: Assessment of patient's pain Using Numeric Rating Scale (NRS)

The scale includes a total of 11 numbers, ranging from (0 to 10) from no pain to the worst possible pain

PartIV:Vasovagal Response Scale

The end part of the instrument tool involved the grades of the vasovagal response scale of (5 grades).

Methods of Data Collection: the researcher used faceto face interviews post percutaneous coronary intervention to collect sociodemographic characteristics and clinical data. Regarding the evaluation of pain and vasovagal response the researcher used a checklist during removal femoral sheath. The researcher check vital signs (heart rate, blood pressure, oxygen saturation, respiratory rate) before 1 min of sheath removal and immediately during sheath removal to identify grade of vasovagal response.

The Analysis of Statistical: The statistical package for social science (S.S.P.S) version 20 was utilized to analyze the data.

RESULTS AND FINDINGS

Table 1: Study Sample Demographic Data with a Comparison Significance

Demographic Data	Rating and Intervals	Statistics	Groups	
			Experimental Group	Control Group
Age	41 – 46	Freq.	2	3
		%	3.1%	4.7%
	47 – 52	Freq.	9	11
		%	14.1%	17.2%
	53 – 58	Freq.	19	16
		%	29.7%	25.0%
	59 – 64	Freq.	21	18
		%	32.8%	28.1%
	65+	Freq.	13	16
		%	20.3%	25.0%
Gender	Male	Freq.	30	34
		%	46.9%	53.1%
	Female	Freq.	34	30
		%	53.1%	46.9%
Marital Status	Single	Freq.	1	0
		%	1.6%	0.0%
	Married	Freq.	55	58
		%	85.9%	90.6%
	Divorced	Freq.	5	2
		%	7.8%	3.1
	Widowed/widow	Freq.	3	4
		%	4.7%	6.3%
Occupational status	Governmental employee	Freq.	15	10
		%	23.4%	15.6%
	Private or self-employed	Freq.	17	27
		%	26.6%	42.2%

	Retired	Freq.	4	7
		%	6.3%	10.9%
	Housewife\ Jobless	Freq.	28	20
		%	43.8%	31.3%
Total		Freq.	64	64
		%	100.0%	100.0%

Table 1: demonstrates that the most of participant in in interventional group are 59-64 years old (**32.8%**%), female (**53.1%**); Married (**85.9**%), Housewife\ Jobless (**43.8**%).

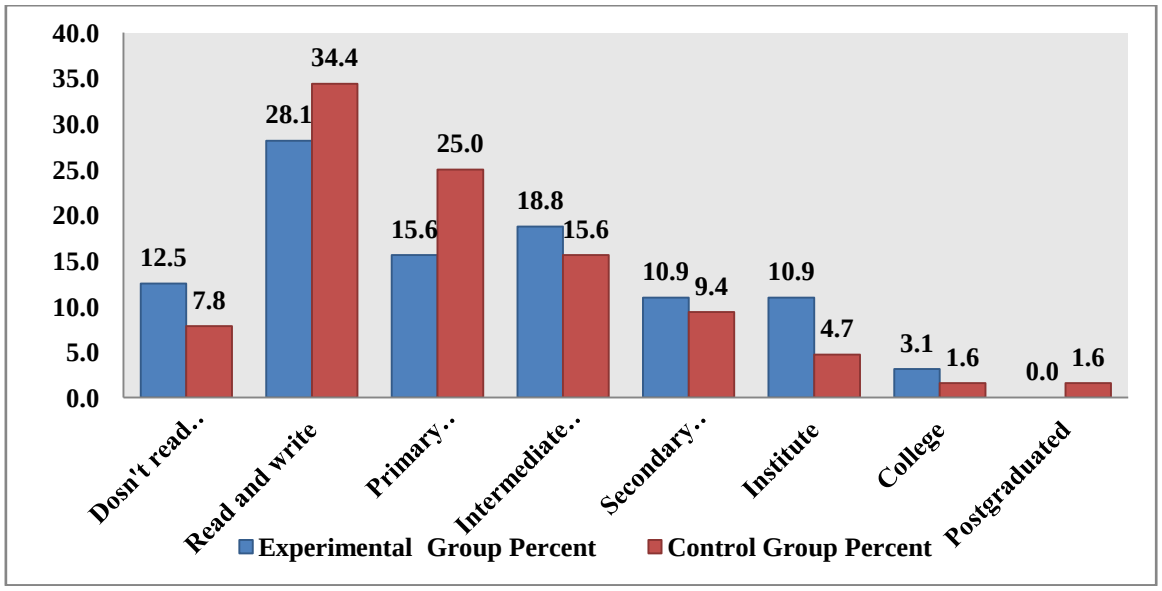

Figure 1: shows Distribution of the Study Sample According to their Levels of Education

Table 2: Study Sample Clinical Data

Present Medical History	**Rating and Intervals**	**Statistics**	**Groups**	
			Experimental Group	**Control Group**
Smoking	Active	Freq.	23	21
		%	35.9%	32.8%
	Passive	Freq.	9	13
		%	14.1%	20.3%
	None	Freq.	32	30
		%	50.0%	46.9%
Past Medical History	Not Present	Freq.	12	11
		%	18.8%	17.2%
	Hypertension	Freq.	37	29
		%	57.8%	45.3%
	DM	Freq.	4	7
		%	6.3%	10.9
	Hypertension and DM	Freq.	11	17
		%	17.2%	26.6
Sheath Size	6F	Freq.	53	51
		%	82.8%	79.7%
	7F	Freq.	11	13
		%	17.2%	20.3%
Duration of Sheath\ Minutes	120 Min.	Freq.	17	17
		%	26.6%	26.6%
	135 Min.	Freq.	13	11
		%	20.3%	17.2%
	150 Min.	Freq.	34	36
		%	53.1%	56.2%

Index Procedure	First time	Freq.	34	25
		%	53.1%	39.1%
	Second time	Freq.	19	15
		%	29.7%	23.4%
	Third time	Freq.	8	12
		%	12.5%	18.8%
	More than third	Freq.	3	12
		%	4.7%	18.8%
Total		Freq.	64	64
		%	100.0%	100.0%

Table 2: demonstrates that the most of participant in intervention group are non-smoking (50.0%), Hypertensive patients (57.8%), 6F sheath size (82.8%), Duration of Sheath in site 150 min, Index Procedure was first time (53.1%).

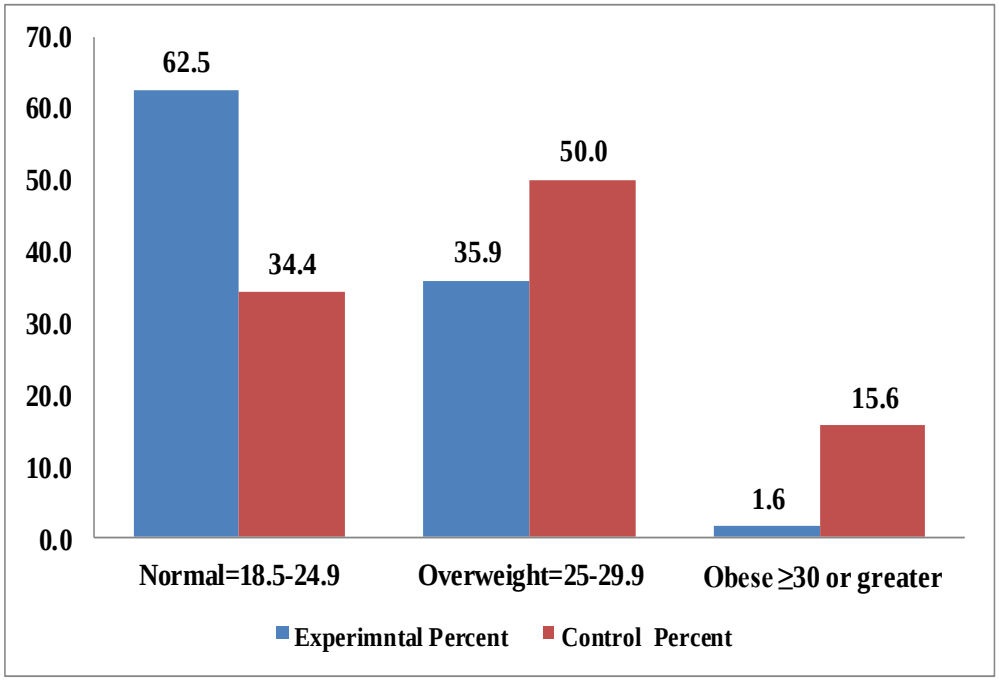

Figure 2: Distribution of the Study Sample According to their Body Mass Index

Table 3: Assessment of Pain Intensity during Removal of Femoral Sheath for Experimental and Control Groups:

Pain Intensity assessment	**Statistics**	**Groups**	
		Experimental group	**Control group**
None	Freq.	48	0
	%	75.0%	0.0%
Mild	Freq.	12	6
	%	18.8%	9.4%
Moderate	Freq.	4	35
	%	6.2%	54.7%
Sever	Freq.	0	23
	%	0.0%	35.9%
Total	Freq.	64	64
	%	100.0%	100.0%

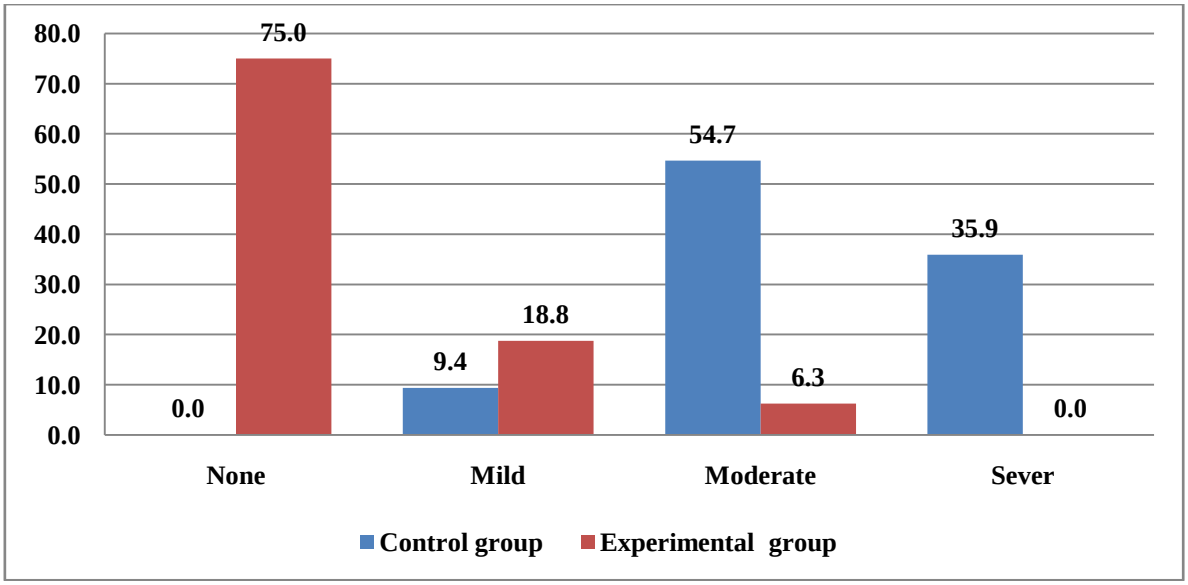

Figure 4: Assessment of Pain Intensity for both Experimental and Control Groupsduring Removal of Femoral Sheath

Table 4: Assessment of Vasovagal Response for both Experimental and Control Groups during Removal of Femoral Sheath:

Assessment of Vasovagal Response	Statistics	Groups	
		Experimental group	Control group
Grade 0 (No response)	Freq.	64	25
	%	100%	39.1%
Grade 1 (mild response)	Freq.	0	9
	%	0.0%	14.1%
Grade 2 (moderate response)	Freq.	0	17
	%	0.0%	26.6%
Grade 3 (severe response)	Freq.	0	11
	%	0.0%	17.2%
Grade 4 (life threatening)	Freq.	0	2
	%	0.0%	3.1%
Total	Freq.	64	64
	%	100.0%	100.0%

Table 4: this table shows the score of vasovagal response in both intervention and control group. Significant Difference between Experimental and Control Groups regarding Pain Intensity:

Pain Intensity	Groups	N	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
	Experimental group	64	45.0	2880	800.0	0.000 S
	Control group	64	84.0	5376		
	Total	128				

Table 5: Significant Difference between Experimental and Control Groups regarding Vasovagal Response:

Vasovagal Response	Groups	N	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
	Experimental group	64	34.53	2210.0	130.0	0.000 S
	Control group	64	94.47	6046.0		
	Total	128				

DISCUSSION

The femoral artery is a large and wide access site, so it is the most common preferred access site in PCI procedure. However, the use of femoral access has increased the risks of life threatening complications [20].

The current study aims to assess the severity of the pain and vasovagal response duringthe removal of femoral sheath amongpatients with elective PCI. The current result indicated that there is a significant reduction in pain level during the removal of the femoral sheath. The study results agree with the study done by[21]Ghods et al., (2022)**,** they reported that the patients in the intervention group had significantly lower pain scores during femoral sheath removal compared to the control group (P < .001). This study showed that the Valsalva maneuver during femoral arterial sheath removal can reduce the severity of the pain without raising the incidence of vasovagal reactions. Additionally , the study done by [20]Alan & Khorshid,(2022)**,** theyreported that the patients in the intervention group that implement Valsalva maneuver had relieved pain during insertion the cannula compared to the control group, all of which were statistically significant (p 0.001) agree with our results.Moreover, the current study corresponded with the study conducted by[22]Mohamed Eldesoky & Elesawy, (2021), they reported that there was a significant difference in in pain severity and anxiety level for Patients undergoing peripheral intravenous cannulation total mean scores at (p<0.05). Furthermore, the present study results agree with the study conducted by [23]Paulsamy et al.,(2021), they reported that it was decreased in the level of pain after doing the Valsalva during spinal procedure maneuver statistically significant at (P<0.01).The present study agree with the study conducted by Babaei et al., (2017),to evaluate the effect of the Valsalva maneuver on pain intensity and hemodynamic changes during IV cannulation .The result showed a significant reduction in pain severity (P≤0.05) .

Study limitation

No limitation influences the generalizability of the study results, the study was based on reliable study instruments.

CONCLUSION

The current study emphasizes the Valsalva maneuver was effective no pharmacological method on managing pain and vasovagal response during the removal of femoral sheath post- percutaneous coronary Intervention.

Recommendations

According to the results of the current study,should implement the Valsalva maneuver for managing pain and vasovagal response during the removal of the femoral arterial sheath.

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