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Effectiveness of Clinical Guideline Regarding Post Arterial Sheath Removal on Reduction of Complications in Patients after Cardiac Catheterization: Randomized Control Trial

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Abstract

Background: *Cardiac catheterization (CC) is an invasive procedure used to diagnose and treat coronary artery disease (CAD). A type of CC used to diagnose and treat CAD is percutaneous coronary intervention (PCI). It may lead to many complications after the removal of the femoral arterial sheath, which may contribute to morbidity and mortality and increase the patient's length of stay and hospital costs.* ***Study Aim:*** *The present study aimed to design and evaluate clinical guideline for removing the femoral arterial sheath on reduction of complications in patients after PCI.* ***Methods:*** *A randomized controlled trial (block randomization), post-test only, was conducted at Al-Najaf AL Ashraf City/ AL-Najaf Center for Cardiac Surgery and Cardiac Catheterization between (10th August 2022 to 17th July 2023). A non-probability (homogenous purposive sample) of (90) patients are involved after PCI (45 patients for each the study and control group). The study group exposed to designed clinical guideline. While, the control group exposed for usual nursing care provided for patients in CCU. In both groups, the relevant complications including hematoma, bleeding, ecchymosis, back pain, and vasovagal reaction.* ***Outcomes:*** *The study results indicated that there is a reduction in all complications (hematoma, bleeding, ecchymosis, back pain, and vasovagal reaction) for patients after femoral arterial sheath removal in the study group compared with those patients in the control group.* ***Conclusion:*** *The study has been concluded that the using of designed clinical guideline for femoral arterial sheath removal for patients after PCI is an effective approach in reduction of complications (hematoma, bleeding, ecchymosis, back pain, and vasovagal reaction).* ***Recommends:*** *Based on the results of the present study, using a designed clinical guideline regarding femoral arterial sheath removal in clinical practice is recommended for reducing complications.*

Keywords: *Effectiveness, Clinical guideline, Complications, Cardiac Catheterization.*

Introduction

Coronary artery disease(CAD) is a serious cardiovascular disease(CVD) affecting people worldwide, and is the main cause of death in both developing and developed countries[1]. Especially among patients ≥80 years of age[2].

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Cardiac catheterization(CC) is one of the invasive interventional procedures used to detect CAD. It is a standard technique used for the anatomic evaluation of CAD and for making decisions about the treatment and management of CAD [3, 4, 5, 6].

Coronary revascularization through CC has a very high success rate. PCI has a high success rate in opening up coronary artery occlusion; it gets beyond 90% and keeps rising year after year, in contrast to fibrinolytic medication treatment, which is only approximately 50%–60% [7, 8, 9, 10].

Cardiac catheterization could result in a number of major and minor complications that could increase mortality and morbidity. Death, myocardial infarction, and stroke are considered major complications. Minor complications include arrhythmias, transient ischemic attacks, vascular access site complications, renal failure, and allergic reactions to contrast agents [11, 12, 13].

The usage of the femoral artery in PCI contributes to further complications, which are considered among the extra-cardiac complications. The most common extra-cardiac complications after femoral arterial sheath removal for patients after PCI are hematoma, bleeding, ecchymosis, and pain (14, 15). Complications that raise morbidity and mortality also cause patients to undergo further diagnostic and therapeutic procedures, lengthening stays in the hospital and raising hospital costs [16, 17].

After the removal of femoral arterial sheath, the homeostasis procedure is typically attained by using a manual compress with a sterile gauze pack for 15-20 minutes, followed by continuous pressure with a bandage for 10 hours. After 6 hours of remaining in the supine position on the bed, the patient can ambulate. In order to reduce the occurrence of vascular complications. This prolonged pressure and bed rest are uncomfortable for the patient and the healthcare provider [18].

One of the strategies used for femoral sheath removal in patients after CC is the application of cold bag compression can reduce or prevent the complications such as hematoma, bleeding, ecchymosis, vasovagal reflex, and back pain after arterial sheath removal because it is a non-pharmacological method that increases the coagulation process by causing vasoconstriction, which leads to decreased blood flow and increased blood viscosity [11].

Generally, there have been no studies focusing on the design of clinical guidelines for arterial sheath removal in health centers and hospitals in Iraq. Therefore, an effective clinical guideline can result in high-quality care, prevent inappropriate clinical practices, aid in making the right clinical decision, improve patient safety and clinical care outcomes, and significantly reduce the cost and time of arterial sheath removal. Therefore, the current study focuses on the most important topic in nursing to fill the research gap in nursing.

The Study Question: Is there a difference in reduction of complications after arterial sheath removal for patients who are exposed to designed clinical guideline compared with those who are not exposed?

The Study Hypothesis: There is a difference in the reduction of complications after arterial sheath removal for patients who are exposed to designed clinical guideline compared with those who are not exposed.

METHODS AND MATERIALS

Design of the Study:

The randomized controlled trial (Block randomization), post test only was implemented in the present study to determine the effectiveness of clinical guideline regarding post-arterial sheath removal on reduction of complications in patients after CC.

Selection of the Study Participants:

The participants in the present study are 110 patients who referred for elective cardiac catheterization, specifically for PCI to Al-Najaf Center for Cardiac Surgery and Cardiac Catheterization who meet the study inclusion criteria. During the time of the study period distributed as following: Ten patients for pilot study are excluded from the study. Two patients with PCI for left main coronary artery (LMS) are also excluded from the study. During the application of manual compression with a cold bag, one patient developed sensitivity to cold and therefore excluded from the study. seven patients with diagnostic cardiac catheterization are also excluded from the study. The remaining 90 eligible patients participated in the present study (total study sample).

Study Sample and Sampling Technique:

A non-probability (homogenous purposive sampling) technique of 90 patients are included in the present study. The study sample is assigned by the block randomization into study and control groups. This study sample was selected based on the inclusion criteria to include the patients in the target population.

Sample Size and Power Analysis:

Based on the special criteria for determining the sample size (statistical power analysis, significance level, and effect size), the sample size for the current study was calculated using the G power software using the following criteria: power (95%), a significance level of 0.05, and a middle effect size (0.32). As a result, the sample size is approximately (54). However, in order to lessen the potential of "false negative and false positive" outcomes, the researcher set the power at (0.99) and the α to (0.01); as a result, the sample size increased to (90) participants [19].

Groups Assignment (Randomization):

The 90 patients in the research sample were divided into two groups randomly. The researcher utilized block randomization through the use of a simple random sampling approach (lottery method). The aim is to remove the source of bias that may occur in the intervention assignment

(**See participant's flowchart 1**).

The study group included (45) participants who were exposed to the designed clinical guideline involving direct cold bag compression for femoral arterial sheath removal (**See Figure 1**). While, the control group (45) Participants were exposed to usual nursing care for removing the femoral arterial sheath in the Al-Najaf Center for Cardiac Surgery and Cardiac Catheterization. Regarding evaluation of effectiveness of designed clinical guideline, the researcher uses five evaluation periods after femoral arterial sheath removal for both groups are 1st hour, 2nd hour, 3rd hour, 4th hour, and follow-up after one day. In both groups, the relevant complications including hematoma ,bleeding ,ecchymosis ,back pain, and vasovagal reaction.

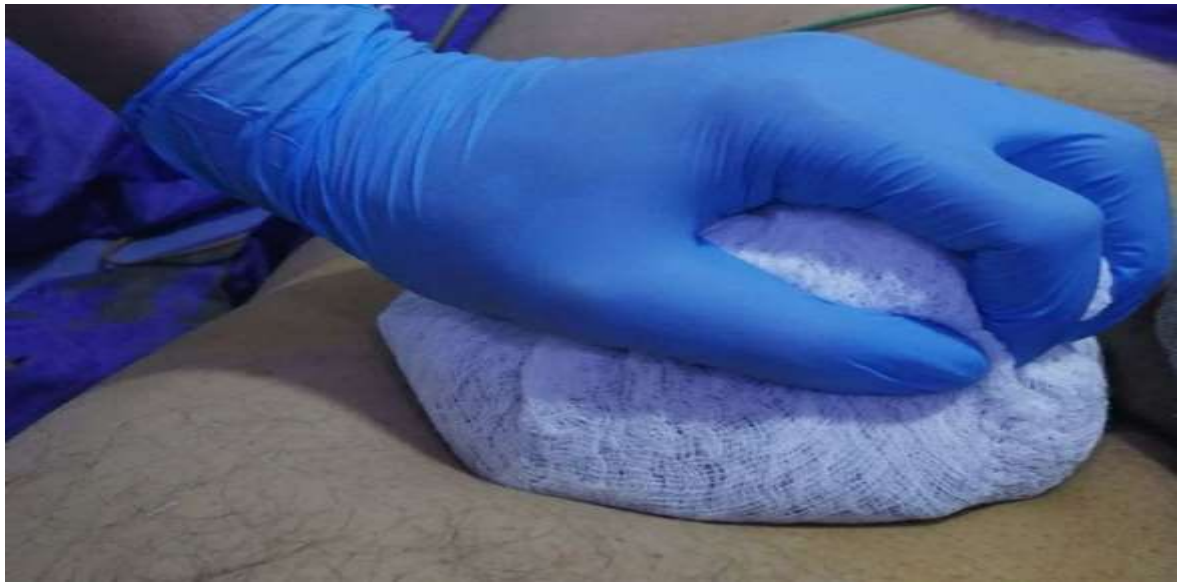
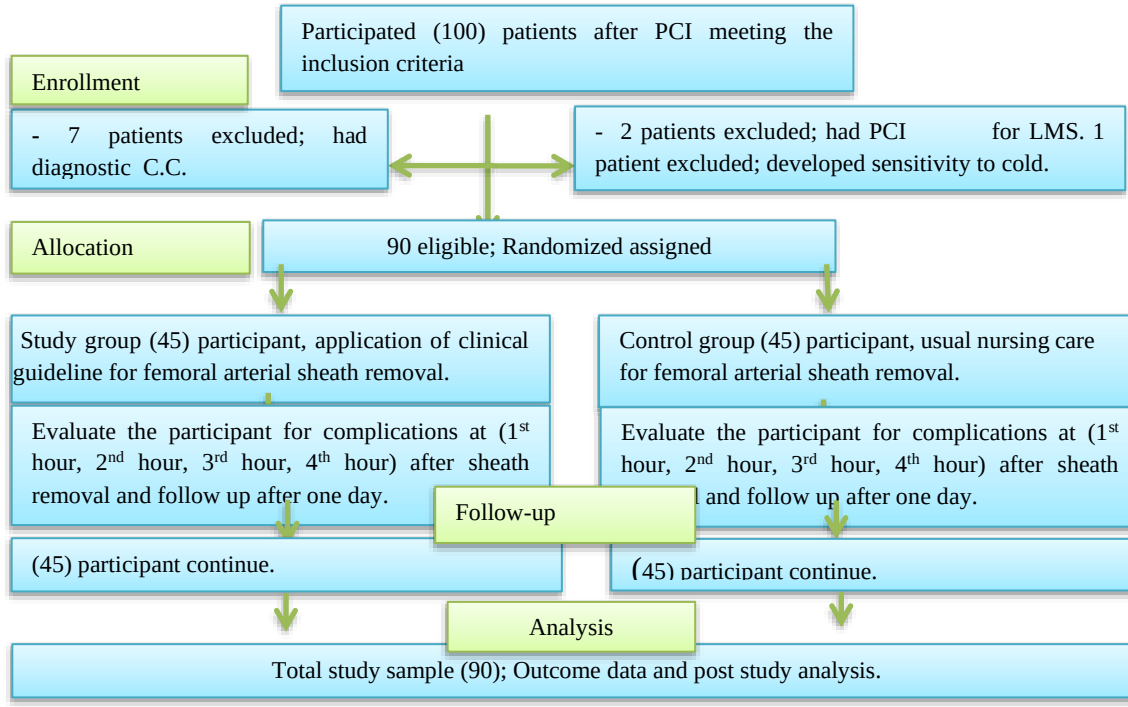


Figure 1: Application of direct cold bag compression for femoral arterial sheath removal in the study group.



Flowchart 3.2: Participants' flow diagram*.

*Researcher wrote the flow diagram according to the CONSORT statement stands for (Consolidated Standards of Reporting Trials) guideline.

Study Instrument: The researcher used a study instrument based on preceding academic scientific literature to examine the phenomenon. The study instrument consists of three parts: Part I: Socio-Demographic Characteristics; Part II: Clinical Characteristics; Part III: Checklist for Determination of Complications after Femoral Arterial Sheath Removal.

Ethical consideration: Before conducting the study, a legal, governmental agreement is obtained from the National Research Ethics Committee (NREC) for ethical study approval in accordance with the standards for conducting human research. Before starting data collection, it is necessary to protect participant rights through informed consent for sharing rights. The researcher presents himself to the participant, explains the purpose of the study and its advantages, ensures the confidentiality of the patient's name and information, and solicits their voluntary participation in the study; and the participant is free to withdraw from the study whenever they choose.

Method of Data Collection: The researcher used face to face interview with each participant to collect the demographic and clinical characteristics. Regarding the evaluation of complications after femoral arterial sheath removal, the researcher depend on especial checklist for all participant after

dividing them randomly into study and control groups. The data collection method started from 23rd November 2022 to 22nd December 2022.

Statistical Analysis: The current study's data were analyzed by Statistical Package for Social Sciences (SPSS) version 20 and Microsoft Excel 2016. The statistician apply the inferential and descriptive data analysis methods as follows:

- **Descriptive Data Analysis:** The statistician used bar charts to present the tables, frequencies, percentages, graphics (Statistical Figures); statistical mean, and standard deviation.
- **Inferential Data Analysis:** According to the distribution and type of the variables, statistical tests such as the Chi-square and Independent Sample t-test were used.

STUDY RESULTS AND FINDINGS

Table (1) Socio demographical Characteristics among Control and Study Groups:

Demographic Characteristics	Rating and Intervals	Control Group		Study Group	
		Freq.	%	Freq.	%
Age / years	30-39	0	0.0%	1	2.2%
	40-49	6	13.3%	8	17.8%
	50-59	21	46.7%	21	46.7%
	60-69	11	24.4%	11	24.4%
	70 and more	7	15.6%	4	8.9%
Total		45	100.0%	45	100.0%
Gender	Male	28	62.2%	33	73.3%
	Female	17	37.8%	12	26.7%
Total		45	100.0%	45	100.0%
Marital Status	Married	41	91.1%	43	95.6%
	Widowed	4	8.9%	2	4.4%

Total		45	100.0%	45	100.0%
Smoking	Active	19	42.2%	15	33.3%
	Passive	4	8.9%	0	0.0%
	None	22	48.9%	30	66.7%
Total		45	100.0%	45	100.0%
Alcohol Intake	Yes	1	2.2%	1	2.2%
	No	44	97.8%	44	97.8%
Total		45	100.0%	45	100.0%

Table (1) shows that the majority of both control and study groups participants are 50-59 years old (46.7%); male (62.2%, 73.3% respectively); married(91.1%, 95.6% respectively); non-smoker(48.9%, 66.7% respectively); and non-alcoholic (97.8%).

Table (2) Clinical Characteristics among control and Study groups:

Clinical Characteristics	**Rating and Intervals**	**Control Group**		**Study Group**	
		Freq.	%	Freq.	%
Past Medical History	Not Present	8	17.8%	7	15.6%
	Hypertension	8	17.8%	8	17.8%
	Diabetes Mellitus	6	13.3%	6	13.3%
	Hypertension And Heart Failure	4	8.9%	1	2.2%
	Hypertension, Heart Failure & Diabetes Mellitus	4	8.9%	7	15.6%
	Hypertension And Diabetes Mellitus	15	33.3%	16	35.6%
Total		45	100.0%	45	100.0%
Past Medication History	Not Present	3	6.7%	1	2.2%
	Antiplatelet Drug	1	2.2%	0	0.0%
	Anticoagulation ,Antihypertensive and	26	57.8%	27	60.0%

	Antiplatelet Drugs					
	Anticoagulation and Antiplatelet Drugs	12	26.7%	13	28.9%	
	Antihypertensive and Antiplatelet Drugs	3	6.7%	4	8.9%	
Total		45	100.0%	45	100.0%	
Loading Dose	Not Present	4	8.9%	15	33.3%	
	Plavix Loading Dose	27	60.0%	16	35.6%	
	Brilinta Loading Dose	8	17.8%	11	24.4%	
	Plavix & Brilinta`	6	13.3%	3	6.7%	
Total		45	100.0%	45	100.0%	
Heparin Dose Received	5000	2	4.4%	0	0.0%	
	6000	0	0.0%	1	2.2%	
	7000	1	2.2%	1	2.2%	
	8000	26	57.8%	27	60.0%	
	9000	4	8.9%	11	24.4%	
	10000	12	26.7%	5	11.1%	
Total		45	100.0%	45	100.0%	
Catheter Size	6F	29	64.4%	25	55.6%	
	7F	16	35.6%	20	44.4%	
Total		45	100.0%	45	100.0%	

Table (2) shows that the majority of both control and study groups participants are hypertension and diabetes mellitus (33.3%, 35.6% respectively); anticoagulation ,antihypertensive and antiplatelet drugs (57.8%, 60% respectively); Plavix loading dose (60%, 35.6% respectively); 8000 heparin dose received (57.8%, 60% respectively); and 6f catheter size (64.4%, 55.6% respectively).

Table (3) The Laboratory Tests Results among Control and Study Groups:

Laboratory Tests	**Groups**	**N**	**Range**	**Minimum**	**Maximum**	**Mean**	**S.D**
PT	Control	45	8.5	11.1	19.6	14.14	1.58
	Study	45	10.1	9.5	19.6	14.33	1.87
t-value (0.537), d.f. (88), p-value (0.593) NS							
INR	Control	45	1.2	.8	2.0	1.20	0.29
	Study	45	1.1	.8	1.9	1.14	0.24
t-value (1.041), d.f. (88), p-value (0.301) NS							
PLT	Control	45	355	157	512	261.67	81.15
	Study	45	249	141	390	246.40	58.46
t-value (1.024), d.f. (88), p-value (0.309) NS							

Table (3) shows the laboratory tests results among control and study groups in pre-test. The result shows that there is a non-significant difference in laboratory tests (PT, INR, and PLT) for the study sample in the control and study groups at a p-value < 0.05.

Table (4) Assessment of Hematoma among both study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	**Results**	**Statistics**	**Groups**		**Sig.**
			Control Group	Study Group	
1st hour	Not Present	Freq.	39	45	X^2 (6.429) d.f. (2) p-value (0.04) S
		%	86.7%	100.0%	
	Small Hematoma	Freq.	2	0	
		%	4.4%	0.0%	
	Moderate Hematoma	Freq.	4	0	
		%	8.9%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd hour	Not Present	Freq.	39	45	X^2 (6.429) d.f. (2) p-value (0.040) S
		%	86.7%	100.0%	
	Small Hematoma	Freq.	4	0	
		%	8.9%	0.0%	
	Moderate Hematoma	Freq.	2	0	
		%	4.4%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd hour	Not Present	Freq.	38	45	X^2 (7.590) d.f. (2) p-value (0.022) S
		%	84.4%	100.0%	
	Small Hematoma	Freq.	6	0	
		%	13.3%	0.0%	
	Moderate Hematoma	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
4th hour	Not Present	Freq.	41	45	X^2 (4.186) d.f. (1) p-value (0.041)
		%	91.1%	100.0%	
	Small Hematoma	Freq.	4	0	
		%	8.9%	0.0%	
Total		Freq.	45	45	

		%	100.0%	100.0%	S
1 day	Not Present	Freq.	30	45	X^2 (18.0)
		%	66.7%	100.0%	d.f. (3)
	Small Hematoma	Freq.	11	0	p-value (0.001) S
		%	24.4%	0.0%	
	Moderate Hematoma	Freq.	3	0	
		%	6.7%	0.0%	
	Large Hematoma	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (4) There is a significant difference in the results of hematoma between the control and study groups at all the different periods of measurement (the p-value > 0.05). Based on the frequency and percentage, the study results indicate that there is a significant reduction in the hematoma among patients in study group compared with control group.

Table (5) Assessment of Bleeding among both study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	**Results**	**Statistics**	**Groups**		**Sig.**
			Control Group	Study Group	
1st hour	Not Present	Freq.	40	45	X^2 (5.294) d.f. (1) p-value (0.021) S
		%	88.9%	100.0%	
	Mild Bleeding	Freq.	5	0	
		%	11.1%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd hour	Not Present	Freq.	40	45	X^2 (5.294) d.f. (1) p-value (0.021) S
		%	88.9%	100.0%	
	Mild Bleeding	Freq.	5	0	
		%	11.1%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd hour	Not Present	Freq.	39	45	X^2

		%	86.7%	100.0%	(6.429)
	Mild Bleeding	Freq.	6	0	d.f. (1)
		%	13.3%	0.0%	
Total		Freq.	45	45	p-value (0.011) S
		%	100.0%	100.0%	
4th hour	Not Present	Freq.	40	45	X^2 (5.294) d.f. (1)
		%	88.9%	100.0%	
	Mild Bleeding	Freq.	5	0	
		%	11.1%	0.0%	
Total		Freq.	45	45	p-value (0.021) S
		%	100.0%	100.0%	
1 day	Not present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (5) shows that there is a significant different in the presence of bleeding between the control and study groups at 1st hour, 2nd hour, 3rd hour, and 4th hour periods of measurement (the p-value > 0.05). Based on the frequency and percentage , the study results indicate that there is a significant reduction in the bleeding among patients in study group comparing with there in control group.

Table (6) Assessment of Back Pain among both Study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	**Results**	**Statistics**	**Groups**		**Sig.**
			Control Group	Study Group	
1st hour	Not Present	Freq.	34	45	X^2 (12.53) d.f. (2) p-value (0.002) S
		%	75.6%	100.0%	
	Mild Back Pain	Freq.	10	0	
		%	22.2%	0.0%	
	Moderate Back Pain	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd hour	Not Present	Freq.	24	44	X^2

		%	53.3%	97.8%	(24.10)
	Mild Back Pain	Freq.	17	1	d.f. (2)
		%	37.8%	2.2%	p-value
	Moderate Back Pain	Freq.	4	0	(0.001)
		%	8.9%	0.0%	S
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd hour	Not Present	Freq.	20	44	X^2
		%	44.4%	97.8%	(31.20)
	Mild Back Pain	Freq.	19	1	d.f. (2)
		%	42.2%	2.2%	p-value
	Moderate Back Pain	Freq.	6	0	(0.001)
		%	13.3%	0.0%	S
Total		Freq.	45	45	
		%	100.0%	100.0%	
4th hour	Not Present	Freq.	16	45	X^2
		%	35.6%	100.0%	(42.78)
	Mild Back Pain	Freq.	16	0	d.f. (2)
		%	35.6%	0.0%	p-value
	Moderate Back Pain	Freq.	13	0	(0.001)
		%	28.9%	0.0%	S
Total		Freq.	45	45	
		%	100.0%	100.0%	
1 day	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (6) shows that there is a significant different in the occurrence of back pain between the control and study groups at 1st hour, 2nd hour, 3rd hour, and 4th hour periods of measurement (the p-value > 0.05). Based on the frequency and percentage , the study results indicate that there is a significant reduction in the back pain among patients in experimental group comparing with there in control group

Table (7) Assessment of Vasovagal Reflex/Heart Rate among both study and Control Groups throughout Different Periods of Measurements post-test:

Periods of Measurements	Results	Statistics	Groups		Sig.
			ControlGroup	Study Group	
1st Hour	Not Present	Freq.	41	45	X^2 (4.186) d.f. (1) p-value (0.041) S
		%	91.1%	100.0%	
	Present	Freq.	4	0	
		%	8.9%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd Hour	Not Present	Freq.	40	45	X^2 (5.294) d.f. (1) p-value (0.021) S
		%	88.9%	100.0%	
	Present	Freq.	5	0	
		%	11.1%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd Hour	Not Present	Freq.	44	45	X^2 (1.011) d.f. (1) p-value (0.315) NS
		%	97.8%	100.0%	
	Present	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
4th Hour	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
1 Day	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (7) shows that there is a significant different in the occurrence of the vasovagal reflex / heart rate between the control and study groups at 1st hour and 2nd hour periods of measurement. Based on the frequency and percentage , the study results indicate that there is a significant reduction in the vasovagal reflex / heart rate among patients in experimental group comparing with there in control group.

Table (8) Assessment of Vasovagal Reflex/Blood Pressure among both Study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	Results	Statistics	Groups		Sig.
			Control Group	Study Group	
1st Hour	Not Present	Freq.	41	45	X^2 (4.186) d.f. (1) p-value (0.041) S
		%	91.1%	100.0%	
	Present	Freq.	4	0	
		%	8.9%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd Hour	Not Present	Freq.	40	45	X^2 (5.294) d.f. (1) p-value (0.021) S
		%	88.9%	100.0%	
	Present	Freq.	5	0	
		%	11.1%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd Hour	Not Present	Freq.	43	45	X^2 (2.045) d.f. (1) p-value (0.153) NS
		%	95.6%	100.0%	
	Present	Freq.	2	0	
		%	4.4%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
4th Hour	Not Present	Freq.	44	45	X^2 (1.011) d.f. (1) p-value (0.315) NS
		%	97.8%	100.0%	
	Present	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
1 Day	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (8) shows there is a significant difference in the occurrence of vasovagal reflex / blood pressure between the control and study groups at 1st hour and 2nd hour of measurement**.** Based on the frequency and percentage , the study results indicate that there is a significant reduction in the vasovagal reflex / blood pressure among patients in experimental group comparing with there in control group.

Table (9) Assessment of Vasovagal Reflex/Cardiac Output among both Study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	**Results**	**Statistics**	**Groups**		**Sig.**
			Control Group	Study Group	
1st Hour	Not Present	Freq.	38	45	X^2 (7.590)
		%	84.4%	100.0%	d.f. (2)
	Nausea	Freq.	3	0	p-value
		%	6.7%	0.0%	(0.022)
	Nausea ,Paler And Diaphoresis	Freq.	4	0	S
		%	8.9%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd Hour	Not Present	Freq.	39	45	X^2 (6.429)
		%	86.7%	100.0%	d.f. (3)
	Nausea	Freq.	1	0	p-value
		%	2.2%	0.0%	(0.093)
	Paler	Freq.	4	0	NS
		%	8.9%	0.0%	
	Nausea ,Paler And Diaphoresis	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd Hour	Not Present	Freq.	39	45	X^2 (6.429)
		%	86.7%	100.0%	d.f. (3)
	Nausea	Freq.	2	0	p-value
		%	4.4%	0.0%	(0.093)
	Paler	Freq.	3	0	NS
		%	6.7%	0.0%	
	Nausea ,Paler And Diaphoresis	Freq.	1	0	
		%	2.2%	0.0%	
Total		Freq.	45	45	

		%	100.0%	100.0%	
4th Hour	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
1 Day	Not Present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (9) shows there is a significant difference in the occurrence of vasovagal reflex / cardiac output between the control and study groups at 1st hour of measurement. Based on the frequency and percentage , the study results indicate that there is a significant reduction in the vasovagal reflex / cardiac output among patients in study group comparing with there in control group.

Table (10) Assessment of Ecchymosis among both Study and Control Groups throughout Different Periods of Measurements in post-test:

Periods of Measurements	**Results**	**Statistics**	**Groups**		**Sig.**
			Control Group	Study Group	
1st hour	Not present	Freq.	45	45	NA
		%	100.0%	100.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
2nd hour	Not present	Freq.	42	45	X^2 (3.103) d.f. (1) p-value (0.078) NS
		%	93.3%	100.0%	
	Small ecchymosis	Freq.	3	0	
		%	6.7%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
3rd hour	Not present	Freq.	35	45	X^2 (11.250) d.f. (1) p-value (0.001) S
		%	77.8%	100.0%	
	Small ecchymosis	Freq.	10	0	
		%	22.2%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	
4th hour	Not present	Freq.	27	45	X^2

		%	60.0%	100.0%	(22.500)
	Small ecchymosis	Freq.	16	0	d.f. (2)
		%	35.6%	0.0%	
	Moderate ecchymosis	Freq.	2	0	p-value
		%	4.4%	0.0%	(0.001)
Total		Freq.	45	45	S
		%	100.0%	100.0%	
1 day	Not present	Freq.	13	40	X^2
		%	28.9%	88.9%	(37.898)
	Small ecchymosis	Freq.	9	5	d.f. (3)
		%	20.0%	11.1%	
	Moderate ecchymosis	Freq.	14	0	p-value
		%	31.1%	0.0%	(0.001)
	Large ecchymosis	Freq.	9	0	S
		%	20.0%	0.0%	
Total		Freq.	45	45	
		%	100.0%	100.0%	

Table (10) shows there is a significant difference in the presence of ecchymosis between the control and study groups at 3rd hour ,4th hour, and follow up after 1 day of measurement. Based on the frequency and percentage , the study results indicate that there is a significant reduction in the ecchymosis among patients in study group comparing with there in control group.

DISCUSSION

The femoral artery approach used in PCI has increased the occurrence of complications, which among the extra cardiac complications are hematoma, bleeding, ecchymosis, back pain, and vasovagal reflex [14].

The general purpose of the present study is to evaluate the effectiveness of designed clinical guideline regarding femoral arterial sheath removal on reduction of complications after cardiac catheterization. The study results reveal that there is a significant reduction in the all complications (hematoma, bleeding, ecchymosis, back pain, and vasovagal reflex) among patients in study group throughout the five evaluation periods (1st hour, 2nd hour, 3rd hour, 4th hour, and follow-up after one day) after application the designed clinical guideline for removing the femoral arterial sheath and compared the study group with those participants in the control group. Moreover, this proves the effectiveness of the clinical guideline regarding femoral arterial sheath removal in reducing the complications for patients after cardiac catheterization.

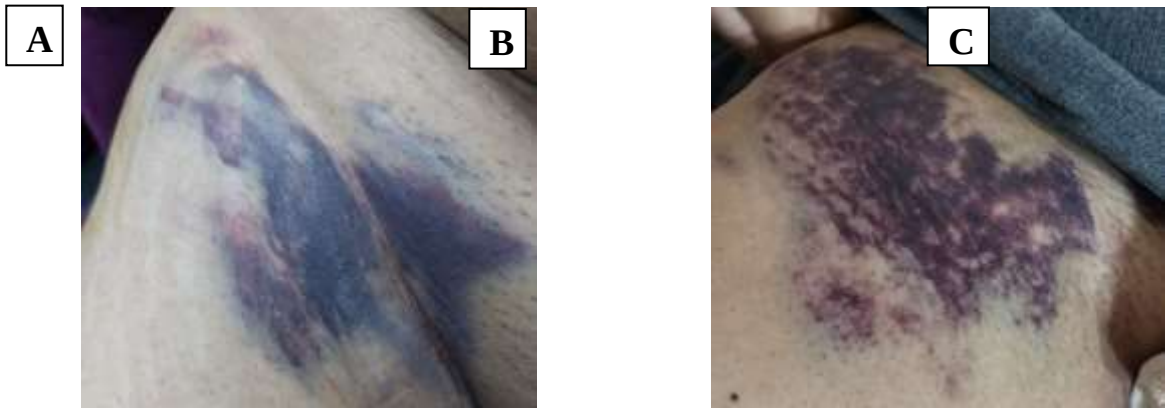
These study results agree with the study done by [20], they reported that there was a significant difference in hemorrhage at all time points except for the first 15 minutes and also 3 hours after

the sheath removal (P <0.001) and there was a statistically significant difference between the two groups at all evaluation times (2, 4, 6, and 24 hours) in their hematoma and ecchymosis (P <0.001). Also, the current study results corresponded with the study done by [21], they reported that there was a significant difference in the hematoma, bleeding, and ecchymosis between control group (sand bag application) and study group (ice bag application) on the second follow up (p-value <0.001) and total follow up complications (p-value <0.001).

Regarding back pain, the present study results agree with the study done by [22], they reported that there was a statistically significant reduction in pain between the study group and the control group, at a p-value < 0.001. Also, they concluded that ice bag application to the femoral region was effective in reducing pain induced by femoral catheter removal in patients undergoing percutaneous coronary intervention. Regard to vasovagal reaction, the present study results corresponded with the study done in Iraq by [23], studied the "Effectiveness of Nursing intervention on Early Complications for Patients Undergoing Coronary Catheterization at Al Najaf Center for Cardiac Surgery and Cardiac Catheterization" reported that there was a statistically significant reduction in vasovagal reflex at the (1st hour, 2nd hour, 3rd hour, 6th hour) periods of measurement, at p-value< 0.05.

The research interpreted these results as cold bag compression is a non-pharmacological method that increases the coagulation process by causing vasoconstriction, which leads to decreased blood flow and increased blood viscosity. Thus, increases in coagulation and decreases in capillary permeability and metabolic needs facilitate control of bleeding at the trauma site. Therefore, a cold bag application for arterial sheath removal for patients after cardiac catheterization can reduce the occurrence of hematoma, bleeding, and ecchymosis [24, 25]. Also, the application of cold compresses can inhibit the fibers of small diameter nerves from delivering pain stimuli. Therefore, there was a significant reduction in back pain and the vasovagal reflex [11].

After the current study results, the researcher confirms that the application of clinical guideline by using cold bag compression for femoral arterial sheath removal was effective in the reduction of complications (hematoma, bleeding, ecchymosis, back pain, and vasovagal reflex)(**See Figure 2**).



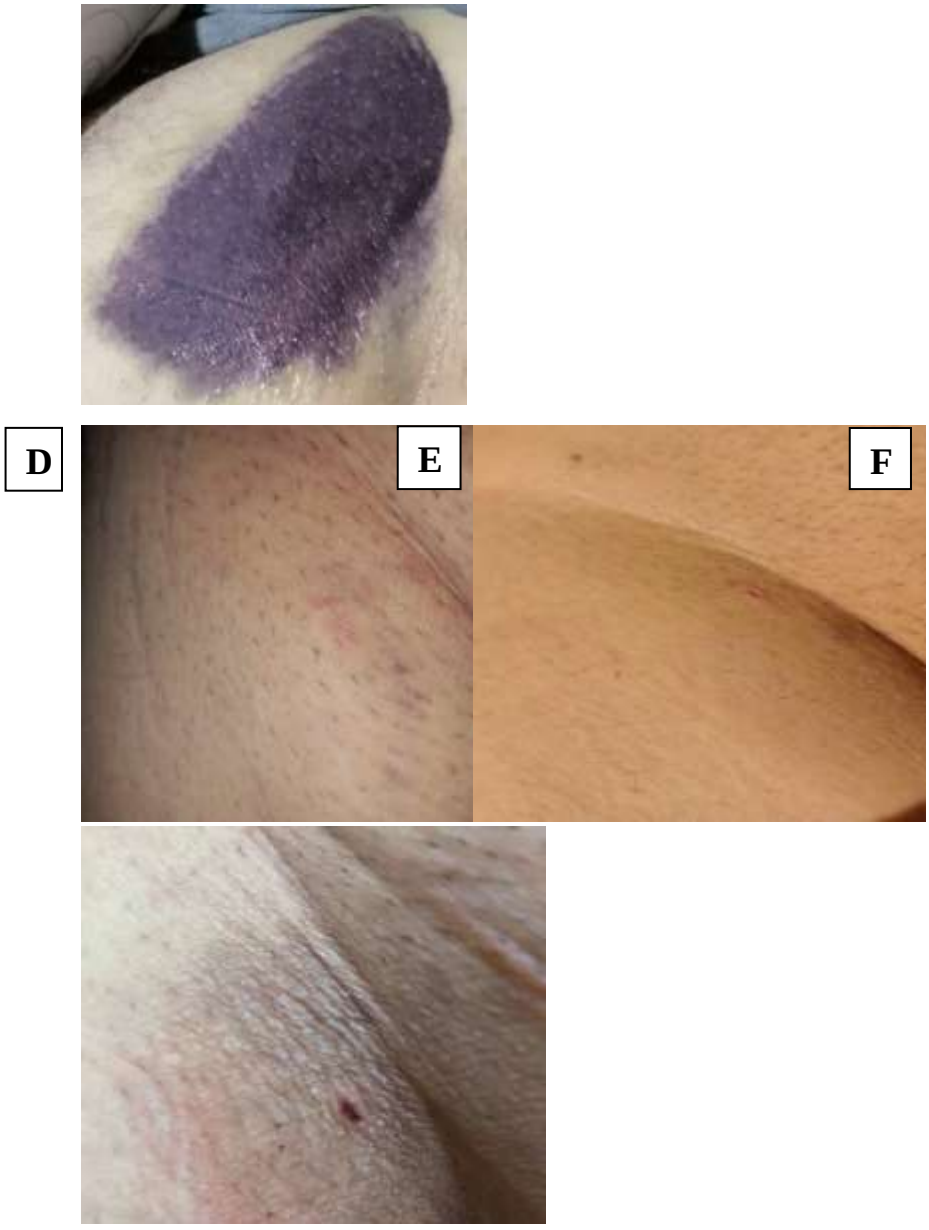


Figure 2: Picture (A,B,C) represent the control group. Picture (D,E,F) represent the study group. This pictures represent the follow up after one day.

CONCLUSION:

Implementation of the clinical guideline for femoral arterial sheath removal in patients after cardiac catheterization can be instrumental in reducing hematoma, bleeding, ecchymosis, back pain, and

vasovagal reaction.

RECOMMENDS:

Based on the results of present study, the using designed clinical guideline regarding femoral arterial sheath removal in clinical practice prevents prevent acts of misconduct, complications, facilitates the effective making of clinical decision, improvement in the patient's safety, and decrease the time and hospital costs.

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CONFLICTS OF INTEREST:

Authors declare no conflict of interest.

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