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ORIGINAL RESEARCH

Effect of Direct Cold Compress for Femoral Arterial Sheath Removal on Reduction of Local Vascular Complications in Patients after Percutaneous Coronary Intervention: A Randomized Controlled Trial.

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) is one of the cardiac catheterization procedures used to diagnose and treat coronary artery disease(CAD). It may lead to local vascular 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.

Objectives: The present study aimed to determine the effect of direct cold compress for femoral arterial sheath removal on reduction of local vascular complications in patients after PCI.

Methodology: A randomized controlled trial, post-test only was conducted on patients in the present study. A non-probability (homogenous purposive sample) of (90) patients are involved after PCI (45 patients for the experimental group and 45 patients for the control group). The experimental group exposed to direct cold bag compression for removing the femoral arterial sheath removal. While, the control group exposed for usual nursing care provided for patients in CCU. The study was conducted at Al-Najaf AL Ashraf City/ AL-Najaf Center for Cardiac Surgery and Cardiac Catheterization. The local vascular complications involved in the present study for both groups are hematoma, bleeding and ecchymosis.

Results: The study results indicated that there is a reduction in local vascular complications (hematoma, bleeding, and ecchymosis) for patients after femoral arterial sheath removal in the experimental group compared with those patients in the control group.

Conclusion: The present study has been concluded that the using of direct cold bag compress for removing the femoral arterial sheath in patients after PCI is an effective approach in reduction of local vascular complications compared with the control group.

Recommends: Based on the results of the present study, the researcher suggests the direct cold bag compress for femoral arterial sheath removal as a nursing intervention to reduce local vascular complications (hematoma, bleeding, and ecchymosis) for patients after PCI.

Keywords: Effect, Local Vascular Complications, Percutaneous Coronary Intervention.

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INTRODUCTION

Cardiac catheterization(CC) is the best approach for treating coronary artery disease. The fastest method (96-99%) for detecting anomalies in the blood vessels of the heart, especially coronary heart disease, is cardiac catheterization (Linton and Matteson, 2022).

Percutaneous coronary intervention(PCI) has a high success rate for opening up occluded coronary arteries; it reaches above 90% and continues to increase from year to year, compared with fibrinolytic drug therapy, which is only about 50–60% (Ginanjar et al., 2018; Mousa & Hassan, 2014; Rgeeb, 2013).

Compared to other diagnostic cardiac catheterizations, PCI complications are more common. The severity and frequency of complications have increased as a result of the revascularization of PCI becoming more complex over time (Dauerman et al., 2011).

Cardiac catheterization can lead to a number of complications large and small that can increase mortality and morbidity. Death, myocardial infarction, and stroke are major complications. Minor complications include arrhythmias, transient ischemic attacks, vascular access site complications, renal failure, and allergic reactions to contrast agents (Kristiyan et al., 2019; Aljanabi & Hassan, 2022). Among the minor complications, vascular complications are more common compared to others. Hematoma, hemorrhage, leakage, and ecchymosis are the most frequent vascular complications following PCI conducted via the femoral artery (Valikhani et al., 2020).

Patients are undergoing percutaneous coronary intervention via the femoral artery access site show life-threatening complications in the range of 2–6% (Kurt and Kaşıkçı, 2019). Complications that raise morbidity and mortality also cause patients to undergo further diagnostic and therapeutic procedures, prolonging hospital stays and increasing hospital costs (Güleser et al., 2014).

Usually, femoral arterial sheaths are removed, and homeostasis following percutaneous coronary intervention is traditionally achieved by using manual compression with a sterile gauze pack for 15-20 minutes with continues pressure by bandaged for 10 hours, ambulation after 6 hours. In order to reduce the incidence of vascular complications, the patient should remain in a supine position on the bed, with prolonged pressure and bed rest uncomfortable for the patient and the healthcare provider (Yi et al., 2022).

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 vascular complications such as hematoma, bleeding, and ecchymosis after femoral 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 (Alikhani et al., 2020).

Generally, there have been no studies focusing on the using of direct cold bag compress for femoral arterial sheath removal in health centers and hospitals in Iraq. Therefore, the present study focus on the most important topic in nursing to fill the research gap in nursing. So, the research question was, is there a difference in reduction of local vascular complications after femoral arterial sheath removal for patients who are exposed to direct cold bag compression compared with those who are not exposed?.

AIMS OF THE STUDY

The present study aimed to determine the effect of direct cold compress for femoral arterial sheath removal on reduction of local vascular complications in patients after PCI.

METHODOLOGY

Design of the Study: The randomized controlled trial, posttest only was implemented in the present

study to determine the effect of direct cold compress for femoral arterial sheath removal on reduction of local vascular complications in patients after percutaneous coronary intervention.

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 experimental and control groups. This study sample was selected based on the inclusion criteria to include the patients in the target population.

Inclusion Criteria:

1. Patients who approved for study participation and were able to speak and communicate and no psychiatric disorders.
2. Adult patient aged 18 years and older and both sex.
3. Patient who underwent to percutaneous coronary intervention with femoral intervention and were inserted a single catheter in a femoral region.
4. Sheath size 6F and 7 F.
5. Patient with blood pressure less than 180/100 mm Hg, no active hemorrhagic disorders, and no history of back pain.
6. Patient who had no allergy to cold, who had no vascular complications (hematoma, ecchymosis, and bleeding) before the sheath withdrawal.
7. Patient who underwent successful percutaneous coronary intervention without complications that require cardiopulmonary resuscitation.
8. Patient who is not scheduled to receive thrombolytic drugs like Actilyze or anticoagulants like Tirofiban after percutaneous coronary intervention.

Groups Assignment (Randomization):

The study sample of 90 patients has been randomly divided into two groups. The researcher uses block randomization through the use of a simple random sampling method (lottery method). The goal of that the eliminates the source of bias in intervention assignments.

The experimental group included (45) participants who were exposed to the direct cold bag compression for femoral arterial sheath removal for 15-20 minutes until the hemostasis is done, and then apply a light dressing. 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 effect of direct cold bag compress, 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 vascular complications including hematoma ,bleeding , and ecchymosis.

Study Instrument:

To investigate the phenomenon, the researcher used a study instrument based on previous scientific types of academic literature. The study instrument consistent of three parts are

- **Part I: Socio-Demographic Characteristic:** This part involved the Socio-demographic characteristics obtained from patients after PCI using an interview. This part which comprised of (7) items, which included age, gender, marital status, level of education, smoking, alcohol intake, and body mass index.
- **Part II: Clinical Characteristics:** The characteristics was obtained from the patients after PCI using an interview. This part included past medical history (hypertension, diabetes mellitus, and heart failure), past medication history (antihypertensive drug, anticoagulant drug, antiplatelet drug, analgesic drug, and sedative drug), laboratory test (Prothrombin Time, International Normalized Ratio, and Platelets Count), loading dose (plavix loading dose and brillinta loading dose), heparin dose received, and catheter size (6F and 7F).

- **Part III: Checklist for Determination of Local Vascular Complications after Femoral Arterial Sheath Removal:** To determine the effect of direct cold compress for femoral arterial sheath removal on reduction of local vascular complications in patients after PCI, the researcher used especial checklist for determination of local vascular complications (Hematoma, Bleeding, and Ecchymosis).

Validity of Study Instrument: The face validity of the study instruments is determined by a panel of (13) experts in the nursing and medicine fields, who have mean years of experience of (18.23) years. All the experts agreed that the instrument is valid with some suggested modifications, which were taken into consideration by the researcher.

Ethical considerations: 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 beginning data collection, it is necessary to protect the subjects' rights through informed consent for participation rights. The researcher introduces himself and his identity to the subject; explains the study's objectives and benefits; ensures the confidentiality of the patient's identity and information; voluntary participation in the study; and the subject's right to withdraw from the study at any time.

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 data of the present study are analyzed through the application of Statistical Package of social Sciences (SPSS) version 20, and Microsoft Excel 2016 using both descriptive and inferential data analysis approaches as follow:

- Descriptive Data Analysis: Presented as tables, frequencies, and percentage.
- Inferential Data Analysis: Statistical tests were applied according to the distribution and type of variables, which include Chi-square.

RESULTS

Table (1) shows that the majority of both control and experimental 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%) (See Table 1).

Table (2) shows that the majority of both control and experimental 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)(See Table 2).

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 (See Table 3).

Table (4) There is a significant difference in the results of hematoma between the control and experimental 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 experimental group compared with control group (See Table 4).

Table (5) shows that there is a significant different in the presence of bleeding between the control and experimental 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 experimental group comparing with there in control group (See Table 5).

Table (6) shows there is a significant difference in the presence of ecchymosis between the control and experimental 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 experimental group comparing with there in control group (See Table 6).

DISCUSSION

The use of the femoral artery approach in percutaneous coronary intervention has increased the occurrence of complications, which are among the extra cardiac complications are hematoma, bleeding, ecchymosis (Young et al., 2014).

The aim of the present study is to determine the effect of direct cold compress for femoral arterial sheath removal on reduction of local vascular complications in patients after percutaneous coronary intervention. The present study results indicate that there is a significant reduction in the local vascular complications (hematoma, bleeding, and ecchymosis) among patients in experimental group throughout the five evaluation periods (1st hour, 2nd hour, 3rd hour, 4th hour, and follow-up after one day) after application the direct cold bag compress for removing the femoral arterial sheath and compared the experimental group with those participants in the control group. Moreover, this proves the effectiveness of the direct cold bag compress regarding femoral arterial sheath removal in reducing the local vascular complications for patients after percutaneous coronary intervention.

These study results agree with the study done by Ebrahimi-Shalmani et al., (2020), 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 Çürük et al., (2017), 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).

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 femoral arterial sheath removal for patients after PCI can reduce the occurrence of hematoma, bleeding, and ecchymosis (Allahbakhshi et al., 2021; Baidhowy et al., 2022).

After the current study results, the researcher confirms that the application of direct cold bag compression for femoral arterial sheath removal was effective in the reduction of local vascular complications (hematoma, bleeding, and ecchymosis).

CONCLUSION

The present study has been concluded that the using of direct cold bag compress regarding removing the femoral arterial sheath for patients after PCI is an effective approach in reduce or prevent the local vascular complications (hematoma, bleeding, and ecchymosis).

RECOMMENDATION

Based on the results of present study, direct cold bag compress for femoral arterial sheath removal may therefore be recommended as a nursing intervention for reduction of local vascular complications (hematoma, bleeding, and ecchymosis) in patients after PCI.

FUNDING: No funding was received for this study.

CONFLICTS OF INTEREST: Authors declare no conflict of interest.

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TAPLES AND FIGURES

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

Demographic Characteristics	Rating and Intervals	Control Group		Experimental 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%**

%= percentage , freq. = frequency.

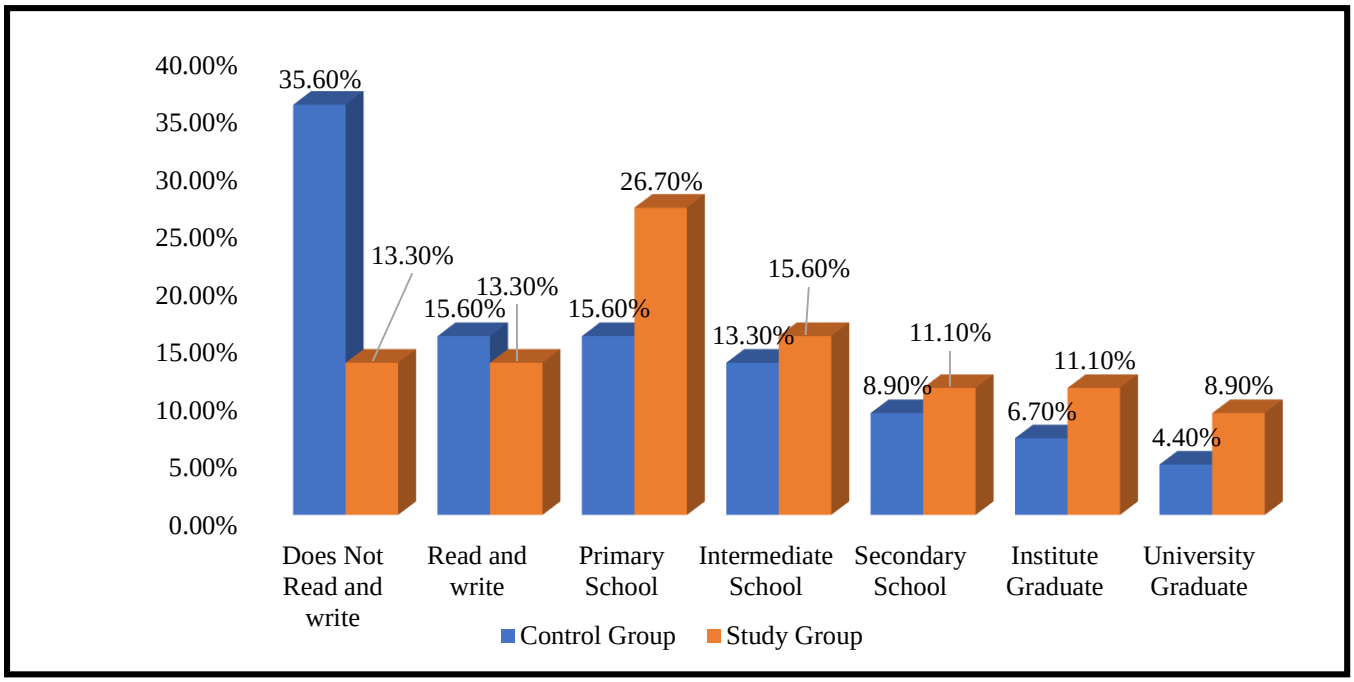

Figure (1): Study Sample Levels of Education

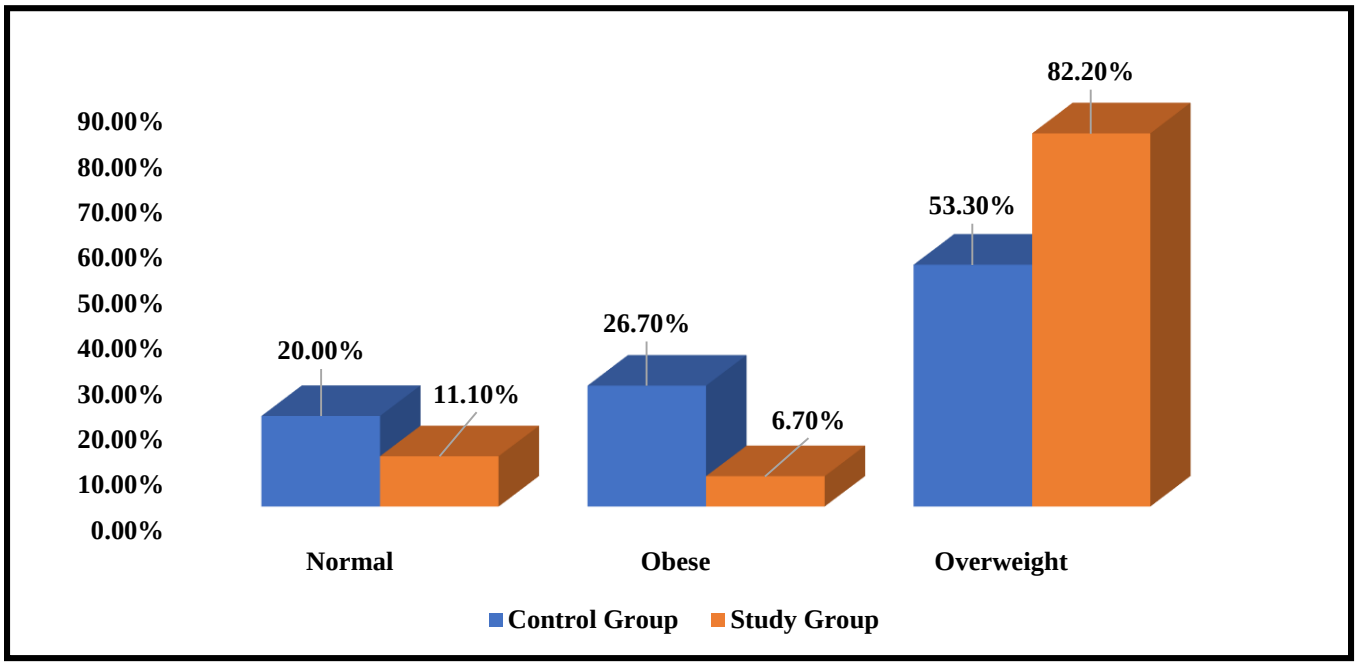

Figure (2): Distribution of the both groups (Control and study) according to their Body Mass Index.

Table (2): Clinical Characteristics among Control and Experimental groups

Clinical Characteristics	Rating and Intervals	Control Group		Experimental 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 Antiplatelet Drugs	26	57.8%	27	60.0%
	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%

%= percentage , freq. = frequency.

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

Laboratory Tests	Groups	N	Range	Minimum	Maximum	Mean	S.D
PT	Control	45	8.5	11.1	19.6	14.14	1.58
	Experimental	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
	Experimental	45	249	141	390	246.40	58.46
t-value (1.024), d.f. (88), p-value (0.309) NS							

S.D: stander deviation, d.f. : degree of freedom, t-value: independent t-test, p- value: probability value, PT: Prothrombin Time, INR: Internationalized Normalized Ratio, PLT: Platelet count, NS: non-significance.

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	**Experimental Group**	
1st hour	Not Present	Freq.	39	45	**X^2 (6.429)**
		%	86.7%	100.0%	**d.f. (2)**
	Small Hematoma	Freq.	2	0	**p-value (0.04)**
		%	4.4%	0.0%	**S**
	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)**
		%	86.7%	100.0%	**d.f. (2)**
	Small Hematoma	Freq.	4	0	**p-value (0.040)**
		%	8.9%	0.0%	**S**

	Moderate Hematoma	Freq.	2	0	
		%	4.4%	0.0%	
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
3rd hour	Not Present	Freq.	38	45	**X² (7.590)**
		%	84.4%	100.0%	**d.f. (2)**
	Small Hematoma	Freq.	6	0	**p-value (0.022)**
		%	13.3%	0.0%	**S**
	Moderate Hematoma	Freq.	1	0	
		%	2.2%	0.0%	
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
4th hour	Not Present	Freq.	41	45	**X² (4.186)**
		%	91.1%	100.0%	**d.f. (1)**
	Small Hematoma	Freq.	4	0	**p-value (0.041)**
		%	8.9%	0.0%	**S**
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
1 day	Not Present	Freq.	30	45	**X² (18.0)**
		%	66.7%	100.0%	**d.f. (3)**
	Small Hematoma	Freq.	11	0	**p-value (0.001)**
		%	24.4%	0.0%	**S**
	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%**	

%: percentage , freq.: frequency, χ2:chi square value, p- value: probability value, d.f.: degree of freedom, S: significance.

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

Periods of Measurements	Results	Statistics	Groups		Sig.
			Control Group	**Experimental Group**	
1st hour	Not Present	Freq.	40	45	**X² (5.294)**
		%	88.9%	100.0%	**d.f. (1)**
	Mild Bleeding	Freq.	5	0	**p-value (0.021)**
		%	11.1%	0.0%	**S**
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
2nd hour	Not Present	Freq.	40	45	**X² (5.294)**
		%	88.9%	100.0%	**d.f. (1)**
	Mild Bleeding	Freq.	5	0	**p-value (0.021)**

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

%: percentage , freq.: frequency, χ2:chi square value, p- value: probability value, d.f.: degree of freedom, S: significance, NA: not assessed, the chi-square test is not calculated because there is no 2*2 table.

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

Periods of Measurements	Results	Statistics	Groups		Sig.
			Control Group	**Experimental 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)**
		%	93.3%	100.0%	**d.f. (1)**
	Small ecchymosis	Freq.	3	0	**p-value (0.078)**
		%	6.7%	0.0%	**NS**
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
3rd hour	Not present	Freq.	35	45	**X^2 (11.250)**
		%	77.8%	100.0%	**d.f. (1)**
	Small ecchymosis	Freq.	10	0	**p-value (0.001)**
		%	22.2%	0.0%	**S**
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
4th hour	Not present	Freq.	27	45	**X^2 (22.500)**
		%	60.0%	100.0%	**d.f. (2)**
	Small ecchymosis	Freq.	16	0	**p-value (0.001)**
		%	35.6%	0.0%	**S**
	Moderate ecchymosis	Freq.	2	0	
		%	4.4%	0.0%	
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	
1 day	Not present	Freq.	13	40	**X^2 (37.898)**
		%	28.9%	88.9%	**d.f. (3)**
	Small ecchymosis	Freq.	9	5	**p-value (0.001)**
		%	20.0%	11.1%	**S**
	Moderate ecchymosis	Freq.	14	0	
		%	31.1%	0.0%	
	Large ecchymosis	Freq.	9	0	
		%	20.0%	0.0%	
Total		**Freq.**	**45**	**45**	
		%	**100.0%**	**100.0%**	

%: percentage , freq.: frequency, χ2:chi square value, p- value: probability value, d.f.: degree of freedom, S: significance, NS: non-significance, NA: not assessed, the chi-square test is not calculated because there is no 2*2 table.