Effect of Ice bag with Direct Pressure in the Prevention of Local Vascular Complications after Femoral Sheath Removal Post-Cardiac Catheterization: A Randomized Clinical Trial

Abbas Baqal[1], Fatma Makee Mahmood[2]
[1, 2]University of Kerbala/College of Nursing/Adult Nursing Department,Ira
Email: abbasbaqal2020@gmail.com

Abstract
Background: Cardiac catheterization is an invasive procedure using image guidance for diagnostic evaluation and therapeutic intervention in managing patients with cardiac diseases This procedure's problems commonly lead to increases in the length of the patient's stay in the hospital, cost, and vascular complications. The purpose of this study was to determine the effect of applying an ice bag with direct pressure to prevent vascular complications (bleeding, hematoma, and ecchymosis) after femoral sheath removal of cardiac catheterization. Method: An experimental study design. A total of 60 patients who underwent cardiac catheterization at the "Karbala Center for Cardiac Diseases and Surgery" between November 2021 and April 2022 participated in the study 30 in the control group and 30 in the experimental group. Result: The study's results showed a statistical significance between experimental and control groups to decrease in vascular complications and getting early ambulation after applying the protocol. Conclusion: According to the study's results, the ice bag with direct pressure effectively reduces the development of the vascular complications rate after the removal of the femoral sheath. Recommendations: Instructed to perform the ice bag with direct pressure after removing the femoral sheath to decrease bleeding severity, hematoma, and ecchymosis. The benefits of applying an ice bag with direct pressure to other invasive procedures such arterial-venous fistula, central venous line, and arterial line should be investigated in another study
Keywords: Ice-Bag,Vascular Complications,Femoral Sheath,Cardiac Catheterization

1. Introduction

Globally, coronary heart disease is the most common cause of death. Out of the 400 million cases of CVD worldwide in 2015, 111 million (or 27%) were due to CHD. The prevalence of CHD has decreased in wealthy nations like the U.S. and England while continuing to rise in developing nations like China and India. In 2030, the WHO predicts that CHD would continue to rank among the top three global killers, accounting for roughly 9.3 million deaths yearly (Ahmadi et al., 2022).

Several risk factors for CHD include family history, hypertension, diabetes, obesity, and smoking. A recent study has found, however, that nontraditional variables, including autoimmune disorders, homocysteine, and susceptible C-reactive protein all play a significant role in the incidence of CHD (Wang et al., 2022).

Musehib & Ali (2010), catheterization can be diagnostic, therapeutic, or electrophysiological. Right-sided or venous catheterization inserts a catheter from a vein into the right atrium (RA), while left-sided or arterial catheterization inserts a catheter from a systemic artery into the left atrium.

One of the technologies that cardiologists have the most access to nowadays is cardiac catheterization. The CC is split into two categories. In order to get an X-ray image of the coronary artery and heart and to measure hemodynamic in the heart and arteries, a small plastic tube (catheter) is inserted into the artery or vein of the heart. A catheter with a balloon is inserted during a percutaneous coronary intervention (PCI) procedure to treat coronary artery blockages. This allows the afflicted coronary artery's blood flow to be restored. Therefore, a metal endovascular prosthesis called a "Stent" is implanted there, with the intention of maintaining the vessel lumen open and integrated to ensure the perfusion of the myocardial (Ginanjar et al., 2018).

In the Iraq holy city of Karbala, the Karbala Center for Cardiac Diseases and Surgery conducted 2506 cardiac catheterizations in the year (2021) (Ministry of Health/ Environment/ Kerbala health director /department's statistics 2022).

When diagnostic and therapeutic catheterization is conducted with a transfemoral technique, vascular access difficulties are the most frequent side effects. Morbidity, mortality, and healthcare costs are all increased by vascular access complications (Ben-Dor et al., 2021).

Femoral vascular complications (FVCs) are severe complications of cardiac catheterization with

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significant morbidity, mortality ,and cost implications. Each year approximately 7 million cardiac catheterization procedures are performed internationally, with a reported access site complication rate of up to 6%. FVCs range from more minor complications, including hematoma, bleeding, ecchymosis pseudoaneurysm ,and retroperitoneal bleed (Williams et al., 2018).

The administration of cold is one method for preventing or reducing vascular problems such bleeding, ecchymosis, pseudoaneurysm, hematoma, and arteriovenous fistula. Because it has physiological effects on the vasculature and provides local anesthetic, the application of cold is frequently employed (Kurt & Kaşkç, 2019).

The cold application increases coagulation by decreasing arteriolar blood flow rate and vasoconstriction and increasing viscosity. Thus, increased coagulation and decreased capillary permeability and metabolic needs facilitate bleeding control at the puncture site. Thus, it can reduce the development of ecchymosis, hemorrhage, and hematoma (Bayındır et al., 2017).

Manual compression (MC) has remained the "gold standard for achieving hemostasis, which leads to a decrease in blood flow. However, this can be time-consuming and staff expensive (20 to 30 minutes or more). Prolonged compression using gauze balls requires prolonged bed rest immobilization in the supine position (4–8 hours) to reduce the risk of developing access site complications. Prolonged compression using gauze balls can be uncomfortable for the patient and the provider" (Noori et al., 2018).

2- Methodology

Design and setting of the study

An experimental study was conducted in the cardiac catheterization word at the "Karbala Center for Cardiac Diseases and Surgery in Holy Karbala, Iraq". The study started on the first of October 2021 to the twenty-fifth of March 2022 to determine the effect of the ice bag with direct pressure. On vascular complications after femoral sheath removal and the relationship between the effect of ice bag application with direct pressure and vascular complications with patient socio demographic characteristic and clinical information.

Sample of the study

This study used probability sampling, a systematic random sample technique, on 60 participants, 30 of whom were in the experimental group and the other the control group.

Steps of the Study

An interventional protocol consisted of applying an ice bag with direct pressure for 20 minutes on the femoral sheath area after removal as shown figure (1), then putting a small dressing on the area where the sheath was inserted and starting early ambulation after two hours complete bed rest. Following the intervention, the severity of the bleeding, the size of the hematoma, and the size of the ecchymosis were assessed at four different periods, as follows after 1: immediately after the intervention. After 2: two hours following the intervention. After 3: four hours following the intervention. After 4: 48 hours following the intervention.

Figure (1): Ice bag with direct pressure application

The study instruments

A questionnaire form with four main sections was created by the researchers to gather all pertinent information about the study population. The initial section of the paper covers participant sociodemographic and medical information that is given in appendix A. The second part measured the severity of bleeding and was developed by (Lewis et al. 2017), as shown in appendix B. The third part includes the hematoma size scale designed by Al-Sadi et al. (2010), as shown in appendix C. The fourth part includes the ecchymosis size scale designed by Hamner et al. (2005), as shown in appendix D.

Statistical Analysis

The study's findings were examined and evaluated using SPSS version 26, and descriptive statistical analysis (percentage and frequency) as well as inferential analysis (repeated measurements ANOVA and chi-square), with a p-value of 0.05 considered regarded statistically significant.

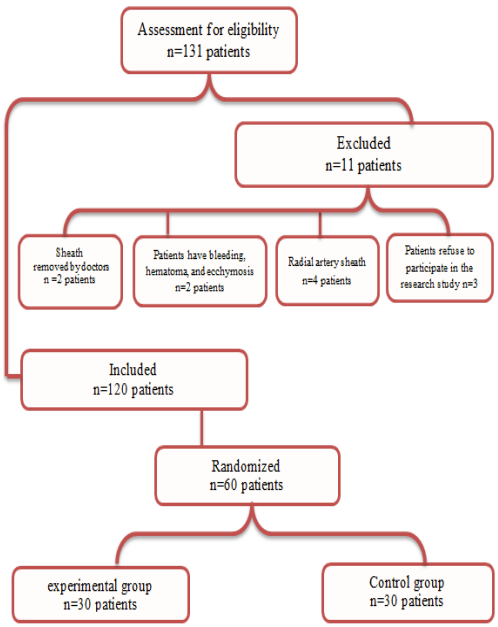

Figure (1): Flowchart of the randomized control trial & eligibility criteria

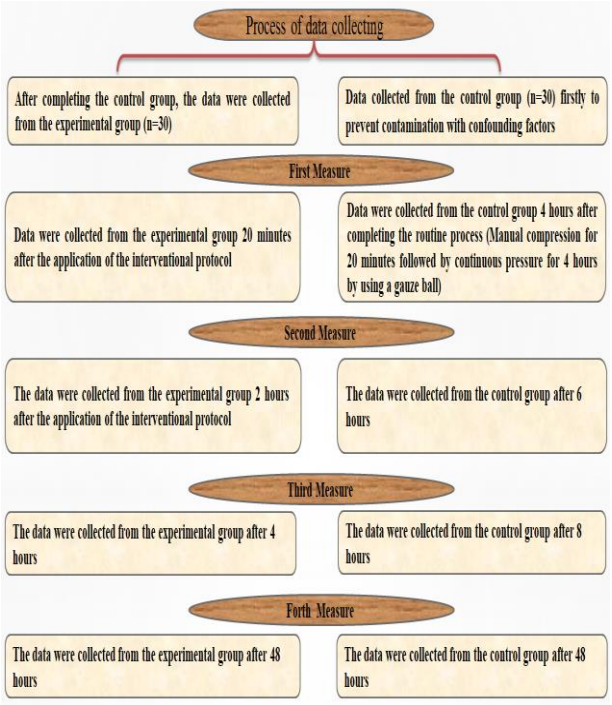

Figure (2): Flowchart of the Data collecting method

3- Results

Table (1): Distribution of the socio-demographic characteristics of patients					
Socio-demographic Characteristics		Control group		Experimental group	
		f.	%	f.	%
Age (Per years)	40 - 49	6	20	7	23.3
	50 - 59	9	30	5	16.7
	60 – 69	11	36.7	12	40
	≥ 70	4	13.3	6	20
	Total	30	100	30	100
Gender	Male	25	83.3	23	76.7
	Female	5	16.7	7	23.3
	Total	30	100	30	100
Smoking condition	Yes	16	53.3	21	70
	No	14	46.7	9	30
	Total	30	100	30	100
Body Mass Index	Normal weight	4	13.3	13	43.3
	Overweight	11	36.7	8	26.7
	Obesity class I	13	43.3	6	20
	Obesity class II	2	6.7	3	10
	Total	30	100	30	100
f.: frequency; %: percentage.					

Table (2): Distribution of participants according to their clinical data:					
Clinical data		Control group		Experimental group	
		f.	%	f.	%
Chronic diseases	H.T.	14	46.7	10	33.3
	DM	6	20	7	23.3
	HT and D.M.	10	33.3	13	43.4
	Total	30	100	30	100
Medication	Aspirin Tab	13	43.3	9	30
	Aspirin And Plavix	17	56.7	21	70
	Total	30	100	30	100
Heparin Dose	Non	11	36.7	13	43.4
	6000 IU - < 8000 IU	6	20	6	20
	8000 IU - <10000 IU	5	16.7	4	13.3
	≥10000 IU	8	26.7	7	23.3
	Total	30	100	30	100
Type of catheterization	Diagnostic	11	36.7	13	43.3
	Therapeutic	19	63.3	17	56.7
	Total	30	100	30	100
Size of sheath	6 Fr	22	73.3	24	80
	7 Fr	8	26.7	6	20
	Total	30	100	30	100
Systolic blood pressure	< 120	4	13.3	4	13.3
	120- 139	8	26.7	7	23.3
	140 - 159	4	13.3	6	20
	≥ 160	14	46.7	13	43.4
	Total	30	100	30	100
Diastolic blood pressure	< 80	5	16.7	5	16.7
	80 - 89	11	36.7	14	46.7
	90 - 99	7	23.3	9	30
	≥ 100	7	23.3	2	6.7
	Total	30	100	30	100
Pulse rate (bpm)	60 - 79	8	26.7	11	36.7
	80 - 99	18	60	15	50
	≥ 100	4	13.3	4	13.3
	Total	30	100	30	100
P C V %	30 – 39	9	30	8	26.7
	40 – 49	15	50	18	60
	≥ 50	6	20	4	13.3
	Total	30	100	30	100
Platelet count (mcL)	< 150000	5	16.7	3	10
	150000 - 450000	21	70	24	80
	> 450000	4	13.3	3	10
	Total	30	100.0	30	100
f.: frequency; %: percentage.					

Table (3): Distributions of bleeding, hematoma, and ecchymosis levels for the experimental and control groups:																
Variables		Control group								Experimental group							
		After 1		After 2		After 3		After 4		After 1		After 2		After 3		After 4	
		f.	%	f.	%	f.	%	f.	%	f.	%	f.	%	f.	%	f.	%
Bleeding	No Bleeding	9	30	28	93.3	30	100	30	100	26	86.7	30	100	30	100	30	100
	Mild	12	40	2	6.7	0	0	0	0	2	6.7	0	0	0	0	0	0
	Moderate	9	30	0	0	0	0	0	0	2	6.7	0	0	0	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Life-Threatening	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Total	30	100	30	100	30	100	30	100	30	100	30	100	30	100	30	100
Hematoma	No Hematoma	11	36.7	20	66.7	26	86.7	30	100	27	90	27	90	30	100	30	100
	Small	14	46.7	7	23.3	4	13.3	0	0	3	10	3	10	0	0	0	0
	Medium	5	16.7	3	10	0	0	0	0	0	0	0	0	0	0	0	0
	Large	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Total	30	100	30	100	30	100	30	100	30	100	30	100	30	100	30	100
Ecchymosis	No Ecchymosis	0	0	0	0	20	66.7	2	6.7	30	100	30	100	30	100	26	86.7
	Small	0	0	0	0	10	33.3	4	13.3	0	0	0	0	0	0	4	13.3
	Medium	0	0	0	0	0	0	10	33.3	0	0	0	0	0	0	0	0
	Large	0	0	0	0	0	0	14	46.7	0	0	0	0	0	0	0	0
	Total	30	100	30	100	30	100	30	100	30	100	30	100	30	100	30	100
f.: frequency; %: percentage.																	

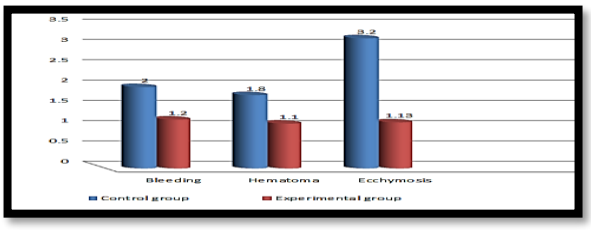

Figure (1) Effect of the ice bag application with direct pressure upon bleeding, hematoma. and ecchymosis

This figure reported significant differences between the effect of interventional protocol and alterations in the mean of bleeding and hematoma that are clearly represented in the first measurement and ecchymosis third measurement.

prevention of the vascular complications after femoral sheath removal of cardiac catheterization with their socio-demographic characteristics

Table (4): Association between the effect of the application of ice bag with direct pressure to								
Variables	Age		Gender		Smoking condition		BMI	
	P- value	Sig.	P- value	Sig.	P- value	Sig.	P- value	Sig.
Bleeding	0.038	S	0.495	NS	0.050	S	0.038	S
Hematoma	0.090	NS	0.314	NS	0.144	NS	0.115	NS
Ecchymosis	0.021	S	0.263	NS	0.035	S	0.353	NS
NS: Non-Significant (P value >0.05); S: Significant (P value ≤ 0.05).								

Table (5) associations between the effect of the application of ice bag with direct pressure in the prevention of vascular complications after femoral sheath removal of cardiac catheterization with their clinical data:						
Variables	Bleeding		Hematoma		Ecchymosis	
	P. Value	Sig.	P. Value	Sig.	P. Value	Sig.
Chronic Diseases	0.048	S	0.011	S	0.032	S
Medication	0.372	NS	0.232	NS	0.160	NS
Heparin Dose	0.019	S	0.012	S	0.002	S
Type Of Catheterization	0.263	NS	0.165	NS	0.102	NS
Size of Sheath	0.273	NS	0.543	NS	0.107	NS
Systolic blood pressure	0.005	S	0.050	S	0.048	S
Diastolic blood pressure	0.305	NS	0.494	NS	0.636	NS
Pulse rate	0.047	S	0.454	NS	0.375	NS
P C V %	0.013	S	0.010	S	0.002	S
Platelet count	0.049	S	0.003	S	0.015	S
NS: Non-Significant (P value >0.05); S: Significant (P value ≤ 0.05).						

2. Discussion

Discussion of socio-demographical characteristics of patients

According to table (1), most participants were between the ages of 60 - 69, accounting for 40% of the experimental group and 36.7% of the control group. Moeinian et al. (2020) study was conducted in Iran to prevent complications after cardiac catheterization and reported that 66.4% of patients were 50-69 years old. According to gender, the

finding of this study indicated that 76.7% of the participants were men, 23.3% were women in the experimental group, 83.3% were men in the control group, and 16.7% of women. The results of this study agree with a study conducted by Athbi & Hassan (2019), which stated that the prevalence of the cardiovascular disease among women and men had a higher incidence rate in males than in females, accounting for 56.3%. Concerning the smoking condition, this study exposed that 70% of the study group and 53.3% of the control group were smokers, consistent with the results of the study done by Ebrahimi et al. (2020) stated that 56.2% of patients with a smoking history. The researcher attributes the cause for the increased rate of participant smokers in the study to Iraqi society's smoking habit (the men smoke more than women). Kudhair et al. (2020) reported that 85% of males were smokers. As for body mass index BMI, this study showed that most participants were within normal weight (18.5-24.9) at 43.3% in the study group and 13.3% in the control group. The results of this study agree with study conducted by Zaki et al. (2020), showing a high body mass index of 40% healthy weight.

Discussion of clinical data of patients

According to the study results shown in Table (2), It was reported that patients in the two groups 43.4% of the study group and 33.3% of the control group had chronic diseases (hypertension and diabetes mellitus). This study agrees with the results of a study by Zhou et al. (2018) in the United States, which confirmed that patients with hypertension are more likely to die from complications of coronary artery disease. This study is in agree with the results of a study conducted by Athbi & Hassan, (2019). in Karbala Center for Cardiac Diseases and Surgery, which confirmed that patients with hypertension and diabetes are more likely to develop coronary artery disease. As for the medication used to treat cardiovascular diseases, it is clear that most patients use anticoagulant drugs in the two groups, 70% in the experimental group and 56.7% in the control group. Also, anticoagulants were used aspirin for 63.6% and Plavix for 39.7% of patients suffering from cardiovascular diseases who had cardiac catheterization in a study conducted in Greek centers by Hahalis et al. (2018). Among the patients participating in this study, the percentage of giving heparin medication for patients after inserting the femoral sheath for cardiac catheterization was 56.4% for the experimental group and 63.3% for the control group. This result is consistent with a study by Bossard et al. (2018) in Canada. The study aimed to reduce the risk of vascular problems during cardiac catheterization. Heparin was used in 68.7% of the cases. The dosage was calculated using body weight as the minimum (50 I.U./kg) and the maximum (100 IU/kg).

The results revealed that most of the participants in the study underwent more therapeutic catheterization than diagnostic catheterization, with 56.7% for the study group and 63.3% for the control group. This result is consistent with the finding of a study conducted by Ul Haq et al. (2019) in the UK on 105 patients who underwent angioplasty. 55% of the catheterization rate was cured. This study showed that 80% of the stydy group and 73.3% of the control group used the size of the femoral sheath of 6 Fr. This finding is consistent with the results of a study conducted by Honda et al. (2021) in Yokohama-shi, Japan on 35 patients and 60% of the femoral sheath was used in a size of 6 Fr. Regarding vital signs, the study's results showed that the rate of hypertension stage 2 among the study participants was 43.4% in the experimental group and 46.7% in the control group. This result was consistent with a study by Mertens et al. (2022). This study was conducted on 98 patients who had a cardiac catheterization through the femoral artery to treat cardiovascular problems. 84.7% of the participants had hypertension.

Regarding heart rate, the study's results showed that 50% in the experimental group, and 60% in the control group, were within the upper limit of the normal range. As for laboratory tests regarding the packed cell volume (P.C.V.) level, the study's results showed that the level was within the upper limit of the normal range. 60% in the experimental group and 50% in the control group. As for the platelet count, the results were within the normal range. 80% in the experimental group and 70% in the control group. Iliescu et al. (2021) showed that 98 patients underwent cardiac catheterization, and the proportion of participants was within the normal platelet range of 43%.

Discussion of bleeding, hematoma, and ecchymosis among the experimental and control groups:As shown in table (3), the result of the four measurements indicates the difference in the levels of bleeding, hematoma, and ecchymosis in the experimental and control groups. The first measurement (after applying the ice bag with direct pressure for 20 minutes) was the development of complications. The proportion of participants who developed bleeding was 13.3% in the experimental group and 70% in the control group. Cold therapy decreases bleeding by constricting arterioles and improves blood coagulation by reducing blood flow and increasing viscosity. As a result, enhancing blood coagulation and decreasing capillary permeability and metabolism requirements are simple methods of reducing bleeding Bayındır et al. (2017). As for the hematoma, this study showed that after implementing the protocol, the proportion of participants in the experimental group was 10%, and in the control group, 63.4% had a hematoma. The results are consistent with a study by Valikhani et al. (2020). Hemostasis stops blood flow immediately through vasoconstriction, platelet aggregation, and blood clotting, making up the three essential parts of the hemostatic process (Zheng et al. (2020). Regarding ecchymosis, the study showed that in the fourth measurement after applying the protocol, in

the experimental group was 13.3%, and in the control group, 93.3% suffered from ecchymosis. Ice therapy can reduce blood flow to the tissue and limit peripheral blood circulation, which helps prevent ecchymosis) Baqal & Mahmood,2022).

Discussion of the association between the effect of the application of ice bag with direct pressure in the prevention of vascular complications after femoral sheath removal of cardiac catheterization patients with their socio-demographic characteristics

Table (4) shows a statistically significant relationship between the effect of the application of ice bag with direct pressure with the following the respondents' socio-demographic characteristics: The results of this study identified the relationship between the bleeding with age group. According to the researcher, bleeding increases with age, which is supported by Kawakami et al. (2021). The researchers refer that in this study, bleeding increase safter 65 years. Also, age raises the risk of ecchymosis due to an increase in bleeding incidence with aging, and this finding comes along with a study conducted by (Ali & Ali 2019) found that ecchymosis incidence increases with age.

Regarding smoking, the researcher believes that smoker patients are more at risk for bleeding, and this believes compatible with the study of Thabet et al. (2021) also referred to half of the patients in the study as risk for bleeding because they were smokers that were the effect on coagulation factors. Although for this reason, this will increase the risk of ecchymosis in smoker patients, and this result was the same found in a study conducted by (Grant et al., 2018 & Al-Hakak et al., 2018).

There is a significant relationship between bleeding and BMI according to the researcher, a patient with a high BMI was at risk for hypertension, leading to an increased risk of bleeding. (Schumann et al. 2021 & AlZeyadi, et al .2019) supported this thinking, finding that obese patient was more at risk for bleeding.

Discussion of the association between the effect of the application of ice bag with direct pressure in the prevention of vascular complications after femoral sheath removal of cardiac catheterization patients with their clinical data

Table (5) shows the result showed there is a relationship between vascular complications with chronic disease special hypertension, and this result was the same found in a study done by Kutkut et al. (2020) also found that patients with hypertension are more at risk for bleeding, hematoma, and ecchymosis when was under cardiac catheterization. Heparin dose was significantly related to bleeding, hematoma, and ecchymosis attributable to heparin work as increased coagulation time, which will increase with dosing. This finding was compatible with a study conducted by Besli et al. (2021) that the patient under cardiac catheterization was more at risk for vascular complications with an increased dose of heparin.

The study findings there is a relationship between vascular complications and Systolic pressure because high systolic blood pressure increases blood flow in the vascular system. This finding is similar to a study by Aguiar Rosa et al. (2021) was patients under cardiac catheterization. High systolic pressure will make them more at risk of bleeding, hematoma, and ecchymosis. A high heart rate increases the risk of vascular complications (Manda & Baradhi, 2018).

Regarding the PCV, platelet count for the participant both has a relationship with bleeding, hematoma, and ecchymosis because the low PCV and platelet count will affect coagulation time. The study was conducted by Boulos et al. (2022), explaining the vascular complication of the patient under cardiac catheterization with thrombocytopenia and low hematocrit.

5. Conclusion

Approximately one-third of the patients participating in this study were elderly, more than three-quarters of the sample were males, nearly three-quarters of the patients in the experimental group were smokers, nearly one-fifth of the experimental group suffered from obesity class i, one-third were in the experimental group was suffering from hypertension, three-quarters of the experiment group used aspirin and Plavix tablets, more than half of the participants in the study used heparin during cardiac catheterization, and therapeutic catheterization was a type of cardiac catheterization for then, more than three-quarters of the participating had a femoral sheath size (6fr) used, about half of the patients had increased systolic blood pressure, and less than half had elevated diastolic blood pressure, pulse rate, PCV, and platelet count were within the normal range for most patients. This study concluded that applying an ice bag with direct pressure positively decreased the level of bleeding severity, hematoma size, and ecchymosis size.

Recommendations

Instructed to perform the ice bag with direct pressure after removal of the femoral sheath to decrease bleeding severity, hematoma size, and ecchymosis size.

Another study should investigate the benefit of applying an ice bag with direct pressure on other invasive procedures such as arterial-venous fistula, central venous line, and arterial line.

Suggest conducting a study by applying an ice bag with direct pressure in the summer to identify the necessary period to obtain the desired benefits.

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Conflict of interest: Nothing that could be damaging to anyone will happen.
Ethical Clearance: The University of Kerbala's Nursing College's Scientific research ethical committee gave its approval. in order for each person to be included in this study, we first got their informed consent. In addition, the researchers give each participant the right to leave the research project at any point during the process.

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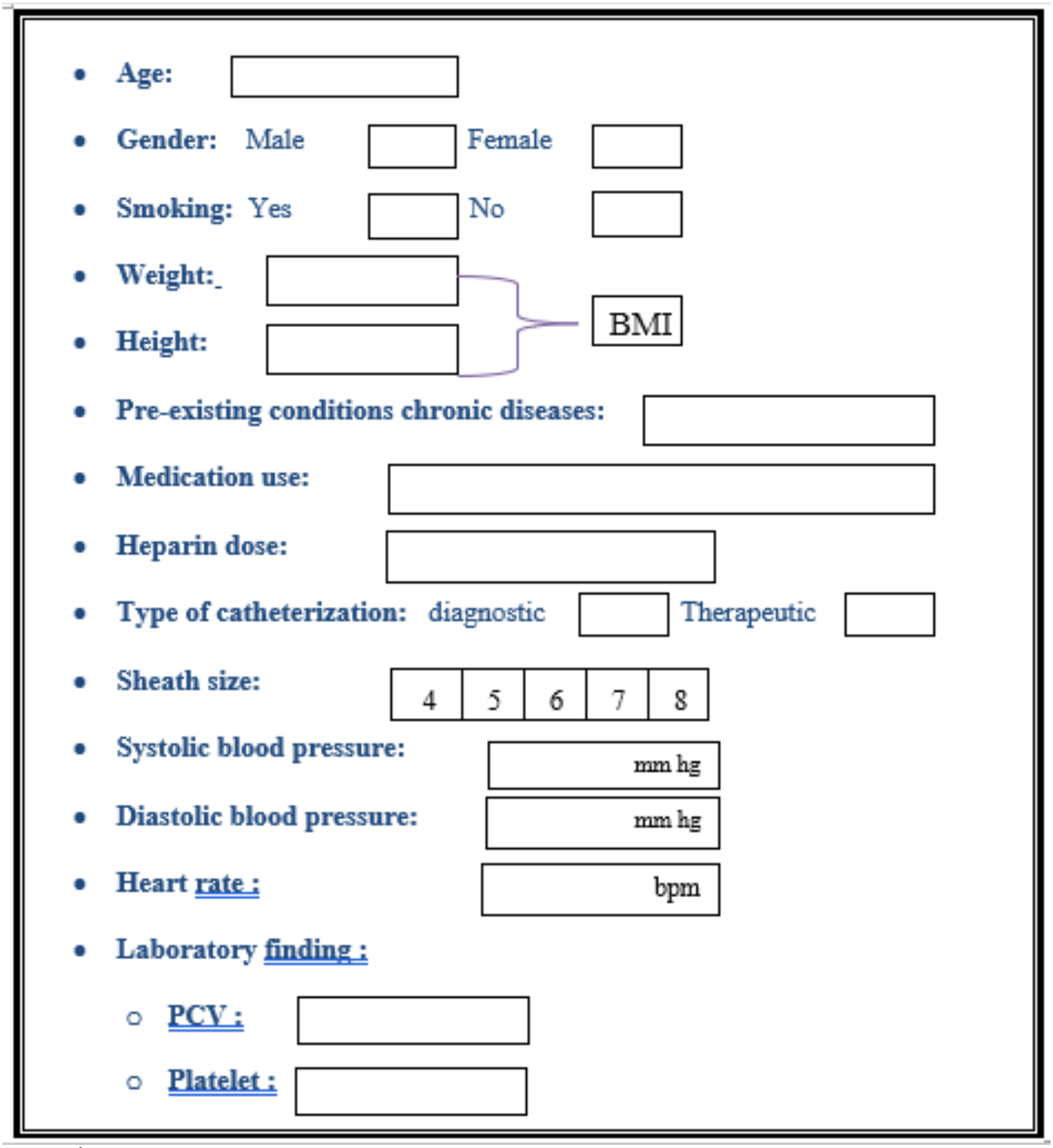

AppendixB

Bleeding scale:					
Bleeding severity	No bleeding ≤ 1 ml	Mild bleeding > 1-5 ml	Moderate bleeding > 5-10 ml	Severe bleeding > 10-50 ml	Life-threatening >50 ml
Grade	0	1	2	3	4

Appendix C

Hematoma Scale:				
Hematoma size	None < 2 cm2	Small 2- < 5 cm2	Medium 5- <10 cm2	Large ≥ 10 cm2
Grade	0	1	2	3

Appendix C

Ecchymosis Scale:				
Ecchymosis size	None < 2 cm^2	Small 2- < 5 cm^2	Medium 5- <10 cm^2	Large ≥ 10 cm^2
Grade	0	1	2	3