University of Kerbala/College of Nursing

Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after Femoral Sheath Removal of Cardiac Catheterization

To the Council College of Nursing/University of Kerbala, in Partial Fulfillment of the Requirements for the Master degree in Nursing Sciences

A Thesis submitted

By

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Supervised

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Dedication

I dedicate my effort and work to:

Who inspired me with knowledge and the ability to work ... ***My God and my Lord.***

The sun that nourishes my life planet with his wisdom rays… ***My father.***

*The spring of my soul…****My mother gives me support and courage with all my love and respect.***

*The shining stars in my life…****My brother and sisters.***

*My love, my dear and my life partner…****My wife.***

To my lovely children ***Yousif, Benin, Mustafa and Zahraa***

who bring the joy to our life.

My dear friends, with my love and respect.

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List of Abbreviations and acronyms

Items	***Meaning***
ACS	Acute Coronary Syndrome
AHA	American Heart Association
ANOVA	Analysis of variance
BC	Before Christ
BMI	Body Mass Index
CA	Cardiac Angiography
CAD	Coronary Artery Disease
CC	Cardiac Catheterization
CHD	Coronary Heart Disease
CP	Closure Pad
CVDs	Cardiovascular Diseases
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
ECG	Electrocardiogram
f	Frequency

FDA	Food And Drug Administration
Fr	French
FVI	Face Validity Index
H.S	Highly Significant
H0	Null Hypothesis
H1	Alternative Hypothesis
HR	Heart Rate
HS	High Significant
I- CVI	Item Level Content Validity Index
I-FVI	Item Face Validity Index
IV	Intravenous
K^{th}	Distans Between Number And Other
MC	Manual Compression
MI	Myocardial Infraction
mmHg	Milliliter Mercury
N.S	Not Significant
ne	Number of Experts In Agreement
No	Number
NS	Non-Significant
PCI	Percutaneous Coronary Intervention
PCV	Packed Cell Volume
POT	Pain Observation Tool
PR	Pulse Rate
PTCA	Percutaneous Transluminal Coronary Angioplasty
S or Sig.	Significant
SBP	Systolic Blood Pressure
S-CVI\Ave	Scale-Level Content Validity Index
S-FVI	Scale Face Validity
SPSS	statistical package of social sciences
STEMI	St-Elevation Myocardial Infarction
TTA	Time to Ambulation
TTH	Time to Hemostasis
UA	Unstable Angina
UA	universal agreement
VAS	Visual Analog Scale
VHD	Valve Heart Disease
VIBe SCALE	Validated Interpretative Bleeding Scale
WHO	World Health Organization
χ^2	chi-square
=	Equal to
%	Percent
&	And
>	More than
<	Less than
≤	Equal or less than

Abstract

Background: Cardiac catheterization is commonly used to diagnostic and therapeutic for acute coronary syndromes. The early complications of this procedure commonly lead to an increase hospitalization period and the costs.

Objective: To determine the effect of application an ice bag with direct pressure to prevent early complications (bleeding, hematoma, ecchymosis, pain, urinary retention, and back pain) after femoral sheath removal post-cardiac catheterization.

Method: An experimental study design, the study was completed with the participation of 60 patients (30 patients in each control and experimental groups) who underwent cardiac catheterization at the Karbala Center for Cardiac Diseases and Surgery from October 1st, 2021, to July 17th, 2022

Result: This study found that approximately 40% of participants were in the age groups of ≥ 60-69 years old, more than 76% of them were males and greater than 53 % were smoking. More than 20 % were classified as obesity class I in the experimental groups. Greater than 33% of the experimental group were suffering from hypertension and more than 56% were using heparin during cardiac catheterization. There were a differences in the bleeding severity, hematoma size, ecchymosis size, pain, urinary retention, and back pain intensity between the experimental and control groups at the different four measurements. The interventional protocol (application an ice bag with direct pressure) was able to reduce the incidence of early complications and getting early ambulation after applying the protocol.

Conclusion: According to the study's results, the ice bag with direct pressure effectively to reduce the development of the early complications after the femoral sheath removal.

Recommendations: Instructed to perform the ice bag with direct pressure after removing the femoral sheath to decrease bleeding severity, hematoma, ecchymosis, and pain. Another study should be conducted to investigate the benefit of the applying an ice bag with direct pressure on other invasive procedures such as remove of arterial-venous fistula, central venous line, and arterial line.

Key words: Ice-Bag, early Complications, Femoral Sheath, Cardiac Catheterization.

Chapter One

Introduction

Chapter One

Introduction

1.1. Introduction:

Coronary heart disease also referred to as ischemic heart disease (IHD), is the primary cause of death on a worldwide. The American Heart Association (AHA), shows that it is estimated during 2030, the number of CHD cases will increase to approximately 100% CHD (Jiang et al., 2022).

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

Cardiovascular diseases (CVDs) are the leading cause of death globally. An estimated 17.9 million people died from CVDs in 2019, representing 32% of all global deaths.7.4 million of these deaths are attributed to coronary heart disease (CHD) (De Hert et al., 2021).

Since 1970, diagnosing and treating people at risk for CHD has been essential in reducing cardiovascular morbidity and death (Mosley et al., 2020).

Many invasive and non-invasive methods have been developed for determining the degree and severity of coronary artery disease (CAD) involvement. Angiography, considered the gold standard for diagnosing It is the traditional way of evaluating CAD and has been the most common diagnostic intervention utilized for people who have cardiac disorders (Valikhani et al., 2020).

Cardiac catheterization is one of the most diagnostic and interventional technologies accessible to cardiologists today. It is performed by inserting a catheter into the vein or artery, often from the femoral or jugular access site, and then guiding it into the heart under

x-ray guidance. The diagnostic catheter is used to evaluate the adequate blood supply via the coronary arteries, blood pressures, blood flow across the heart chambers, and the anatomy and function of the cardiac chambers, valves, and coronary arteries. Therapeutic one is an alternative to open-heart surgery for septal defect closure, expansion of constricted passageways such as pulmonary stenosis, and stent implantation (Henedy& El-Sayad, 2019).

Percutaneous coronary intervention (PCI) is a procedure that is often used to treat parts of the heart arteries that have become narrow without surgery. Heart muscle blood flow is restored by opening and removing plaques or constricting portions of the coronary arteries. PCI is the recommended reperfusion therapy for most CAD patient. It includes balloon angioplasty, atherectomy, and stent placement (El-Aty et al., 218). PCI using coronary stenting is one of the most commonly used therapeutic procedures to increase coronary blood flow and restore myocardial reperfusion (Lao& Chair, 2022).

The right or left femoral artery is often utilized as the common vascular access point for diagnostic and therapeutic cardiac catheterization. Avoid femoral access in patients with previous artificial, aorto-ileo femoral grafts, big abdomen aneurysms, severe peripheral vascular disease, auscultation bruits in femoral artery, and reduced femoral pulse. The right femoral artery is frequently the preferred site of entry owing to its overall ease (Kacharava et al., 2015).

Katrcbaş et al. (2018), reported that the femoral artery is most common vascular access site used for diagnostic and therapeutic vascular interventions in treating coronary and peripheral arterial disease.

After the angiography, the sheath and vascular access should be removed and closed. Due to the strong blood flow to the artery and the several tissue layers that must be traversed to access the femoral

artery, the closure of the arterial access site may be highly challenging. However, angiography via the femoral artery is linked with various problems, including hematoma, hemorrhage, and infection, making the care of the arterial puncture site essential (Moeinian et al., 2020).

Revascularization procedures are often performed using catheterization of the femoral artery. This is because it very simple to access the artery, and the fact that it is such a large artery enables the use of a wide-bore catheter. Possible complications involving the femoral artery include the development of bleeding, pseudoaneurysm, retroperitoneal hematoma, ecchymosis, urinary retention, arteriovenous fistula, vascular occlusion, and back pain. In addition, having access to the femoral artery is a painful and uncomfortable process for patients, who must stay supine for between 4 and 6 hours after the procedure and be able to be moved (Khanna et al., 2020).

De Hert et al. (2021), stated that the most common complications of diagnostic and therapeutic catheterization procedures performed by the transfemoral route are vascular access problems. Complications associated with vascular access increase morbidity, mortality, and healthcare expenses. There are two types of complications that accurse with catheterization, general and vascular. The general catheterization include hypovolemic, arterial embolism, cardiac tamponed, cardiac arrest, pneumothorax, and dysrhythmia, while the vascular complications of the cardiac catheterization procedure include hematoma, hemorrhage, vascular aneurysm, edema, embolism, arteriovenous fistula, arterial spasm, arterial occlusion, painful catheter insertion site, and retroperitoneal hematoma. The femoral arteries are where PCI complications are most likely (Valikhani et al., 2020).

1.2. Importance of the study:

Globally, coronary artery disease is the leading cause of death and loss of Disability-Adjusted Life Years (DALYs). A significant proportion of this burden falls on low and middle-income countries, which account for about 7 million death & 129 million DALYs every year (Ralapanawa & Sivakanesan, 2021).

Globally, cardiovascular disease is the leading cause of death. According to the AHA in 2019 report, there were about 17.6 million deaths worldwide from cardiovascular disease in 2016, and that statistic is expected to increase to more than 23.6 million in 2030, with a mortality rate that outpaces both cancer and chronic lung illnesses. The primary medical problem for many individuals is CHD, the most significant risk factor for cardiovascular disease and the leading cause of cardiac death (Huang et al., 219).

Serruys et al. (2019), reported that the CAD is the leading cause of morbidity and mortality around the world. It is the cause of chronic heart failure and myocardial ischemia, which includes angina pectoris and myocardial infarction, among other heart diseases. Coronary artery disease continues to be treated and managed all over the globe, in spite of the fact that the number of patients undergoing coronary revascularization procedures is on the increase.

In the Australian state of Victoria, elective PCI accounts for 47 % of the roughly 10,000 procedures performed yearly (Liew et al., 2020).

In the United States, PCI is widespread, with around 600,000 PCI procedures done yearly (Amin et al.,2018).

In the 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).

Unstable angina (UA) is a life-threatening CAD. PCI is the most common revascularization technique for patients with CAD, and over 5 million PCI procedures are conducted annually around the world (Zhang et al., 2022).

1.3. Statement of the problem:

According to the WHO, coronary heart disease was globally the major cause of death in 2016. About 17.5 million cardiovascular disease-related deaths globally are attributable to coronary heart disease. CHD is also one of the risk factors for cardiac arrest. Heart and blood vessel disease is increasing and will place an increased cost on the patient's family, community, and region regarding sickness, disability, and economic difficulties (Wicaksono & Djamil, 2020).

The IHD is the major cause of death for both men and women of all ages. In addition to age, gender, hypercholesterolemia, diabetes, arterial hypertension, smoking, obesity, and a person's personality are all important factors in the development of CVD (Nasiowska-Barud et al., 2017).

Coronary artery disease is one of the most common heart and blood vessel diseases in the world. It has been shown that this disease is the leading cause of mortality in both the developing and developed worlds (Malakar et al., 2019).

If treatment is delayed or ineffective, significant complications can develop following a MI. Identifying and treating these complications is critical to minimizing their effect on the patient's condition because they represent a new source of mortality and morbidity. Complications following a heart attack can be divided into five categories: ischemic (angina), arrhythmic (tachycardia and bradycardia), mechanical (cardiogenic shock), inflammatory (acute peritonitis or Dressler's syndrome), and embolic sudden cardiac death

and obstructive shock are examples of complications that fall into this category (Stephens et al., 2019).

Hodge (2019), early intervention is needed for patients suffering from ST-elevation myocardial infarction (STEMI). In the cardiac catheterization room, this may be conducted by PCI or via the administration of medications.

Moeinian et al. (2020), indicate that to achieve hemostasis after removing the femoral sheath post-cardiac catheterization, manual compression (MC) applied to the sheath area for 10 to 20 minutes, and the patient remains in a supine position for 4-6 hours to avoid vascular complications, researchers can conduct an experimental study to reduce this period.

Manual compression was done after femoral sheath removal for at least 15 minutes until the bleeding should have stopped (bandaged for 10 hours, ambulation after 12 hours). In order to minimize the incidence of vascular complications, the patient should be remain in a supine position on the bed, it causes patient discomfort by inducing back pain (Yi et al., 2022).

The cold compresses reduce vascular complications after cardiac catheterization Valikhani et al., (2020), either Kurt & Kashikji, (2019), Bayındır et al., (2017), Çürük et al., (2017), and (Wicaxono & Djamil, 2020). The study conducted by Moeinian et al. (2020) indicate that direct pressure on the punctured artery after removing the femoral sheath post-cardiac catheterization helps reduce vascular complications.

The researcher believes that applying the ice bag with direct pressure of 20 minutes helps reduce early complications, including (hematoma, hemorrhage, ecchymosis, early ambulation, microvascular aneurysm, edema, painful catheter insertion site, embolism, arterial occlusion, arterial spasm, arteriovenous fistula, and retroperitoneal hematoma).

1.4. Study Objectives:

1. Determine the effect of applying an ice bag with direct pressure in the prevention of early complications after femoral sheath removal of cardiac catheterization.
2. Find out the relationship between the effect of the application of an ice bag with direct pressure in the prevention of early complications with patients' socio-demographic and clinical data.

1.5. Research question:

Does the applying of an ice bag with direct pressure can decreased the incidence of early complications after femoral sheath removal of cardiac catheterization**?**

1.6. The Study Hypothesis:

1.6.1. Null Hypothesis (H0): There is no effect of the application of ice bag with direct pressure in the prevention early complications after femoral sheath removal of cardiac catheterization.

1.6.2. Alternative Hypothesis (H1): The application of on ice bag with direct pressure has a positive effect in the prevention of early complications after femoral sheath removal of cardiac catheterization.

1.7. Definition of Terms:

1.7. 1. Effect:

a. Theoretical Definition:

The result or outcome of a cause, where the cause here may either be a disease or treatment technique to produce the effect (Kumar, 2011).

b. The Operational Definition:

The value or degree when using an ice bag to reduces complications after removal of the femoral sheath post cardiac catheterization.

1.7. 2. Ice Bag:

a. The Theoretical Definition:

A waterproof bag to hold ice or cold water for local application that controls bleeding by causing vasoconstriction in the arterioles, increasing clotting and relieves acute pain by producing a localized anesthetic effect in the insertion site (Zaki et al., 20210).

b. The Operational Definition:

Is a non-pharmacological method used to reduce early complications after removal of the femoral sheath post cardiac catheterization.

1.7. 3. Early complications:

a. The Theoretical Definition:

Several problems that occur after removal of the femoral sheath post cardiac catheterization. These complications include hemorrhage, hematoma, ecchymosis, local pain, urinary retention, and back pain (Panizza et al., 2017).

b. The Operational Definition:

The complications that occur for patients after removal of the femoral sheath post-cardiac catheterization include hemorrhage, hematoma, ecchymosis, pain, urinary retention, and back pain.

1.7. 4. Femoral sheath:

a. The Theoretical Definition:

Vascular line that contain rigid, detachable dilators made of Teflon or polyethylene and its basic structure includes a 3-way plug and a back-bleed protection valve/diaphragm, although their length, diameter, and stiffness vary. Diagnostic and therapeutic cardiac catheterization often use the size of sheaths are 4-7 French (Fr) (Kacharava et al., 2015).

b. The Operational Definition:

It is a plastic tube that is inserted through the femoral artery during cardiac catheterization. The femoral artery is the most frequently used site for cardiac catheterization and is removed post-cardiac catheterization is completed.

1.7. 5. Cardiac Catheterization.

a. The Theoretical Definition:

A diagnostic and therapeutic technique used to identify and treat various cardiac diseases, including angina, MI, congenital heart disease, arrhythmias, cardiac valve abnormalities, heart failure, and microvascular heart problems (Mohammed et al., 2021).

b. The Operational Definition:

A procedure performed that involves diagnosing the structure and function of the cardiac chambers, valves, and coronary arteries and treating opening narrowed or blocked coronary arteries using a balloon or stent to ensure good perfusion of the heart muscle.

Chapter Two

Review of Literature

Chapter Two

Review of Literature

Outline Review of Literature

2.1. Overview of cardiac catheterization:

Cardiac catheterization is considered the gold standard for diagnosing, assessing, and treating heart disorders. CC is a very helpful way to find out about the structure of the heart and how the coronary arteries, valves, and heart chambers work. This method also includes investigations of the heart's and coronary arteries' right or left sides (Feroze et al., 2017).

Several invasive techniques assessing the degree and severity of CAD involvement. Angiography, considered the gold standard for diagnosing CAD and has lately become the most prevalent diagnostic intervention, is the conventional procedure for assessing CAD. PCI refers to all CAD restorative procedures done by catheterization and fluoroscopic guiding, including stenting, atherectomy, and balloon angioplasty. Approximately 95 % of the approximately 3 million PCI angioplasty procedures annually in the world are done through femoral arteries (Valikhani et al., 2020).

The percutaneous vascular access technique has included the radial, brachial, and femoral arteries. The femoral artery was chosen because it provided a big access point but a less complex route to the coronary arteries (El-Aty et al., 2018).

Femoral catheterization is the primary diagnostic and therapeutic procedure that is used for the treatment of cardiovascular disorders during this procedure, a catheter is placed in the femoral artery and then pushed into the coronary arteries or the left ventricle of the heart. After this, a diagnostic or therapeutic procedure may be performed through the catheter. In Germany, there were around 845,000 diagnostic catheterizations and 304,000 therapeutic catheterizations conducted in 2008. (Walter et al., 2017).

2.2. Historical background about cardiac catheterization.

Interventional medicine may be dated back to 3000 before Christ BC when the Egyptians employed a metal tube to catheterize the bladder. In 400 BC, ancient scholars examined the function of the heart valve using a reed. In 1929, Werner Forssmann began clinical trials of cardiac catheterization. After a preliminary test on the cadaveric, he inserted a catheter measuring 65cm into the vein in his elbow and transmitted it to the right atrium. The first x-ray image of a CC in human history was obtained. It is the origin of CC in humans. Since then, Forssmann has attempted several peripheral veins nine times in his right heart catheterization. He also conducted the first right ventricular angiography using a catheter and a solution of concentrated sodium iodide (Wang & Luo, 2017).

Klein experiment with right heart catheterization conducted in 1930 was not confirmed by an x-ray, but it allowed him to measure cardiac output by using a peripheral artery blood sample and a right heart blood sample. Essentially demonstrated catheter insertion. It occurred in Prague. X-ray confirmation of right cardiac catheterization did not occur until 1931. In the 1950s, cardiac catheterization was often used in Australia to detect and identify congenital heart disease, valvular disease, and pulmonary hypertension. The using of coronary artery catheterization to find obstructed arteries or narrow causing chest discomfort, also known as coronary angiography, was low, mostly owing to the lack of physical space resulting from increased tuberculosis admissions (Curtis et al., 2020).

Previously, cardiac catheterization was performed by the venous cut-down procedure. However, this procedure has several problems, such as infection, hemorrhage, and arterial transaction.

Percutaneous access to the coronary arteries was developed in 1953, hence avoiding the cut-down technique (Curtis et al., 2020).

In 1964, Dotter successfully treated a patient suffering from a severe femoral artery embolism using a balloon catheter he invented. Although this treatment was not performed for cardiac-related reasons, it was a significant step in the evolution of interventional cardiac catheterization (Wang & Luo, 2017). Germany performed the first peripheral angioplasty in 1968. A patient with left femoral artery stenosis underwent the procedure to improved circulation to the left lower leg, reducing pain and promoting the healing of a chronic foot ulcer (Curtis et al., 2020). Dotter was also the first to use catheter-directed thrombolysis to treat acute thrombus in 1972. When identified, a catheter was inserted inside or directly next to the thrombus, and streptokinase was infused to destroy the clot (Lintin & Uberoi, 2021).

Andreas Gruentzi, considered the father of interventional cardiology, first used balloon catheter technology in the coronary arteries in 1974. The 15th of September in 1977 is a historic day in coronary intervention. That day, Gruentzi ushered in a new phase of CHD interventional therapy. Using a single balloon catheter, he performed the first percutaneous transluminal coronary angioplasty (PTCA) in medical history a 38-year-old male, Bachmann, who had stenosis of 85 % in the mid-section of the left anterior descending coronary artery. In 1985, Gruentzi ushered performed 2623 PTCA procedures on his own, with a success rate of over 90 % and just two death (Wang & Luo, 2017).

Since 1977, PCI has been the most prevalent technique in the world for detecting and treating cardiovascular disorders, including congenital heart disease and revascularization of coronary arteries (Anjum et al., 2017).

The United States "Food and Drug Administration (FDA)" authorized the first stent in 1987. It was the first stainless steel, slotted, balloon-expandable device and one of the most studied and used stents in the 1990s. Several stents were created in the early 1990s (Iqbal & Serruys, 2019). There is no update or created in the PCI technique because of using the same methods discovered from 1977 until now.

2.3. Indication of cardiac catheterization:

Acute ST-elevation myocardial infarction is a major contributor to early death and chronic heart failure. Primary PCI tries to restore blood flow in the obstruction coronary artery by balloon angioplasty and stent insertion (Carrick et al., 2016).

For many years, coronary angiography has been the primary method for determining the degree of atherosclerosis and CAD. However, the link between coronary stenosis on angiography and the presence or absence of myocardial ischemia is complicated. Recent technical developments permit the evaluation of coronary physiology during catheterization (Shah & Pfau, 2019).

Manda & Baradhi (2018), reported that diagnostic or therapeutic cardiac catheterization is a common technique. The examination and treatment of the following conditions, a procedure is used coronary artery disease for:

- Evaluation of the right and left ventricular hemodynamics
- Assess the function of the left ventricle
- Evaluation and management of cardiac arrhythmias
- Diagnosis and treatment of heart valve disorders
- Pericardial blood vessels
- Diagnosis of congenital heart disorders
- Heart failure evaluation
- Revascularization of CAD

2.4. Type of cardiac catheterization.

An invasive technique called cardiac catheterization may be used in many situations. Patients with cardiac disease may benefit from cardiac catheterization (Thabet et al., 2019). The two types of cardiac catheterization are diagnostic (coronary angiography) and therapeutic (angioplasty) (Ginanjar et al., 2018).

Femoral cardiac catheterization is the gold standard for cardiovascular disease diagnostic and therapeutic. A diagnostic or therapeutic technique may be performed using a catheter inserted into the coronary arteries or left ventricle through an incision in the femoral artery (Walter et al., 2017).

2.4.1. Diagnostic catheterization:

Cardiac catheterization is an invasive procedure conducted in an angiographic room with the insertion of an arterial catheter into the radial or femoral artery to access the coronary arteries and view myocardial perfusion using contrast media (Sardinha et al., 2020).

Cardiac angiography is one of the most frequent and accurate key ways to diagnose coronary heart disease. Coronary angiography has recently become very popular due to the benefits it provides in a short time for patients with cardiac disorders such as MI, angina, CAD, congenital heart, and valve heart disease (VHD) (Feroze et al., 2017).

2.4.2. Therapeutic catheterization:

Sven-Ivor Seldinger, a radiologist, created the percutaneous procedure that is commonly used today. PCI, often known as angioplasty, is performed on open-heart coronary arteries. It increases blood flow and reduces mortality in patients with the acute coronary syndrome. Most cardiac procedures are conducted by catheterization with femoral or radial access (Anjum et al., 2017).

If accessible, emergency PCI is the treatment of choice for myocardial infarction. Its' objective is reopen the closed artery within 90 minutes of the patient's presentation at the emergency department. In the cardiac catheterization room, many PCI procedures may be done, including PTCA or balloon angioplasty, intracoronary stent insertion, and atherectomy. A catheter is inserted through a peripheral artery often the femoral artery into the obstructed coronary artery during PTCA. A balloon at the tip of the catheter to compress the atherosclerosis plaques and dilate the artery. The majority of PTCA procedures include intracoronary stent placement. Stents are devices positioned into a closed artery using a balloon-tipped catheter and left to support the arteries (Elgazzar & Keshk, 2018). The recommended therapeutic method for people having stable angina and CHD is therapeutic cardiac catheterization (Fearon et al., 2018).

The angioplasty technique is a therapy for coronary artery obstructions that involves inserting a catheter with a balloon to restore blood flow to the occlusion coronary artery. So, an all-metal endovascular prosthesis known as a "Stent" is inserted to maintain the lumen of the conduit open and integrated, guaranteeing myocardial perfusion and preventing the creation of a new blockage in that branch (Sardinha et al., 2020).

2.5.Nursing role for patients undergoing cardiac catheterization:

Cardiac catheterization is a life-threatening public health procedure that needs standard intervention strategies and a qualified and highly qualified health care professional to achieve the best possible treatment outcomes (Elgazzar & Keshk, 2018).

Patients undergoing CC need nursing care from a skilled professional who is aware with the potential complications and has the

evaluation expertise to identify problems. During the pre/post catheterization session, the combination of nursing knowledge and skills aim to provide a safe accurate procedure, improve health, and quality of life (Mustafa et al., 2020).

1.5.1 Nursing role before cardiac catheterization procedure:

Education of the patient before cardiac catheterization is necessary. The caregiver must explain the technique to the patient. In addition, patients must visit the catheterization station and see a video of the process. The nurse is responsible for monitoring and caring for the patient after cardiac catheterization to avoid complications (Thabet et al., 2019).

Before the procedure, nursing care aims for maintaining optimal hydration, improving patient comfort, and preparing the patient psychologically for the procedure. The nurse assessing the patient's physical and psychological health, identify any conditions that may provide a procedural risk, obtain a baseline electrocardiogram (ECG), and collect a blood sample. Antiplatelet medications should be administered orally to patients to prevent thrombotic problems during and after the procedure. In addition, the nurse should provide intravenous (IV) fluids as recommended and instruct the patient to shave the procedure area and fast after midnight before the procedure (El-Aty et al., 2018).

2.5.2 Nursing role during cardiac catheterization procedure:

During the procedure, nursing care focusing on maintaining the patient's comfort and safety and working with the cardiologist to achieve better outcome. Nurses evaluate ECG , direct arterial pressure, monitoring and reporting any cardiac parameters alterations that may accompany the dose of medication, signs of ischemia or chest pain,

noticing clinical signs of contrast sensitivity, and all patients during the procedure give anticoagulant (Morton & Fontaine, 2018).

2.5.3 Nursing role after cardiac catheterization procedure:

As part of the post-procedure nursing care plan, patients will be monitored for symptoms such as chest discomfort and vital signs, and the catheter insertion site will be monitored for evidence of peripheral circulation notes (such as changes in skin color, warmth, peripheral pulses, and capillary refill). It is necessary the patient's limb with catheterization site is in a stable position, give the necessary medications, monitor the patient's fluid intake/output, and record any abnormal results (Batiha et al., 2016).

2.5.4 Femoral sheath removal:

Kern et al. (2018), stated that after PCI, the sheath may be removed in the catheterization room or at the patient's bedside. The manual removal of the sheath goes as described. Before manual sheath removal, several considerations must be made; Adjust bed height or use a footstool to exert maximal pressure downward for puncture site compression with minimal fatigue.

Steps of femoral sheath removal include:

1. The procedure must be explained to the patient, and the patient should be supine.
2. Before removing the sheath, apply a local anesthetic (10–20 mL of 1% lidocaine) to the skin around the sheath. The nurse should also administer analgesics intravenously and prepared atropine and pain medication.
3. Before removing the sheath, the nurse make sure that the heparin has been discontinued, that the vital signs are in normal state, there is no chest discomfort, and that there are no plans to other CC .

4. If both arterial and venous sheaths were used, remove the arterial sheath to maintain venous access in the case the peripheral IV fails.
5. Avoid applying increased pressure on the femoral vein. A venous thrombus may be caused by prolonged venous occlusion, mainly if pressure devices induce it.
6. Direct pressure lasts between 15 to 20 minutes, depending on the size of the sheath. Continuous pressure by the bandage lasts for 4 hours.
7. Check for cyanosis in the leg and foot.
8. Immobility for 4 hours after removal of the femoral sheath.
9. The femoral arterial site has been used most frequently among the many arterial access methods in angioplasty. However, many patients report discomfort, pain, and vascular complications when the removed of femoral sheath (Bayındır et al., 2017).

2.5.5 Nursing role after patients discharge:

Providing patients with information upon discharge increases their trust and comfort in their patient education. During the recovery time, patients need specific instructions about catheter insertion site care, potential problems, medications, nutrition, and activities. Also, educate him\her about potential changes in lifestyle, chest discomfort treatment, sexual activity directions, and follow-up appointments (El-Aty et al., 2018).

2.6. Complications after femoral sheath removal:

According to Ali & Ali (2019), vascular access-site complications are a significant cause of mortality and morbidity that are primarily related to artery percutaneous intervention procedures. To get

the best possible results from management, safe and standardized care policies must be put in place.

Nearly 3 million CA and PCI procedures are performed annually. These patients run the risk of vascular access issues due to the percutaneous femoral arterial technique utilized for CA and PCI (Bangalore et al., 2021).

Vascular access complications are most common complications of diagnostic and therapeutic catheterization performed via the transfemoral approach. Vascular access complications increase morbidity, mortality, and healthcare costs (Ben-Dor et al., 2021).

Complications from femoral artery access are the main safety risks while undergoing femoral coronary angiography. These complications include groin hematoma, pseudoaneurysm, bleeding, pulsatile mass, stenosis or closure of the femoral artery, and other developed complications. These complications were reported with a complication rate of 3.5 %, of which the majority were considered minor complications, 74.4 %. On either limb, 10.5 % needed surgical intervention, 9.7 % required anticoagulant medications, and 9.7 % required blood transfusions. These problems lead to prolonged hospital stays, leading to greater healthcare costs (Jakobsen et al., 2022).

Femoral vascular complications (FVCs) are a major cardiac catheterization complication associated with considerable morbidity, mortality, and economic consequences. Globally, over 7 million cardiac catheterization procedures are performed each year, with an access site complication incidence of up to 12%. FVCs vary from mild complications such as hematoma, hemorrhage, ecchymosis pseudoaneurysm, and retroperitoneal bleed to more serious complications (Williams et al., 2018).

2.6.1. Early complications after femoral sheath removal:

Patients undergoing a therapeutic or diagnostic cardiac catheterization may experience early vascular complications after removing the femoral sheath. These problems include hemorrhage, hematoma, vasovagal reactions, urine retention, and back discomfort (mustafa et al., 2020).

Early vascular complications are one of the most common complications after the femoral sheath removal post-cardiac catheterization hematoma was 47.5%, and bleeding was 43.4% (Ebrahimi et al., 2020). Also, Kurt & Kaşıkçı (2019) reported that 15.5% of patients had hematoma, 1.5% had bleeding, pain during removal of the catheter 99%, and ecchymosis 73%. Hajizadeh et al. (2018) found that several complications that occur after angiography are embolism at the catheter entrance 27.3%. Vasovagal reactions 25% Al-Sadawi et al., (2019). Urinary retention was 21%, and 26% in back pain (Mustafa et al., 2020).

2.6.2. Late complications after femoral sheath removal:

According to Madia (2019), the incidence of pseudoaneurysms as late complications after femoral sheath removal ranged from 0.2 % to 0.5 % after diagnostic procedures and up to 8 % after therapeutic techniques.

The most common late vascular complications after removal of the femoral sheath post PCI were arteriovenous fistulas 1.0%, pseudo-aneurysms 0.7%, and infection at the local femoral sheath site 2.7% (Yorgun et al., 2019). Peripheral neuropathy is 0.4% sensory neuropathy of the femoral nerve 0.17% (Haq et al., 2018).

2.7. Measures help in the prevention of early complications after femoral sheath removal:

Eleshra et al. (2018), stated that the MC of an access site is the method that is the most widely accepted and most cost-effective method of achieving hemostasis following endovascular intervention. However, it is reported that this procedure is time-consuming and painful for the patients. Additionally, its process of hemostasis does not lead to the immediate closure of the artery; consequently, it is more prone to bleeding issues and hematoma, particularly if the patient's participation is less than optimum. Arterial closure devices have been developed in order to immediately close the punctured artery, which allows for these problems to be minimized, as shown in figure (2-1).

figure (2-1) applying manual compression after femoral sheath removal (Eleshra et al., 2018).

Bracon et al. (2017), used the method to achieve hemostasis after femoral sheath removal, has been used a "Z"-stitch on the sheath area, as shown in figure (2-2) was used a nylon size (2/0). The suture was removed after 18 to 24 hours of suturing the femoral sheath, and the researchers recommended using the method is safe, early ambulation, and effective for achieving hemostasis to reduce vascular complications.

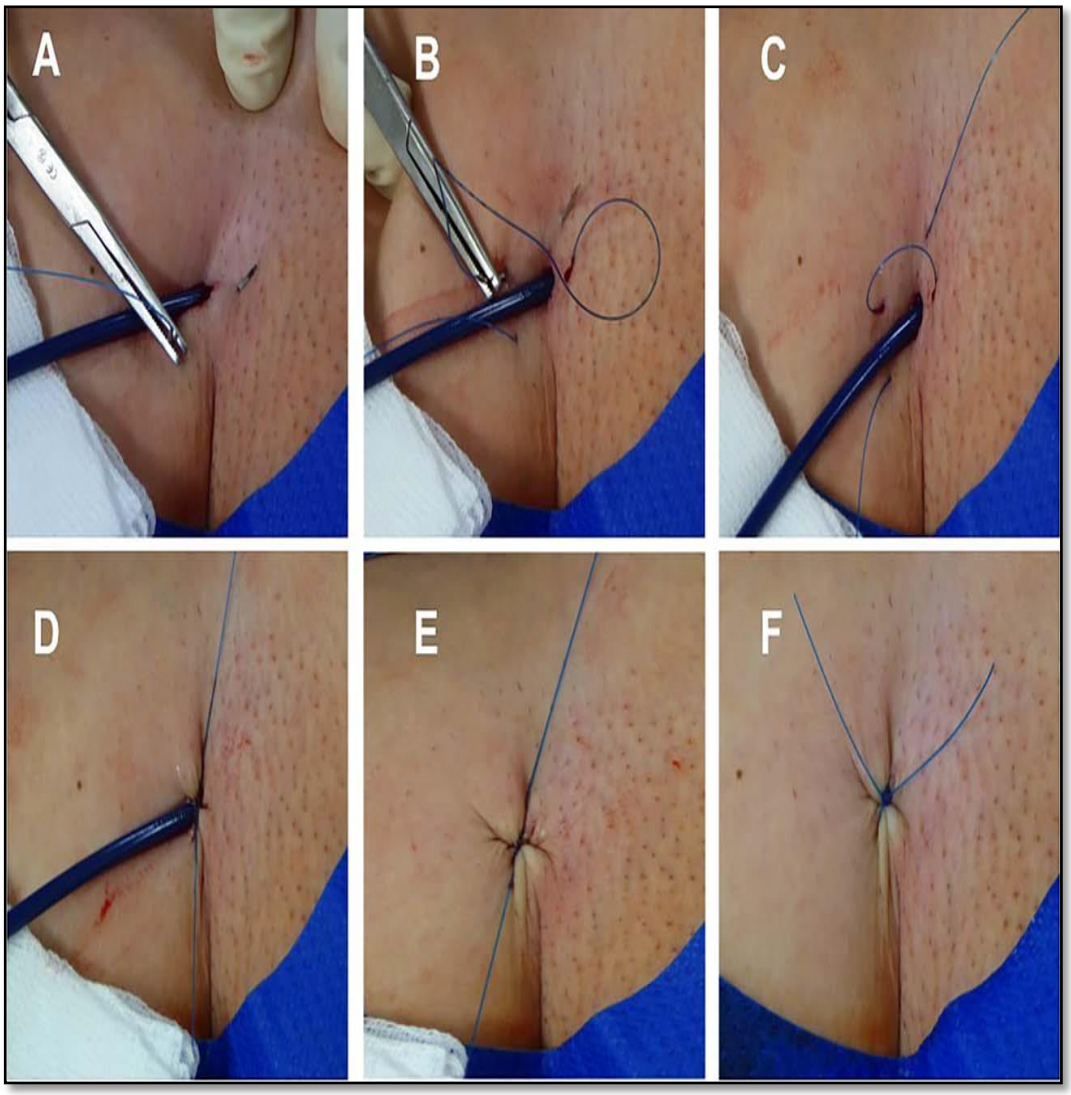


figure (2-2) Application of the "Z"-stitch method(A) Before removing the sheath, the stitch is passed through subcutaneous tissue on one side of the sheath(B) The stitch is moved across the sheath to the other side(C) Again, the stitch is passed well into the skin(D) The suture is tied over the skin(E) After the removal of the sheath, the suture is tightened(F) Hemostasis is achieved immediately (Bracon et al., 2017).

A study conducted by Saini et al. (2022), showed that the mynxgrip vascular closure device in the size of sheath 6/7 Fr was used to prevent vascular complications after removal of the femoral sheath for patients who underwent cardiac catheterization, as shown figure (2-3).

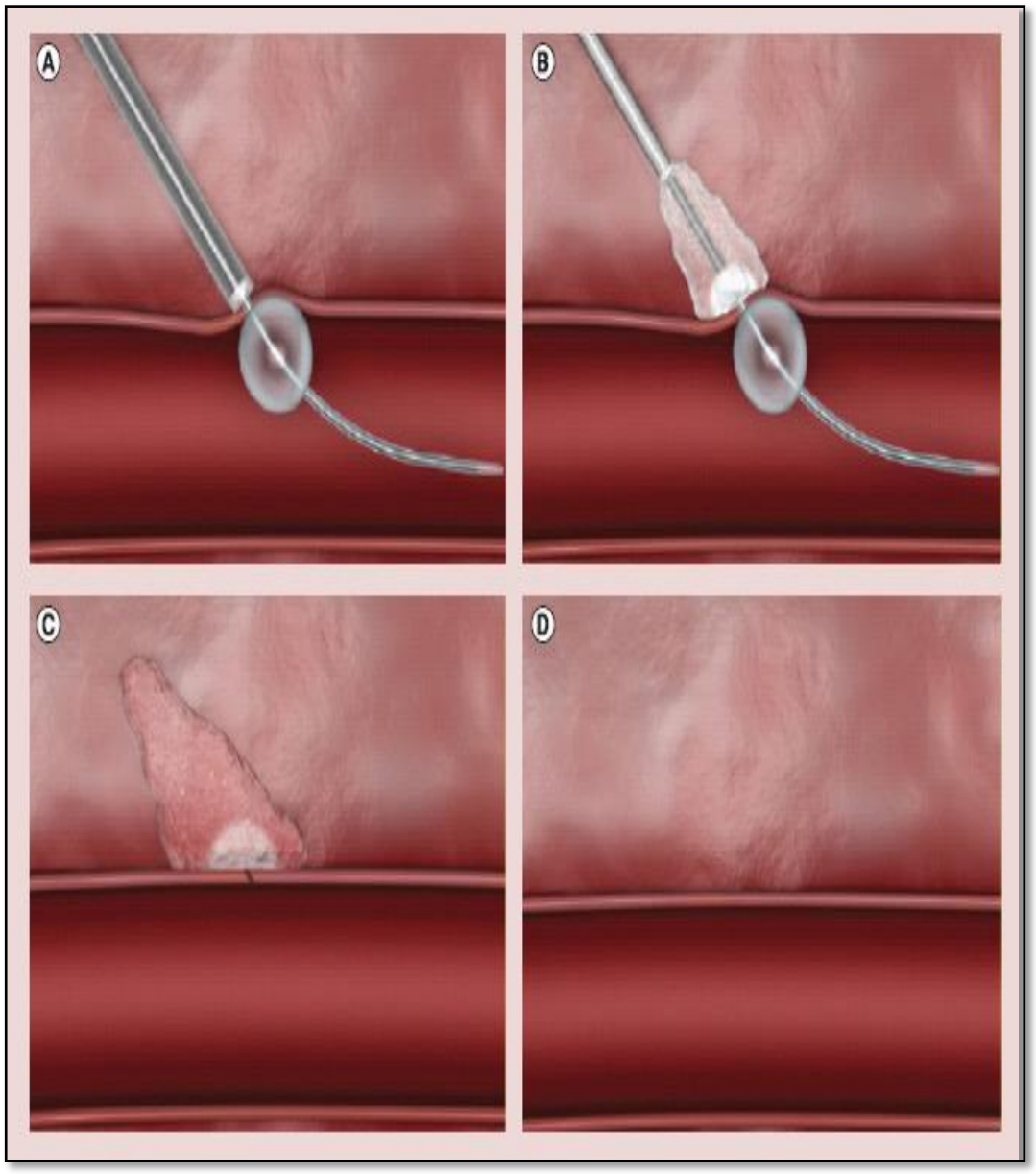


Figure: (2-3) A soft, bioabsorbable polyethylene glycol (PEG) plug is used to achieve hemostasis, which includes: (A) To establish temporary hemostasis, first insert the device into the femoral sheath and inflate the tiny, semi-compliant balloon (B) After that, the PEG sealant is applied to create a state of homeostasis that is permanent (C) remove the device (D) The PEG sealant dissolves within 30 days (Jakobsen et al., 2022).

Angio-seal is a medical device used in patients who have undergone angiography or angiograplsty procedures to close the femoral artery puncture site and shorten the time required for hemostasis, as shown in figures (2-4) (Essibayi et al., 2021).

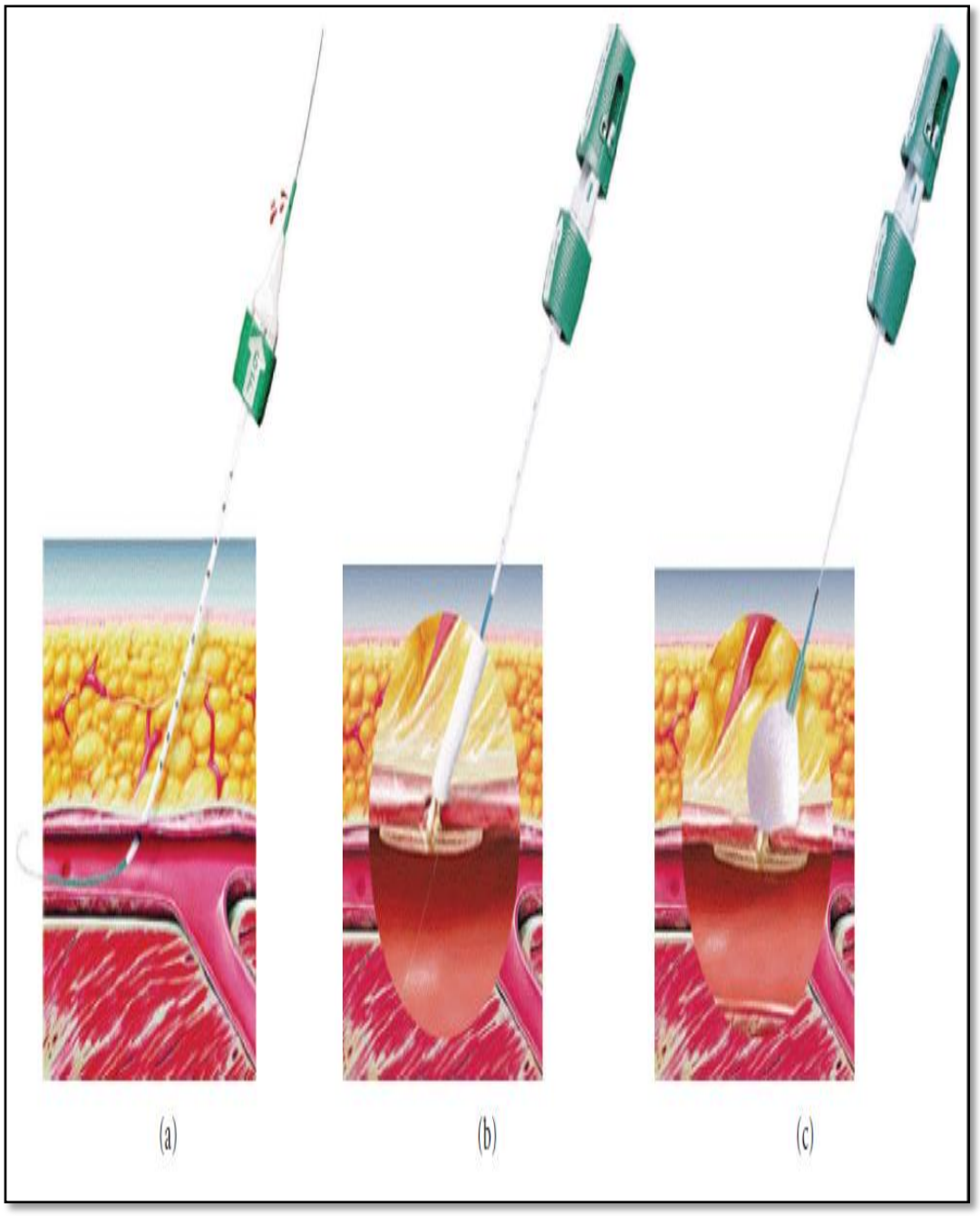


Figure: (2-4) the Angio-Seal device is explained (A) a specific wire is inserted into the artery, and then an artery locator and a percutaneous closure device are inserted(B) and (c) The device creates a mechanical seal by placing on the artery Bioabsorbable collagen sponge dissolves in 60 to 90 days (Devriendt et al., 2019).

The results of a study conducted by Cambron & Miller (2020), femostop devices are reliable in achieving hemostasis to reducing vascular complications after removal of the femoral sheath post-cardiac catheterization, as shown in figure (2-5).

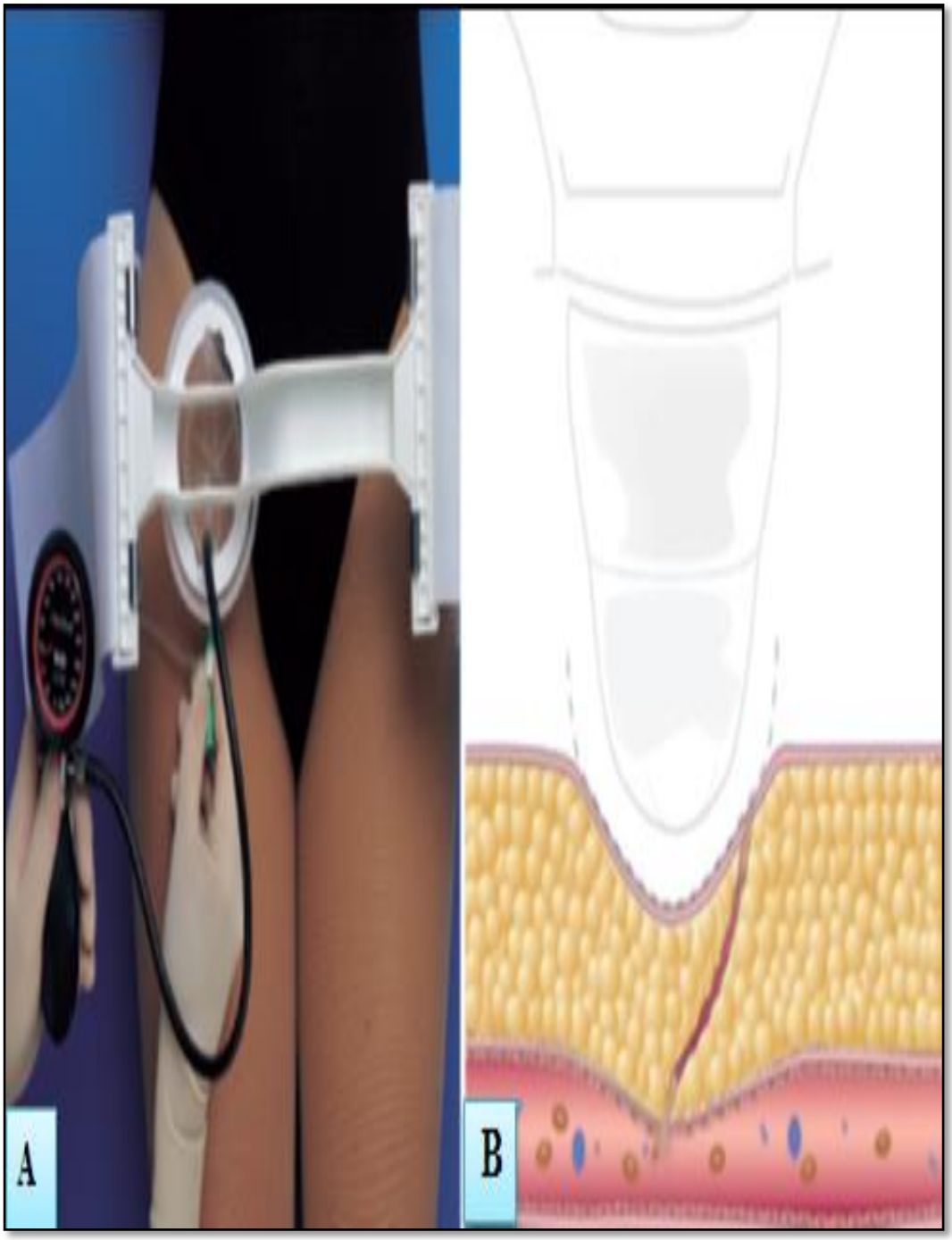


Figure (2-5) (A) Femostop compression system (B) deep homeostasis provided using external compression of the vessel (Cambron & Miller, 2020).

Mechanical and continuous pressure on the artery to obtain hemostasis and allow for hands-free catheter removal. A flat metal C-clamp is placed, below the patient's thigh, with a rubber band to apply pressure to the femoral sheath area to achieve hemostasis, as shown in figure (2-6) (Merriweather et al., 2012).

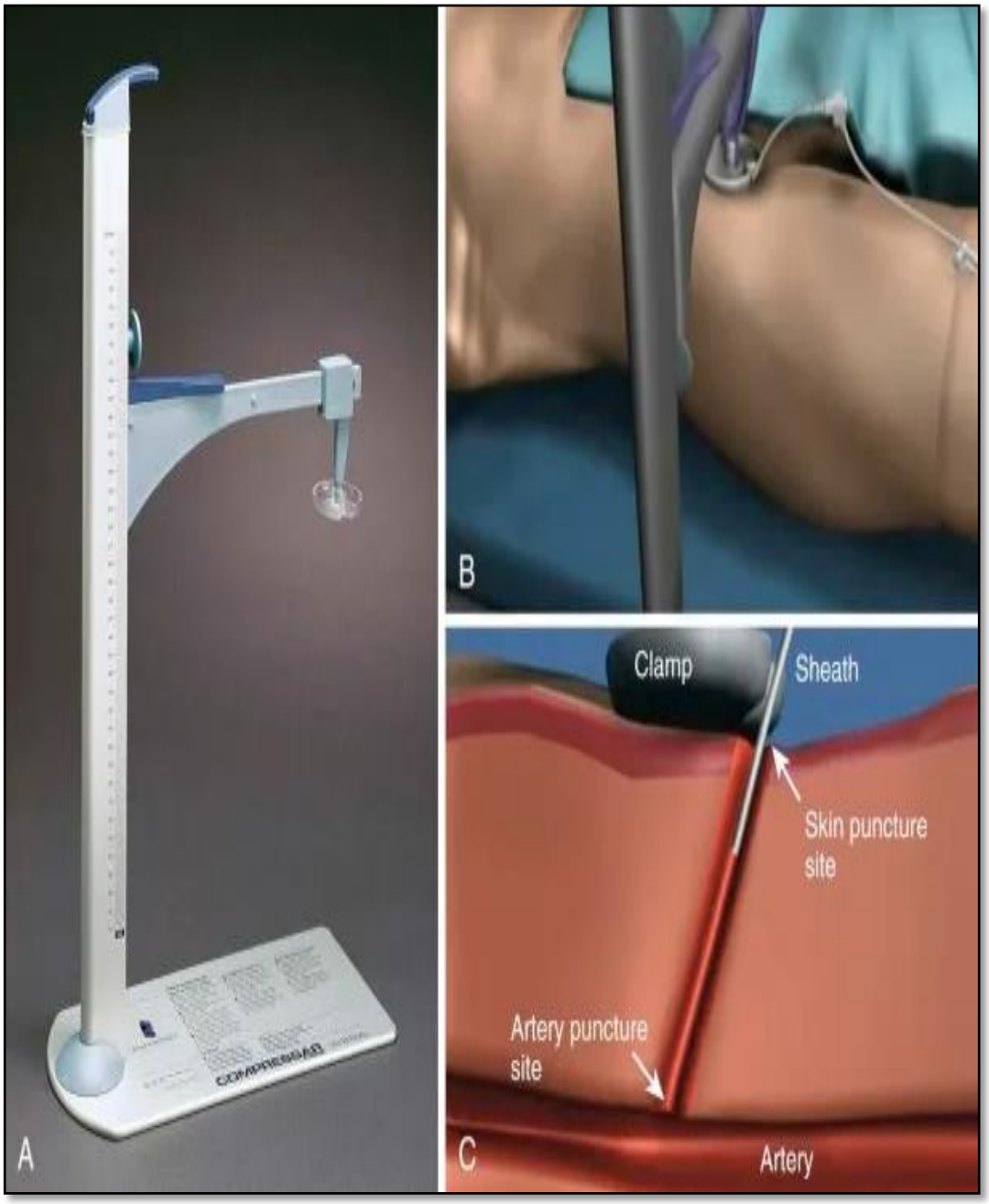


Figure (2-6) (A) C-clamp device (B)The C-clamp arm is lowered into the position of the femoral sheath(C) The C-clamp is positioned above the artery puncture site and not the skin puncture site (Merriweather et al., 2012).

Kor et al. (2021), stated that the use of a sandbag for 6 hours on the sheath area as shown in figure (2-7), to achieve hemostasis after removal of the femoral sheath is effective in reducing vascular complications (hematoma and bleeding) and increased pain at the site of the sheath and patient discomfort.

Figure (2-7) pressure by sandbag (Kor et al,. 2021).

2.8. Application of ice bag for prevention of early complications after femoral sheath removal:

According to Kurt & Kaşkci (2019), the application of cold is one method that may be used to avoid or decrease complications such as ecchymosis bleeding, discomfort, hematoma. The use of cold has both physiological and anesthetic effects on the vasculature, making it a good choice for a variety of medical procedures. According to Bayndr et al., (2017), the application of cold causes a reduction in the rate of vascular blood flow as well as vascular constriction, which together lead to an increase in viscosity. At the location of the puncture, increased coagulation, lower capillary permeability, and decreased metabolic demands all contribute to prevent the development of bleeding, ecchymosis, and hematoma.

Ice is a non-pharmacological accessible and economical way of pain control that has been frequently utilized in orthopedic surgery and sports injuries has shown excellent results in pain management (Mazloum et al., 2018). The application of cold increases the pain threshold and decreases in conduction velocity of nerve fibers that transmit pain sensations from the peripherally to central nervous system (Wang & Ni, 2021).

2.9. Application of direct pressure for prevention of early complications after femoral sheath removal:

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

Manual compression after femoral sheath removal for at least 15-20 minutes and continues pressure by bandaged for 10 hours, ambulation after 12 hours). In order to minimize the incidence of vascular complications, the patient should be remain in a supine position on the bed (Yi et al., 2022).

2.10. Theoretical framework: Core, Care, Cure model:

Introduction of theorist:

Lydia Hall was born in New York City in 1906. She graduated from York Hospital School of Nursing and Columbia University's Teacher's College. In 1969, she died of cardiac disease at Queens Hospital (Alligood, 2017). Hall based her opinion on her observations of hospital care at the time. She was also opposed to the philosophy of team nursing, which was popular at the time in many acute care facilities (Alligood, 2014). Hall believes direct nursing care improves patient outcomes. Hall thought the focus should be on care, and nurses were best prepared to help patients attain their full potential (Priyadarshini, 2021).

Aspects of Hall's theory:

Core: Sumarno (2019), define it as the patient and all of his or her needs, including physical, social, emotional, spiritual, and intellectual demands, are at the core of the nursing process, with the patient serving as the primary focus. To assist in the process of increasing the patient's overall awareness, the nurse provides descriptions and management goals in the "core" component (Umara, 2018).

Care: Sumarno (2019), define it as what the nurse provides for the patient's physical well-being.The goal of physical therapy is to make the patient more comfortable .According to Hall's thesis, the role

of nurses in healthcare is prevention, or prevention and healthcare (Umara, 2018).

Cure: Sumarno, (2019), define it as the results from a nurse's medicinal, surgical, and rehabilitative care in the comforter position .With therapy and medical care, the patient was cured. In this instance, the nurse and doctor care for patients (Umara, 2018).

Meta-paradigm concept of Hall:

- **Person:** Hall was of the belief that the patient will eventually emerge from this process as a whole individual.
- **Health:** is the patients' self-awareness that is associated by the deliberate selection of behaviors that are most appropriate for that individual. The requirement to assist the patient in exploring the meaning of his or her behavior in order to recognize and solve difficulties through the development of self-identity and maturity is part of the definition of health (Alligood, 2017).
- **Environment:** Hall believed that the patient would benefit from the experience that the hospital atmosphere offers while receiving treatment for acute disease.
- **Nursing:** Contribution in the patient's care, including its care, core, and cure components (Smith, 2010).

Clinical application of theory:

- **Core:** After removing the femoral sheath, the patient suffers from early complications include ecchymosis, local pain, hematoma, and bleeding.
- **Care:** The nurse helps patients apply the ice bag with direct pressure for 20 minutes on the sheath area.
- **Cure:** The nurse solved the patient's problems (bleeding, hematoma, ecchymosis, local pain, urinary retention, and back

pain) by applying the interventional protocol (ice bag with direct pressure), help prevent early complications**.**

2.11. Previous related studies:

First Study:

Yi et al. (2022) conducted A randomized controlled trial entitled "A novel femoral artery compression device (butterfly compress) versus MC for hemostasis after femoral artery puncture: a randomized comparison" to assess the hemostatic efficiency of a new femoral artery compression device in patients undergoing interventional procedures involving femoral artery puncture for time to hemostasis (TTH) and time to ambulation (TTA). This study included 616 patients in China. The study showed that there were 22.1% aged > 75 years, 75.9% male, 19.2% smoking, and no significant changes between the MC group and the group using the new femoral artery compression device (butterfly compress). Concluded the new femoral artery compression device is associated with a significant decrease in TTH and TTA and helps in achieving hemostasis in patients undergoing femoral artery puncture.

Second Study:

Kor et al. (2021), conducted a clinical trial on 140 patients in Iran entitled "Effect of changing sandbag weight on complications of femoral artery catheterization and patient comfort: A clinical trial study." The purpose of this study is to investigate the effect of using a sandbag on the vascular complications, pain, and level of patient comfort after the removal of the femoral sheath. The study showed that the patient was 60% and none of the patients had any signs of bleeding and hematoma development throughout the procedure. There was a significant difference in pain and patient satisfaction between groups ($P<0.05$). 6 and 8 hours after angiography, the patients in the third intervention group reported the least discomfort and the most

satisfaction. The control group also had the most discomfort and pain. Conclude the sandbag reduces vascular complications. It causes back pain and patient discomfort.

Third Study:

Wicaksono and Djamil (2020) conducted an experimental study of 30 patients in Indonesia 2020 entitled "Effectiveness of Cold Compress with Ice Gel on Pain Intensity among Patients with Post (PCI) to examine the effect of cold compress with ice gel on pain intensity among patients with femoral sheath post- PCI. The study showed that the patients were males 93.3%, and a significant difference in the experimental group's pain intensity decreased from the control group. Conclude the cold compressed with ice gel effectively reduces pain intensity in femoral sheath patients with post PCI. A cold compress (ice gel) is a nurse's independent action to reduce the pain intensity scale and increase comfort during the treatment phase.

Fourth Study:

Valikhani et al. (2020) conducted an experimental study of 60 patients in Iran entitled "The Effect of Simultaneous Sand-Ice Bag Application on Hemorrhage and Hematoma after Percutaneous Coronary Intervention: A Randomized Clinical Trial". This study aimed to determine the effect of using sand and ice bags ware used simultaneously for 15 mints and then 45 mints with the pressure of the sandbag only, on hematoma and hemorrhage after PCI. The study showed that the ware male 63.3%, patients not smoking was 80%, HT and DM were 23%, and the rate of hemorrhage after the intervention was significantly reduced in the intervention group compared to the control group. Conclude the simultaneous sand-ice bag application can reduce post-PCI hemorrhage and hematoma.

Fifth Study:

Moeinian et al. (2020), conducted a clinical trial with a total of 238 patients in Iran entitled "Comparison of the effect of MC and closure pad on post angiography complications: A randomized controlled trial" to compare the effects of MC and closure pad (CP) on vascular problems (hematoma and bleeding) during coronary angiography. According to the study, the age > 60 years was 62.2%, the male was 45.6%, the smoking rate was 19.3%, and the MC and CP groups' post-angiography hematoma rates were 9.5% and 2.4%, respectively. However, there was no statistically significant difference between the groups. In the MC group, 7.1% of patients had rebleeding after hemostasis, but none of the participants in the CP group experienced rebleeding. There's no significant difference in the level of bleeding that occurred between the groups. Conclusion the findings showed that both the MC and CP techniques were equally effective in avoiding vascular problems after angiograms. The CP technique is recommended for catheterization because of its advantages, which include the ability to change the patient's bed position and greater physical comfort.

Sixth Study:

Either Kurt & Kashikji (2019), also conducted a quasi-experimental study on 200 patients in Turkey entitled "The effect of the application of cold on hematoma, ecchymosis, and pain at the catheter site in patients undergoing percutaneous coronary intervention." The purpose of this study is to assess the impact that applying cold has on hematoma, ecchymosis, and discomfort in patients who are having PCI. The study showed that the elderly patients were 35%, the males 78%, and a significant difference between the intervention and control groups had reduced vascular problems and discomfort at the catheter entrance

site. Conclude the using cold therapy helped patients feel less pain, ecchymosis, and hematoma after the femoral arterial catheter was taken out.

Seventh Study:

Isnaini et al. (2018), conducted a quasi-experimental study on 40. The sample was divided into 20 patients in the intervention group and 20 patients in the control group at PKU Muhammadiyah Hospital Yogyakarta "Effect of Combination of Slow Deep Breathing and Ice Therapy towards Comfort Level in Arteriovenous Fistula Insertion of Hemodialysis Patients in PKU Muhammadiyah Hospital Yogyakarta" to determine the effect of the combination of slow deep breathing and ice therapy on the comfort level of arteriovenous fistula insertion. The study reported that the patients were males 65%, females 35%, elderly participants 60%, and there was a significant difference between the intervention and control groups. Conclude that slow deep breathing relaxation and ice therapy affect the pain and discomfort of arteriovenous fistula insertion in patients with chronic renal failure undergoing hemodialysis therapy.

Eight Study:

Çit & Senturan (2018), The researchers conducted an experimental study on 49 patients at an orthopedic clinic in Turkey entitled "Pressure Application to Prevent Bruising in Subcutaneous Heparin Injection" to examine the effect of applying pressure for a minute on bruising in subcutaneous heparin injection. The study reported that the patients were males 87.8%, elderly participants 67.3%, and bruising occurred significantly ($p < 0.05$) less in the area on which pressure was applied for a minute using dry cotton compared with the area where pressure was applied for a short time. Conclude that this

method was effective in preventing the formation of bruising in subcutaneous heparin injection practices.

Ninth Study:

Hajizadeh et al. (2018), a clinical trial study was performed randomly on 136 patients in Iran al- Ahvaz undergoing angiography in 2 groups of sandbag and ChitoHem entitled "Comparison of ChitoHem Powder and Sand Bag for Controlling Bleeding After Femoral Angiography" with a view to performed to compare the ChitoHem powder and sandbag in controlling bleeding after femoral angiography. The study found that 51.5% in the age group was 51 to 60 years, and bleeding in the sandbag group compared to the ChitoHem group was significantly different ($p = 0.00$) because the post-angiography complications in ChitoHem were less than in sandbags. Conclude that this method had a positive effect on controlling bleeding and reducing the time of homeostasis; therefore, its use is suggested after coronary angiography.

Tenth study:

Bayındır et al. (2017) also conducted an experimental study on 104 patients in Turkey entitled "Effect of Ice Bag Application to the Femoral Region on Pain in Patients Undergoing Percutaneous Coronary Intervention". The purpose of this study is to evaluate the efficacy of applying ice bags to the femoral area of patients having PCI in reducing their level of pain. The study found that 75% of patients were male, 41% were HT, and 30% were diabetic, with significant differences between the intervention and control groups. Conclude that applying an ice bag to the femoral area significantly reduced the discomfort caused by the removal of the femoral catheter in patients undergoing PCI. In these kinds of situations, the local use of an ice bag is suggested as a nursing intervention for pain management.

Eleventh study:

Çürük et al. (2017) conducted an experimental study on 298 patients in Turkey entitled "The Effect of Ice-Bag Applied to Femoral Region of Individuals with PCI on Local Vascular Complications and Low Back Pain" to assess the impact of local ice-bag use on local vascular problems and low back discomfort in PCI patients. The study showed that the patients were males (64%), elderly participants (30%). At the first follow-up, the group that had the least problems was the ice bag group ($p>0.05$), and at the second and total follow-up, the group that had the least complications was the ice-bag group ($p<0.001$). The visual Analog Scale (VAS) score of all groups was gradually increased, and the lowest increase was in the ice-bag group. Follow-up times and VAS scores of groups were determined as statistically significant ($p<0.001$). Conclude the application of the ice bag is effective in reducing the development of complications and lower back pain after removing the femoral sheath. Therefore, it is recommended that this approach be incorporated into nursing practices.

Summary of previous studies:

Previous studies indicated that most patients were elderly, male, and suffering from of the chronic diseases HT and DM. The researchers apply many interventions to reduce the vascular problems and local pain, urinary retention, and back pain that occur after femoral sheath removal for patients undergoing CC. These interventions include ice bag application, cold compress with ice gel, MC and closure pad, compression device (butterfly compress), ChitoHem Powder and Sand Bag, and slow deep breathing and ice therapy. The researchers concluded that the above interventions were able to minimize the discomfort, reducing the development of early complications such as

hematoma, ecchymosis, bleeding, local pain, back pain, and urinary retention.

Chapter Three

Methods and Procedures

Chapter three

Methods and Procedures

This chapter will go through each and every one of the research methods employed in this study in great depth. These procedures included study design, administrative arrangements, ethical consideration, settings of the study, method of sample selection, steps of the study, inclusion/exclusion criteria, instrumentation, methods of data collection, and data analysis.

3.1. Design of the Study:

An experimental study was designed in which a patient with coronary artery disease who had a cardiac catheterization who was able to deal with an ice bag with direct pressure and then measured the effect in the prevention of early complications after femoral sheath removal. The study was conducted at Kerbala Center for Cardiac Diseases and Surgery wards in Holy Kerbala governorate, the period of the study was from October 1st, 2021, to July 17th, 2022.

3.2. Administrative arrangements:

Formal administrative authorization was sought to conduct this research before collecting the data from the following institutions.

1- University of Kerbala/College of Nursing (appendix AI).
2- Ministry of Health/Kerbala Health Directorate/Kerbala Center for Cardiac Diseases and Surgery (appendix AII).
3- Ministry of Health/Kerbala Health Directorate/Training and Human Development Center (appendix AIII).

3.3. Ethical consideration:

These University of Kerbala College of Nursing study ethics committee granted ethical authorization for the confidentiality and anonymity of the participants' names, as indicated in appendix BI. The participants were thoroughly informed of the current study and its

goals, and it was clearly explained to them that they had the right to withdraw from the study at any time, so they voluntarily agreed to participate orally and in writing as shown appendix BII. Additionally, the researcher thought about the confidentiality of the information obtained.

3.4. Settings of the Study:

This study was conducted in the cardiac catheterization wards to the Kerbala Center for Cardiac Diseases and Surgery, which established in 2009 contains surgical and medical wards. This center contains of two cardiac catheterization rooms, two open heart surgery room, a cardiac care unit that include 25-beds, 20-beds surgical ward, and a cardiology consultant clinic.

3.5. Sample size:

The sample size was chosen to be 60 patients classified into two groups. Each of the control and experimental groups had 30 patients. The sample was chosen using a systematic random sampling method. All members of the population were put on a list. Using a randomly selected beginning point of number two, each individual was selected to be added to the list. The needed sample decided the population's size and several elements. The population size then was divided by the sample size requested, giving k^{th}, the size of the gap between the selected items from the list. As the access population was N = 145 and the needed sample size was n = 60, the value of k^{th} will be: $k^{th} = 145 \div 60 = 2.4 \approx 2$. As a result, $k^{th} = 2$, implying that the sample included every second patient on the list. To avoid bias during the sample selection process and strengthen the research, the researcher excludes himself from selecting the sample elements and delegates the work to another individual. (Gray et al., 2016).

3.6. Sample of the Study:

Patients who underwent cardiac catheterization in Kerbala Center for Cardiac Diseases and Surgery were randomly selected for a probability (systematic random sampling). A control group of 30 patients was selected, and a study group of 30 patients was required to participate. The intervention protocol was given in the study group (the 20-minute ice bag application with direct pressure). The follows were the selection criteria:

3.6.1. Inclusion Criteria:

- Patients with cardiac catheterization that aged 18 years and above.
- Patients with cardiac catheterization that was performed through the femoral artery with a single catheter in the groin area.

3.6.2. Exclusion Criteria:

The researcher excluded all of the following, as shown in figure (3-1)

- Pilot study participants.
- Patients refuse to participate in the research study.
- Patient with double femoral sheath region.
- Patients with peripheral catheterization.
- Bleeding and hematoma in the femoral artery area before sheath removal.
- Patients with clotting factors disorders.

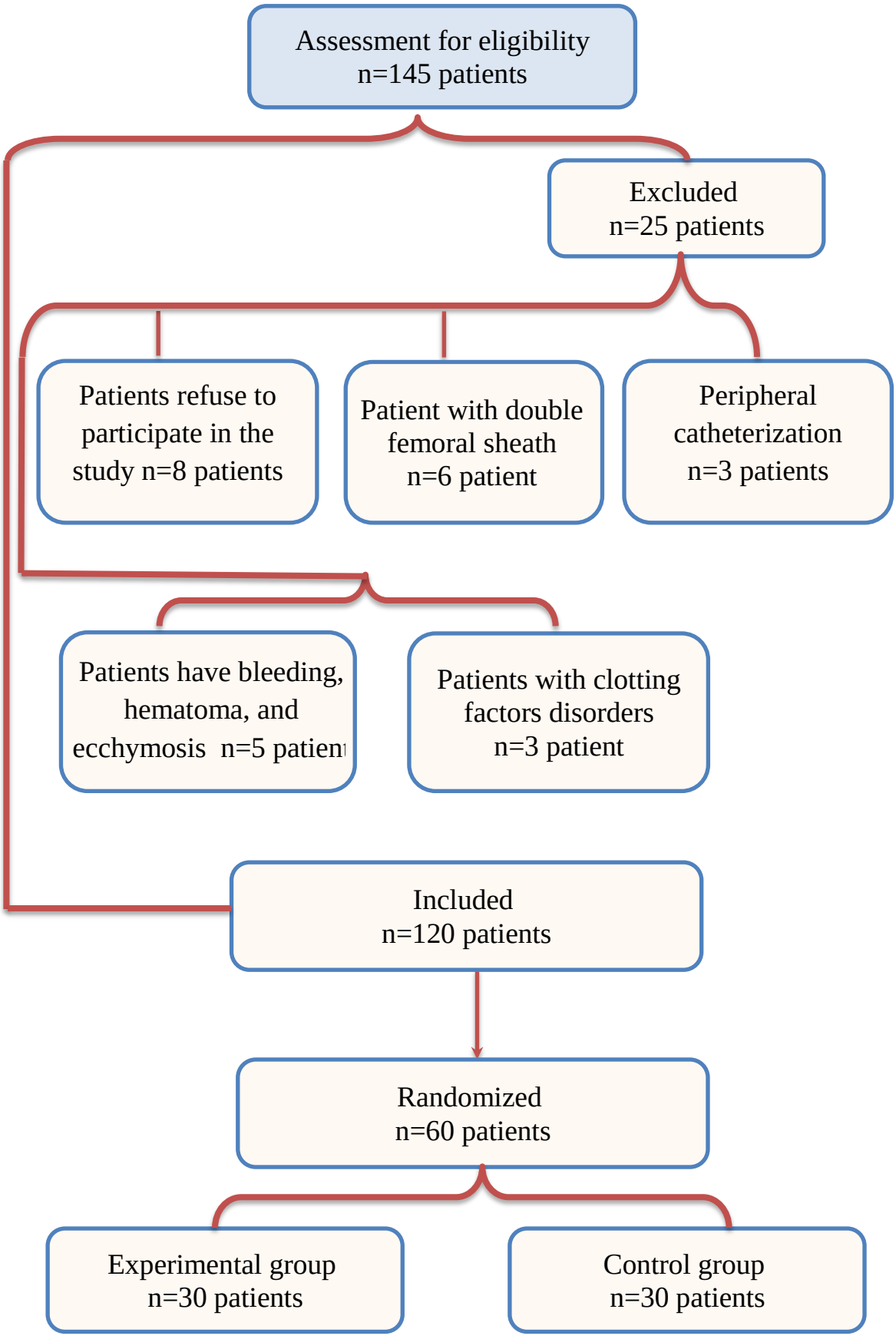


Figure (3-1): Flowchart of the randomized control trial & eligibility criteria

3.7. Steps of the Study:

This study is performed as the following steps:

3.7.1. Interventional protocol:

The interventional protocol was established based on information gathered from a review of the scientific literature and previous studies, as well as the researcher's experience in the care of cardiac catheterization patients and their needs to reduce complications of the procedure. This protocol includes applying an ice bag with direct pressure as shown in appendices CI, CII, CIII, and CIV. The patient is placed in a supine position, then the femoral sheath is removed, an ice bag with direct pressure is applied for 20 minutes, then a small dressing is placed over the insertion area, and starts early ambulation after two hours of bed rest from removing of the femoral sheath.

3.7.2. The study instruments:

To achieve the study's objectives, the researcher was used on appropriate questionnaire that consists of six parts:

Part 1: This part consists of socio-demographic and clinical data of patients that includes age, gender, smoking status, body mass index (BMI)**,** chronic diseases, chronic medications use, heparin dose, type of catheterization, size of the sheath, systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse rate, packed cell volume (PCV), and platelets count, as shown in the appendix DI.

Part 2: The researcher used an adopted scale which named Validated Interpretative Bleeding scale (VIBe SCALE) to measure the severity of bleeding. It contains five items and is a suitable scale to measure the study phenomenon. This scale was developed by Lewis et al., (2017), as described in appendix DII. The researcher get a permission to use from the designer as shown in appendix EI.

Part 3: This part includes the Hematoma Scale: which consists of 4 items. as shown in appendices DIII, to measure the severity of a patient's hematoma. This scale was adopted from Al Sadi et al. (2010), The researcher get a permission to use from the scale creator as shown in appendix EII

Part 4 Hamner et al. (2010), adopted the Ecchymosis Scale, which consists of 4 items to measure the ecchymosis size, as shown in appendices DIV. The researcher get a permission to use from the scale creator as shown in appendix EIII.

Part 5: This part includes the Pain Observation Tool (POT), to measure the severity of pain that contains of four items which was designed by Gélinas et al. (2006), as described in appendix DV, The researcher get a permission to use from the scale creator as shown in appendix EIV.

Part 6: Urinary retention and back pain measurement chart: this part includes checking incidence of urinary retention and back pain for four period as shown in appendix DVI.

3.8. Testing the validity and reliability of instrumentation:

3.8.1. Study instrument validation:

The instrument validation indicates how well it reflects or measures the phenomena being examined. The validation procedure is a result of study validation of an experimental research represents the degree to which the research examines the hypothesis support for the concept of study, its theoretical framework (Gray et al., 2016). Panel of (19) experts revised the interventional protocol and study instrument. appendix FI show that these experts have over 10 years of experience. Each expert member was asked to examine the study instrument's content, simplicity, relevance, style, and applicability.

3.8.1.1. The **content validation:**

Bleeding severity, hematoma size, ecchymosis size, and pain intensity Yusoff (2019), define the content validity as "the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose" content validation process are:

1. Preparing the validation form to the review panel of the experts that will had the understanding about the process and the clear expectations.
2. The researcher distributed questionnaires to (8) review panel of experts with more than ten years of professional experience in the field of specialty, and these experts are (5) members from college of nursing - University of Baghdad, (1) member form the college of nursing - University of Babylon, (1) member form the college of nursing - University of Al ameed university, and (1) member form the college of nursing\University of Kerbala.
3. Content validity is conducted face-to-face through researcher meetings with experts and non-face-to-face by sending the form to experts online.
4. Reviewing items are clearly provided to the experts, and they provide scores on each item, comments on some items, and all comments the researcher considered.
5. The scores provided through the experts on each the item independent based on relevant scales.
6. Finally, calculate the content validation index (CVI) as fallow:

a. Bleeding scale: Eight experts agreed on each question (8,8,8,7, and 8). Each object had UA (1, 1, 1, 0, and 1). I-CVR (item level content validity index) for each item was (1, 1, 1, 0.75, and 1) S-CVI. Ave (the scales levels of content validation index based on an average

method) of this scale was (0.95), and this value was acceptable for CVI (Yusoff, 2019). Yusoff (2019), defines S-CVIUA as a "scale-level content validity index based on universal agreement". The average proportion of relevant items among 8 experts was 0.97 (appendix GI).

b. **Hematoma scale :** Eight experts were able to be observed for the hematoma scale, and all of them reached the agreement for each question (7,8, 8, and 8). Each of these things possessed universal agreement (UA), and they were all (0, 1, 1, and 1).I-CVR, were calculated for each item (0.75, 1, 1, and 1). The S-CVI-Ave for the scale's levels of content validation index was (0.93), and this result was considered acceptable for CVI (Yusoff, 2019). Yusoff (2019), offers a definition for the S-C VI UA, which is as follows: "scale-level content validity index based on the universal agreement method". It was (0.75), while the appendices GII reveal that the average proportion of all elements that were considered to be relevant among 8 experts was (0.96). as shown in the appendix GII.

c. **Ecchymosis scale :** There were eight experts in all who agreed on each question (7,8, 8, and 8). Each item had UA of (0,1,1, and 1). I-CVR for each item was (0.75,1,1, and 1). It was determined that the S-CVI \Ave was (0.93), which was considered acceptable for S-C VI UA define as a "scale-level content validity index based on the universal agreement technique," according to Yusoff, (2019). The average of proportions of all elements considered relevant by eight experts was (0.96) as shown in the appendix GIII.

d. **Pain scale :** Each question had an expert panel of eight, with eight experts in agreement (8,8, 8, and 7). Each item has UA of (1,1,1, and 0). I-CVR for each item was (1,1,1, and 0.75). The S-CVI Ave of this scale was (0.93) and this Value was acceptable for CVI (Yusoff,

2019). S-CVIUA is a "scale-level content validity index based on the universal agreement technique," according to Yusoff (2019). The average of proportions of all items considered relevant by eight experts was (0.96) as shown in the appendix GIV.

3.8.1.2. Face validity:

Commonly, response process validity evidence is performed after content validity has been established. The responses the process of the validation were refer to the degree to which test respondents view the content of a test and item as relevant to the context in which the test is being administered (Yusoff, 2019).

The following are the six steps of response process validation:

1. The first step was preparing responses steps of validity form to that the. Raters who had understanding for this process and the clear expectations.
2. The researcher distributed questioner to (11) review panel of experts with ten years of professional experience in their fields. These experts are (6) faculty member form the college of nursing-University of Baghdad, (1member form the college of nursing-University of Karbala, (1) member form the college of nursing-University of Kirkuk, (1) member form the college of nursing-University of Kufa, (1) member form the college of nursing-University of Warith Al-Anbiyaa, and(1) member form the college of medicine-University of Karbala.
3. The process of response validity done by face, to, face or by the online assessment method.
4. In this step, domain of items were sent to panel of the raters. Reviewers were asked to review these items before submitting the score for these items. Reviewers are encouraged to provide a written commitment to improving each item's understanding and clarity.

5. after complete of review each item, the reviewers were asked for providing the scores for all items. The researcher received scores of responses from the reviewers.
6. There were 2 form of FVI, (I-FVI) for the items and S-FVI for the scale and items the proportion of scale that completes comprehension scales and a clarity of three or four by all reviewers (S-FVI/UA). In this last step the face Viability Index (FVI)was calculated :

a. Bleeding scale: The total number of raters was (11). the raters agreed on each question (10, 11, 11, 11, and 11). When it came to each item, there was a UA (0, 1, 1, 1, and 1). Each item's I- FVI (item face validity index) score was (0.9, 1, 1, 1, and1). S-CVI \ Ave of this scale was (0.98) is an acceptable average value for the FVI (Yusoff, 2019). S-FVI was (0.8). Proportion average that the average score for elements such as judgement and comprehension among the eleven experts was (0.96) as shown in appendix HI.

b. Hematoma scale: The total number of raters was (11). the raters agreed on each question (10, 11, 11, and 11). When it came to each item, there was a UA (0, 1, 1, and 1). Each item's I- FVI (item face validity index) score was (0.9, 1, 1, and1). S-CVI \ Ave of this scale was (0.97) is an acceptable average value for the FVI (Yusoff, 2019). S-FVI was (0.75). Proportion average that the average score for elements such as judgement and comprehension among the eleven experts was (0.97) as shown in appendix HII.

c. Ecchymosis scale: The total number of raters was (11). the raters agreed on each question (11, 11, 10, and 11). When it came to each item, there was a UA (1, 1, 0, and 1). Each item's I- FVI (item face validity index) score was (1, 1, 0.9, and1). S-CVI \ Ave of this scale was (0.97) is an acceptable average value for the FVI (Yusoff,

2019). S-FVI was (0.75). Proportion average that the average score for elements such as judgement and comprehension among the eleven experts was (0.97) as shown in appendix HIII.

d. Pain scale: The total number of raters was (11). the raters agreed on each question (11, 11, 11, and 10). When it came to each item, there was a UA (1, 1, 1, and 0). Each item's I- FVI (item face validity index) score was (1, 1, 1 , and 0.9). S-CVI \ Ave of this scale was (0.97) is an acceptable average value for the FVI (Yusoff, 2019). S-FVI was (0.75). Proportion average that the average score for elements such as judgement and comprehension among the eleven experts was (0.97) as shown in appendix HIV.

3.8.2. Pilot Study:

In Kerbala center for cardiac diseases and surgery in Holy Kerbala city the researcher conducted, a pilot study from January 3th, 2022, to January 18 th, 2022, it was done on ten patients who met the same criteria as the research sample. It was collected using a systematic random sampling technique. The sample of pilot study was excluded from the original sample of the study.

3.8.2.1. The purposes of pilot study:

1. Check the questionnaire reliability.
2. To sure if the questionnaire is feasible.
3. To determine the total time each participant will need.

3.8.2.2. The result of pilot study:

1. The questionnaires were easy to understand.
2. The time required to fill out the socio-demographic and clinical data part was 10-15 minutes
3. The time required to check four scales (bleeding scale, hematoma scale, ecchymosis, and scale pain scale) was 10-15 minutes.

4. The total of time that was necessary to finish all of the data related to the questionnaire was 20-30 minutes.
5. Time required to collect data from the first measurement (after implementing the intervention) to the fourth measurement (48 hours after the intervention) was two days.

3.8.3. Reliability of the questionnaire format items:

Munro (2005) defines reliability as " reliable were used to determine the questionnaire accuracy, since the results show very high levels of stability and internal consistency of principle parts concerning item's responses' of the questionnaire." This study used the Cronbach alpha coefficient test to analyze the internal consistency reliability. The reliability score was (r=0.85) for the bleeding severity scale, (r=0.90) for the hematoma size Scale, the ecchymosis size Scale (r=0.80), and the pain scale (r=0.74) (Table 3-1). Nieswiadomy (2012) reported that reliability coefficients of ≥ 0.70 are considered acceptable, and it is not suggested to use an instrument with reliability of < 0.70.

Table (3-1): Reliability coefficients of the studied questionnaire concerning internal consistency (Alpha Cronbach)

Reliability Coefficients of the studied Questionnaire	Alpha (Cronbach - α)	Standard lower bound	Assessment
Bleeding severity scale	**0.85**	**0.70**	Passed
Hematoma size scale	**0.90**	**0.70**	Passed
Ecchymosis size scale	**0.80**	**0.70**	Passed
Pain intensity scale	**0.74**	**0.70**	Passed

3.9. Data Collection:

The data collection process was carried out through the interviewing technique, and the researchers measured the bleeding severity, hematoma size, ecchymosis, and pain intensity by themselves and recorded them in the study instrument. The data were collected for the study sample from January 20th, 2022, to March 29th, 2022. The data were collected four times, as shown the figure (3-2).

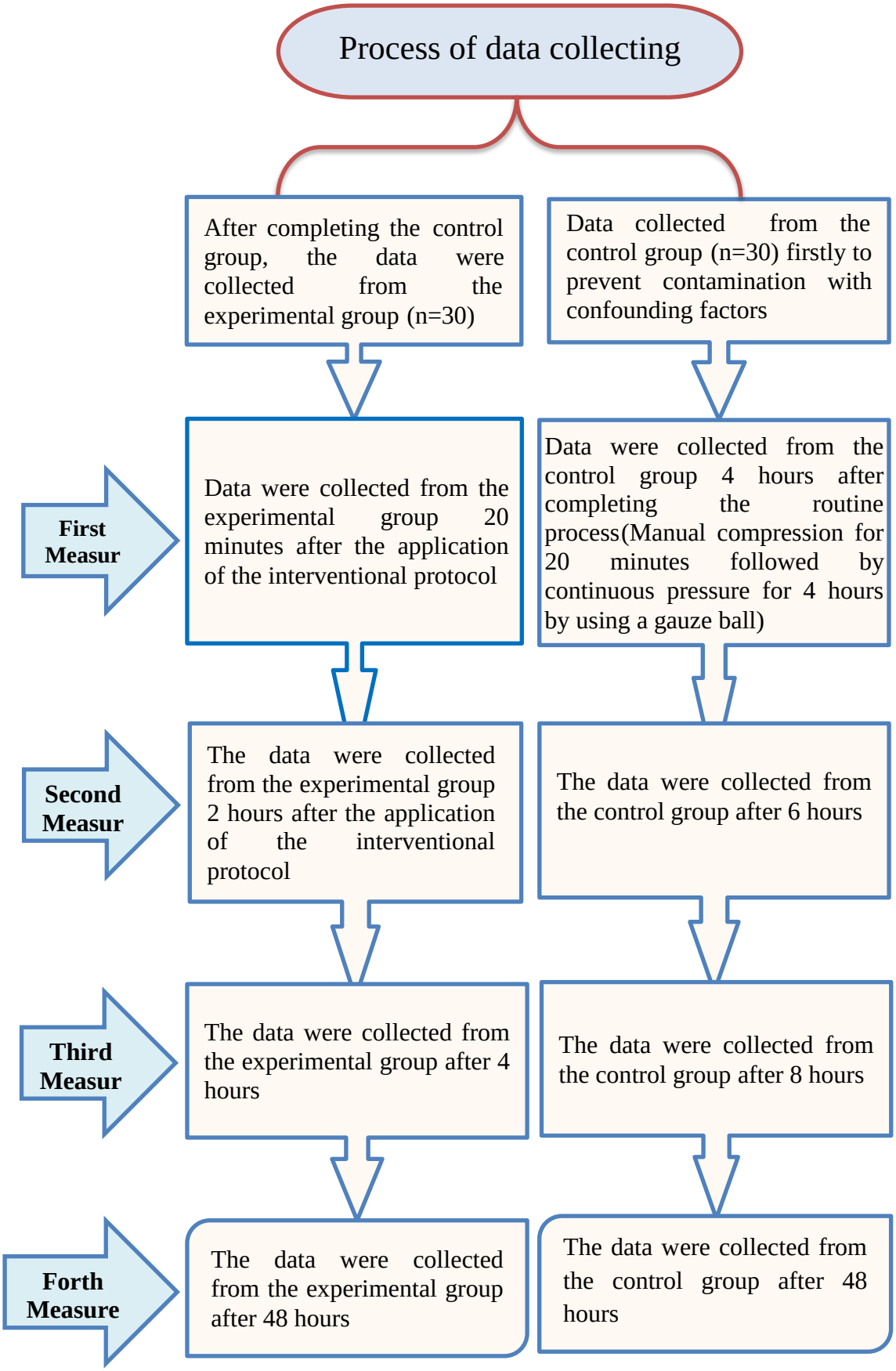


Figure (3-2): Flowchart of the Data collecting method

3.10. Limitations:

A few limits in this study are:

1. Several post cardiac catheterization complications such as arteriovenous fistulas, pseudoaneurysm, and infection at the local femoral sheath site have not been studied due to the lack of facilities.
2. Many laboratory tests, such as partial thromboplastin time (PTT), prothrombin time (PT), activated coagulation time (ACT), and international normalized ratio (INR) cannot be examined due to the lack of facilities.

3.11. Rating and scoring:

Data was rating and scoring as the following patterns:

3.11.1. Rating and scoring for (BMI):

The BMI measurement was as outcome of checking the weight and height and then applying the following formula:

BMI = weight in kilograms /(height in meters)^2 .Whereas BMI was categorized as follows:

- Underweight = <18.5.
- Normal = 18.5–24.9.
- Overweight = 25.0–29.9.
- Obesity I = 30.0–34.9.
- Obesity II = 35.0–39.9.
- Obesity III = ≥ 40 (Hughes 2022).

3.11.2. Rating and scoring for hematoma:

The bleeding was classified into five parts:

- No bleeding (≤ 1ml).
- Mild bleeding(1 > 5 ml).
- Moderate bleeding (5-10 ml).
- Severe bleeding (10> - 50 ml).

- Life-threatening bleeding (> 50 ml) (Lewis et al., 2017).

The hematoma was classified into four parts:

- No hematoma (<2 cm^2 in diameter).
- Small hematoma (2- ≤ 5 cm^2 in diameter).
- Medium hematoma (5- ≤ 10 cm^2 in diameter).
- Large hematoma (≥ 10 cm^2 in diameter) (Al Sadi et al., 2010).

The ecchymosis was classified into four parts:

- No ecchymosis (<2 cm^2 in diameter).
- Small ecchymosis (2- ≤ 5 cm^2 in diameter).
- Medium ecchymosis (5- ≤ 10 cm^2 in diameter).
- Large ecchymosis (≥ 10 cm^2 in diameter) (Hamner et al., 2010).

The pain was classified into four parts:

- No pain (0 score).
- Mild pain (>0- ≤ 3 scores).
- Moderates pain (>3-≤ 6 scores).
- Severe pain (>6- 8 scores) (Gélinas et al., 2006).

3.12. Statistical data analysis:

The program SPSS Version 26 was use to analysis of data by using both descriptive and inferential statistical analysis approaches which are as follows:

3.12.1. Descriptive statistical analysis:

Include the percentages (%),frequencies, and mean. the percentages (%) value was calculated according to the following formula:

% = (Frequencies / Sample size) × 100.

3.12.2. Inferential statistical analysis:

3.12.2.a. A parametric test known as the analysis of variance (ANOVA) statistic, also known as the repeated-measures analysis of variance, provides researchers with the ability to determine the means

of more than two measurements taken from the same individual are comparable or dissimilar.

3.12.2.b. Chi-Square was the statistical approach that was used to evaluate the relationships between the independent variables and the impact of the interventional procedure. Chi-Square is a statistical method that was employed.

3.12.2.c. Significance levels a probability value of ≤0.05 was considered statistically significant (Abd El Aziz et al., 2016). The accepted probability value for significance was < 0.05% to > 0.01%, indicating statistically significant, and < 0.01% indicating highly significant statistical results (Al-Kerety 2017). Nieswiadomy (2012), define the significance level as the probability value of rejecting a null hypothesis when it is true.

3.12.2.d. Cronbach's alpha coefficient test, is a test to measure the internal consistency reliability. The reliability is an alternative way of looking at the extent to which items go together, similar to the factor analysis itself. Also, reliability computations are useful for further identifying weak items that may be omitted in subsequent analysis (Munro, 2005).

Chapter Four

Results & Findings

Chapter Four

Results and Findings

This chapter summarizes the findings of the data analysis, which are in line with the goals stated earlier. The following is how the results were organized:

Table (4-1): Distribution of participants according to their* Socio-demographic characteristics*:

Socio-demographic Characteristics		Control group			Experimental group		
		f.	%	M St.	f.	%	M St.
Age	40 - 49	6	20	**2.43 0.97**	7	23.3	**2.56 1.07**
	50 - 59	9	30		5	16.7	
	60 - 69	11	36.7		12	40	
	70 - 79	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); M(Mean); St. (Std. Deviation)

Table (4-1) indicates that more than one-third of the patients participating in the experimental and control groups were within the age groups of ≥ 60-69 years old and accounted for 40 % for the experimental group and 36.7 % for the control group. 76.7% of the experimental group and 83.3 % of the control group were males. While the greater percentage of 70 % and 53.3 % of the patients who participated in the experimental and control groups respectively are

smoking. 43.3% of the patient participant in the control group were classified as obesity class I, and 20 % for the experimental groups.

Table (4-2)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**
Antiplatelet Medication	Aspirin Tablet	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**
SBP (mm hg)	< 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**
DBP (mm hg)	< 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**
PCV%	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**	**30**	**100**

Table (4-2) shows that the experimental and control groups had chronic diseases. In the control group nearly half 46.7% and 33.3% of the experimental group had hypertension. The two groups were treated with antiplatelet medication. A 56.7% of the control and 70% of the experimental group were treated with Aspirin and Plavix. As for heparin used during cardiac catheterization, it was used by 63.3% in the control group and in the experimental group 56.6%.

Regarding the type of cardiac catheterization, therapeutic catheterization was performed more than diagnostic catheterization in the control 63.3% and experimental 56.7% groups. The size of (6fr) the femoral sheath was used more than the size (7fr) in cardiac catheterization, as shown in the control group at 73.3% and the experimental group at 80%. Regarding vital signs, the systolic blood pressure of about half of the participants in the two groups suffers from an increase of more than 160 mm hg, 46.7% in the control group and 43.3% in the group concerning diastolic blood pressure. Less than half of the patients had elevated diastolic blood pressure in the experimental group, 46.7%, and the control group, 36.7%**.** As for the pulse rate, the two groups were within the upper limit of the normal heart rate, 50% for the experimental group and 60% for the control group. Regarding laboratory tests, the packed cell volume (PCV) of 40-49% is considered within the normal range, was 60% for the experimental group and 50% for the control group. The platelets count within the normal range for the two groups, 80% for the experimental study and 70% for the control study.

Table (4-3): Distributions of bleeding, hematoma, ecchymosis, and pain 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	30	100	30	100	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**
Pain	No Pain	0	0	5	16.7	21	70	30	100	22	73.3	26	86.7	30	100	30	100
	Mild	9	30	17	56.7	9	30	0	0	4	13.3	4	13.3	0	0	0	0
	Moderate	15	50	8	26.7	0	0	0	0	4	13.4	0	0	0	0	0	0
	Sever	6	20	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**

f: frequency; %: percentage. After 1: 20 minutes after implementing the intervention. After2: two hours after implementing the intervention. after3: four hours after implementing the intervention. After 4: 48 hours after implementing the intervention. NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01).

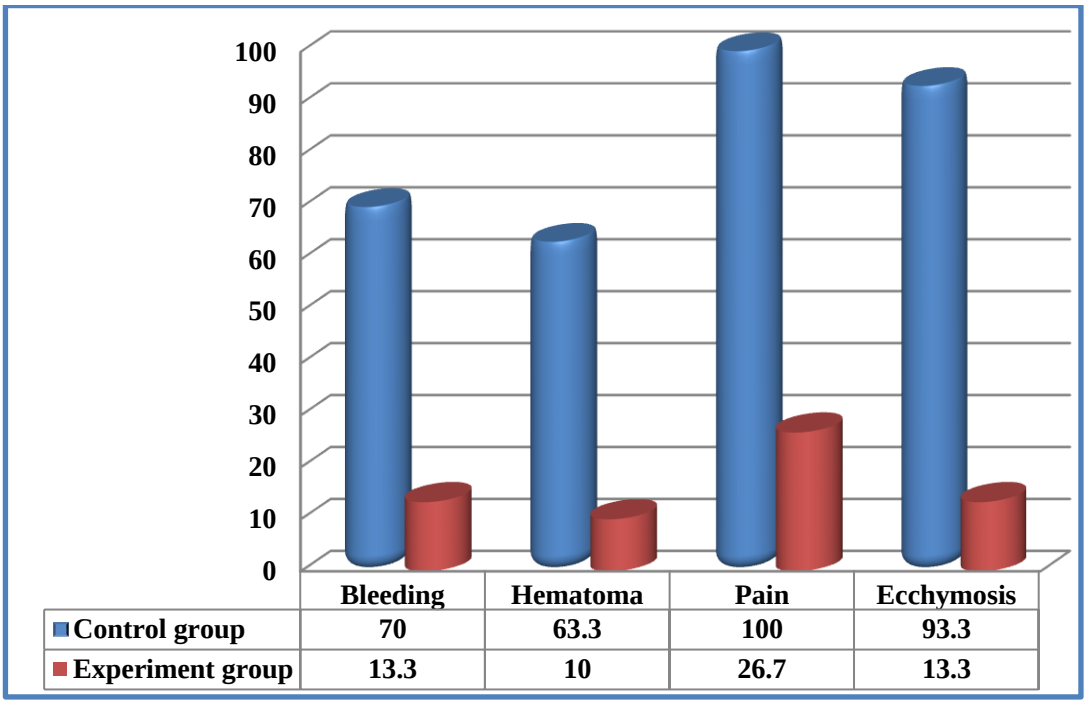
This table shows the differences in the bleeding severity, hematoma size, ecchymosis size, and pain intensity between the experimental and control groups at the first measurement periods. As shown in the experimental group, the level of bleeding severity was 13.3% of patients bleeding, while 70% were in the control group. Regarding the hematoma size levels, the results found that 10% of patients had hematoma in the experimental group and 63.3% control group. Regarding the ecchymosis size, the fourth measurement shows a difference between the two groups, as 13.3% of patients in the experimental group had ecchymosis while 93.3% in the control group. Finally, 26.7% of the experimental group had pain, while 100% of the control group also did.

Table (4-4) The comparison significant between the mean of the readings of bleeding severity, hematoma size, ecchymosis size, pain intensity, urinary retention, and back pain. for the experimental group and control group:

Variables	Control group					Experimental group				
	After 1	After 2	After 3	After 4	p-value (Sig.)	After 1	After 2	After 3	After 4	p-value (Sig.)
Bleeding	2.0	1.06	1.00	1.00	0.000 HS	1.20	1.00	1.00	1.00	0.056 NS
Hematoma	1.8	1.43	1.13	1.00	0.000 HS	1.10	1.10	1.00	1.00	0.083 NS
Ecchymosis	1.00	1.00	1.33	3.20	0.000 HS	1.00	1.00	1.00	1.13	0.043 S
Pain	2.90	2.10	1.30	1.00	0.000 HS	1.40	1.13	1.00	1.00	0.005 S
Urinary retention	1.00	1.00	1.63	1.0	0.000 HS	1.00	1.00	1.00	1.00	NS
Back pain	1.00	1.00	1.72	1.0	0.000 HS	1.00	1.00	1.00	1.00	NS

After 1: 20 minutes after implementing the intervention. After2: two hours after implementing the intervention. after3: four hours after implementing the intervention. After 4: 48 hours after implementing the intervention. NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01).

This table shows significant statistical differences between the mean bleeding severity, hematoma size, ecchymosis size, pain intensity, urinary retention, and back pain for the control group, that mean there were differences between the means of four measurement because these problems accrue gradually. While there clearly, the experimental group showed significant statistical differences between the mean of ecchymosis size and pain intensity because they were had differences in the mean. Bleeding severity, hematoma size, urinary retention, and back pain had no significant statistical differences between the mean of them because the interventional protocol reduce incidence them.



	Bleeding	Hematoma	Pain	Ecchymosis
Control group	70	63.3	100	93.3
Experiment group	13.3	10	26.7	13.3

Figure (4-1) Effect of the application of ice bag with direct pressure upon bleeding, hematoma, pain, and ecchymosis:

This figure reported a significant differences between the effect of interventional protocol and alterations in the percentage of bleeding, hematoma, and pain that are clearly represented in the first measurement. Also reported that there was a significant differences between the effect of interventional protocol and alterations in the percentage of ecchymosis that represented in the fourth measurement.

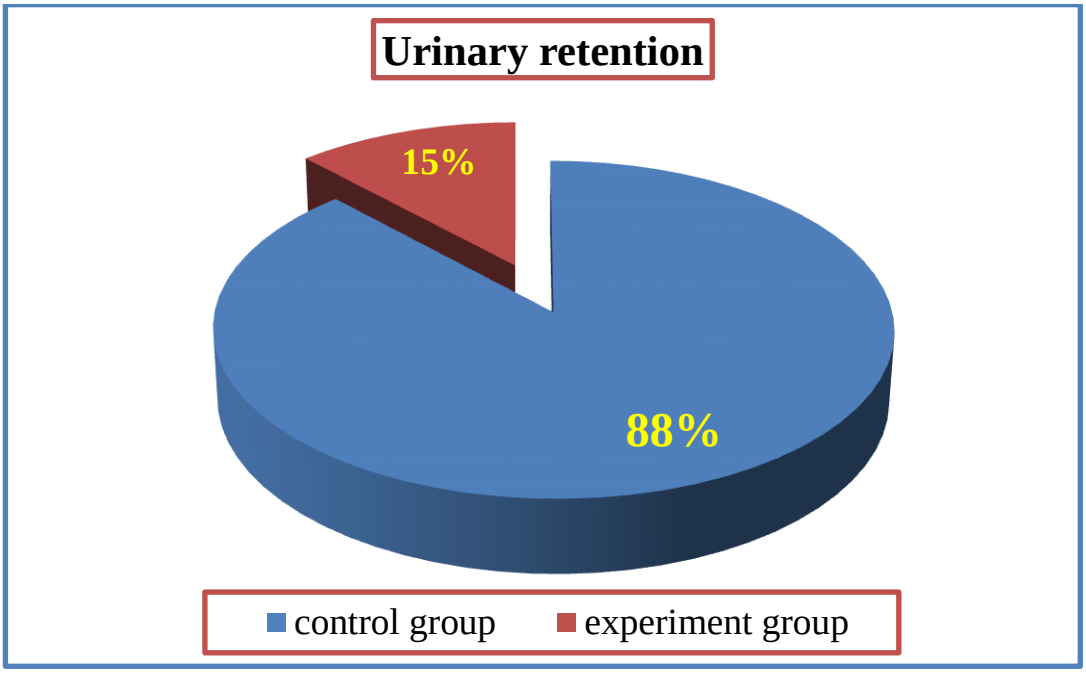


Figure (4-2) Status of urinary retention

This figure reported that 88% of patients in control group had urinary retention, while only 15% of patients in experiment group. It represent that in the third measurement.

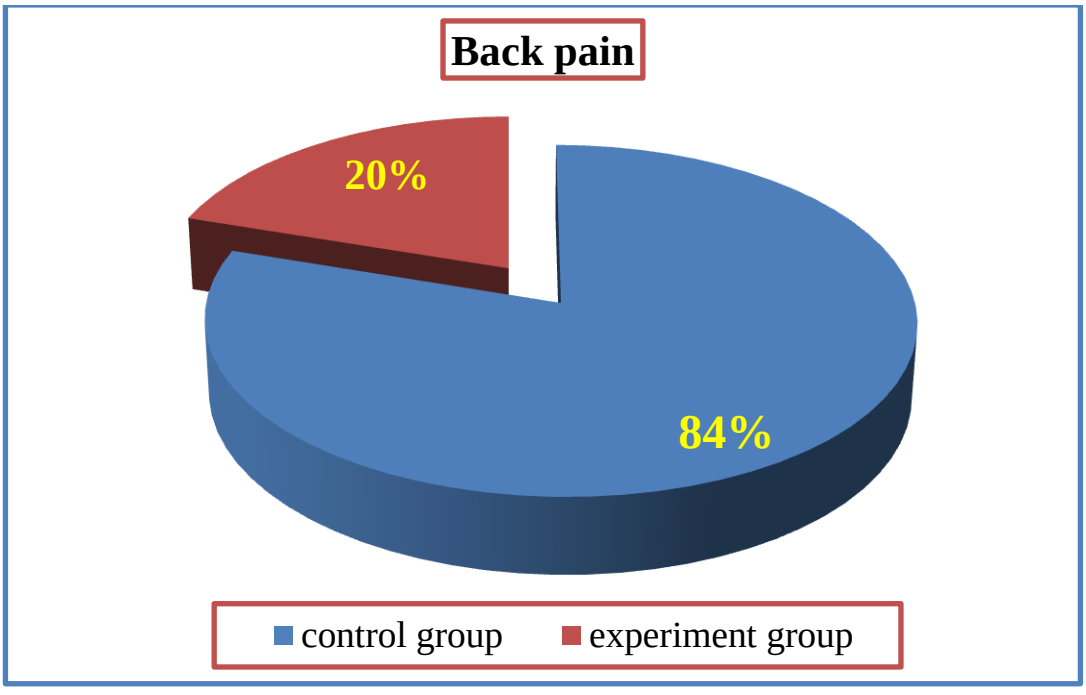


Figure (4-3) Status of back pain

This figure reported that 84% of patients in control group had back pain, while only 20% of patients in experiment group. It represent that in the third measurement.

Table (4-5): Pairwise comparisons of the bleeding readings under the effect of the application of ice bag with direct pressure between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	**2**	0.200	0.101	0.056	**NS**
	3	0.200	0.101	0.056	**NS**
	4	0.200	0.101	0.056	**NS**
2	**1**	-.200-	0.101	0.056	**NS**
	3	0.000	0.000	-	**NS**
	4	0.000	0.000	-	**NS**
3	**1**	-.200-	0.101	0.056	**NS**
	2	0.000	0.000	-	**NS**
	4	0.000	0.000	-	**NS**
4	**1**	-.200-	0.101	0.056	**NS**
	2	0.000	0.000	-	**NS**
	3	0.000	0.000	-	**NS**

****The mean difference is significant at the 0.05 level based on estimated marginal means NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01). (I) time = The measurement to which it is compared. (J) time = Measurements that compare to the main measurement.***

The pairwise comparisons table shows that there was a no significant difference in bleeding readings between first measurement as the periods of the application of the interventional protocol (application of ice bag with direct pressure for 20 minutes) and second measurement (application of ice bag with direct pressure for two hours) at a P-value of 0.056, it represents that the bleeding occurred in small amount and began to disappear gradually.

Table (4-6): Pairwise comparisons of the hematoma readings under the effect of the application of ice bag with direct pressure between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	**2**	0.000	0.000	-	**NS**
	3	0.100	0.056	0.083	**NS**
	4	0.100	0.056	0.083	**NS**
2	**1**	0.000	0.000	-	**NS**
	3	0.100	0.056	0.083	**NS**
	4	0.100	0.056	0.083	**NS**
3	**1**	-.100-	0.056	0.083	**NS**
	2	-.100-	0.056	0.083	**NS**
	4	0.000	0.000	-	**NS**
4	**1**	-.100-	0.056	0.083	**NS**
	2	-.100-	0.056	0.083	**NS**
	3	0.000	0.000	-	**NS**

.S.*The mean difference is significant at the 0.05 level based on estimated marginal means. NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01). (J) time = Measurements that compare to the main measurement.

The pairwise comparisons table shows that there was no a P-value of hematoma size readings between first measurement and second measurement because they had the same of mean. And show that also no significant difference in hematoma size readings between the first measurement and third measurement at a P-value of 0.083, although the hematoma did not appear in the third measurement, there is very little difference between them.

Table (4-7): Pairwise comparisons of the ecchymosis readings under the effect of the application of ice bag with direct pressure between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	**2**	0.000	0.000	-	**NS**
	3	0.000	0.000	-	**NS**
	4	-.133-	0.063	0.043	**S**
2	**1**	0.000	0.000	-	**NS**
	3	0.000	0.000	-	**NS**
	4	-.133-	0.063	0.043	**S**
3	**1**	0.000	0.000	-	**NS**
	2	0.000	0.000	-	**NS**
	4	-.133-	0.063	0.043	**S**
4	**1**	0.133	0.063	0.043	**S**
	2	0.133	0.063	0.043	**S**
	3	0.133	0.063	0.043	**S**

****The mean difference is significant at the 0.05 level based on estimated marginal means. NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01). (J) time = Measurements that compare to the main measurement.***

The pairwise comparisons table shows that there was no a P-value of ecchymosis size readings between first measurement and second measurement and between first measurement and third measurement because they had the same of mean. And show that there was a significant difference in ecchymosis size readings between the first measurement and fourth measurement at a P-value of 0.043, that represent the appear of ecchymosis after 48 hours.

Table (4-8): Pairwise comparisons of the pain readings under the effect of the application of ice bag with direct pressure between the four measurements periods among the study group:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value	Sig.
1	**2**	0.267	0.082	0.003	**HS**
	3	0.400	0.132	0.005	**HS**
	4	0.400	0.132	0.005	**HS**
2	**1**	-.267-	0.082	0.003	**HS**
	3	0.133	0.063	0.043	**S**
	4	0.133	0.063	0.043	**S**
3	**1**	-.400-	0.132	0.005	**HS**
	2	-.133-	0.063	0.043	**S**
	4	0.000	0.000	-	**NS**
4	**1**	-.400-	0.132	0.005	**HS**
	2	-.133-	0.063	0.043	**S**
	3	0.000	0.000	-	**NS**

The mean difference is significant at the 0.05 level based on estimated marginal means. NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01). (J) time = Measurements that compare to the main measurement.

The pairwise comparisons table shows a highly significant difference in pain level readings between the first and second measurement at a P-value 0.003 that represents the pain reduce after two hours. And there was a highly significant difference in pain level readings between the first and third measurement at a P-value 0.005 that represents the pain disappear after four hours. Finally there was a highly significant difference in pain level readings between the first and forth measurement at a P-value 0.005 that represents the pain disappear after 48 hours.

Table (4-9): Association between the effect of the application of ice bag with direct pressure in the prevention of early complications after femoral sheath removal of cardiac catheterization with their socio-demographic characteristics:

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**
Pain	0.333	**NS**	0.493	**NS**	0.159	**NS**	0.503	**NS**

NS: Non-Significant (P-value >0.05); S: Significant (P-value ≤0.05- >0.01) ; HS : Highly Significant (P-value = ≤0.01).

This table exposed that there was a statistically significant association between the improvement in the bleeding with age group, smoking, and BMI condition. In addition, the ecchymosis size had a statistically significant association with the age group and smoking conditions.

Table (4-10): association between the effect of the application of ice bag with direct pressure in the prevention of early complications after femoral sheath removal of cardiac catheterization with their clinical data:

Variables	Bleeding		Hematoma		Ecchymosis		Pain	
	P. Value	Sig.	P. Value	Sig.	P. Value	Sig.	P. Value	Sig.
Chronic Diseases	0.048	**S**	0.011	**S**	0.032	**S**	0.640	**NS**
Antiplatelet Medication	0.372	**NS**	0.232	**NS**	0.160	**NS**	0.285	**NS**
Heparin Dose	0.019	**S**	0.012	**S**	0.002	**HS**	0.065	**NS**
Type of Catheterization	0.263	**NS**	0.165	**NS**	0.102	**NS**	0.089	**NS**
Size of Sheath	0.273	**NS**	0.543	**NS**	0.107	**NS**	0.192	**NS**
SBP (mm hg)	0.005	**HS**	0.050	**S**	0.048	**S**	0.551	**NS**
DBP (mm hg)	0.305	**NS**	0.494	**NS**	0.636	**NS**	0.557	**NS**
Pulse Rate	0.047	**S**	0.454	**NS**	0.375	**NS**	0.455	**NS**
PCV %	0.013	**S**	0.010	**HS**	0.002	**HS**	0.108	**NS**
Platelet Count	0.049	**S**	0.003	**HS**	0.015	**S**	0.156	**NS**

This table (4-10) exposed that a highly statistically significant association between the improvement in the bleeding with SBP and statistically significant association with chronic diseases, heparin dose, pulse rate, PCV, and platelet count. In addition, the improvement of hematoma had highly statistically significant association with PCV and platelet and statistically significant association with chronic diseases, heparin dose, SBP. finally, the improvement in the ecchymosis had a highly statistically significant association with heparin dose and PCV and statistically significant association with chronic diseases, SBP, and platelet.

Chapter Five

Discussion

Chapter Five

Discussion

It is possible to prevent or relieve some early complications that occur after femoral sheath removal post-cardiac catheterization to reduce the hospitalization period, cost, and mortality rate. A 60 male and female patients that enrolled in this study who had a cardiac catheterization to determine the effect of the application of an ice bag with direct pressure in the prevention of early complications after femoral sheath removal of cardiac catheterization.

5.1. Discussion of socio-demographical characteristics of patients:

Regarding the social-demographic characteristics of the patients participating in this study the result in table (4-1) showed that most participants were 60-69 years old, representing 40% of the study group and 36.7% in control group. Moeinian et al. (2020) conducted a study was in Iran to prevent complications after cardiac catheterization and reported that 66.4% of patients were 50-69 years old. The researcher believes that older patients are the most susceptible group to cardiovascular disease because many older people suffer from chronic diseases such as diabetes and hypertension, lack of daily activities, increased accumulation of triglycerides and cholesterol in the blood vessels, and low elasticity of the arterial wall. These are consistent with Yeh et al. (2019), who found that most patients in the middle age and elderly population have triglyceridemia and cholesterolemia.

As for gender, the results 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% wear women. The finding this study agree with a study done by Wicaksono & Djamil (2020), which stated that the prevalence of cardiovascular disease had a higher incidence rate in males than in females, accounting for 93.3%.

Colafella et al. (2018), found that males are more likely than women to have cardiovascular disorders.

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. Kudhair et al. (2020) reported that 85% of males were smokers.

As for 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 a study conducted by Zaki et al. (2020) showing a high BMI of 40% healthy weight. The researcher believes that because one-third of the participants were older adults who had loss appetite, started a stage of catabolism, and a quarter of participants were diabetic patients. Nguyen et al. (2019) conducted a study on elderly diabetic patients, which exposed that 84.9% of males and 79.3% of females were of normal weight.

5.2. Discussion of clinical data of Patients:

According to the study results shown in table (4-2), it was found that patients in the two groups suffered from chronic diseases (hypertension and diabetes mellitus), 43.4% of the experimental group and 33.3% of the control group. The result of 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 CAD. These findings come in conjunction with the study conducted by Strain et al. (2018) reported that complications of diabetes mellitus are a major cause of cardiovascular disease. While disagree with the results of a study done by Ahmed and Ayasra (2020) showed that 16% of chronic diseases. My point of view the incidence of chronic diseases among the participants in the study is due to the

number of elderly participants, and this age group is more susceptible to chronic diseases. A study conducted by Wang et al. (2020) agrees about the relationship between age and chronic diseases for patients with cardiovascular diseases. The results showed that the proportion of participants in the study > 65 years old was suffering from chronic diseases.

As for the medication used to treat CVD, it is clear that most patients use antiplatelet drugs in the both groups, 70% in the experimental and 56.7% control groups. Also, antiplatelet were used aspirin for 63.6% and Plavix for 39.7% of patients suffering from CVD who had CC in a study conducted in Greek centers by Hahalis et al. (2018). The researcher believes that the percentage of patients who use antiplatelet is one of the essential procedures in treating heart disease as it also prevents blood clotting, which leads to constriction or blockage of the coronary arteries. Support the results of the study done by Mangieri et al. (2020) on the use of antiplatelet in the CVD, and the study emphasized the use of anticoagulants for the treatment of heart disease after a cardiac catheterization stand coronary and acute vascular occlusion to prevent thrombus formation.

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 study group and 63.3% the control group. This finding consistent with the finding of a study conducted 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 IU/kg) and the maximum (100 IU/kg). The researcher believes that using heparin during cardiac catheterization is one of the essential things preventing blood clotting. These results support Aminian et al. (2018) conducted in Japan, where

the heparin use rate was 97.7% during cardiac catheterization to prevent complications during and after cardiac catheterization such as sheath obstruction, coronary stand, and vascular thrombus.

The results revealed that most of the participants in the study underwent more therapeutic catheterization than diagnostic catheterization, with 56.7% for experimental group and 63.3% in control group. This finding 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. Researcher suggested a therapeutic catheterization often due to the increased number of coronary artery diseases, which are critical, and to reduce cardiac complications. These results come in conjunction with the study conducted by Potala et al. (2022), which stated that angioplasty is the optimal treatment for coronary artery stenosis or occlusion and reduces critical complications.

This study showed that 80% of the study group and 73.3% in the control group used the size of the femoral sheath of 6 Fr. This result consistent with the a study results 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. my point of view that the frequent use of the femoral sheath size of 6 Fr, is to reduce the complications that may occur after removing the sheath. This result is consistent with a study conducted by Chung et al. (2018) in Singapore on 320 patients comparing the femoral sheath sizes 4-Fr 52.5% while 6-Fr 47.5%. The study's results proved that there is no statistical significance between the two sizes in terms of the incidence of vascular complications.

Regarding vital signs, the study's finding shows that the rate of hypertension stage 2 among the study participants was 43.4% in experimental group and 46.7% in 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. my point of view that the high percentage of participants is older adults with chronic diseases, one of which is hypertension, one of the causes of coronary heart problems. Wang et al. (2020) this study, which was conducted in China, proved that the proportion of participants with hypertension is one of the risk factors for cardiovascular disease.

Regarding heart rate, the study's results showed that 50% in experimental group, and 60% in control group, were within the upper limit of the normal range. A study was conducted on the factors associated with bleeding with cardiac intervention. An elevated heart rate increases blood flow in the arteries, making it more difficult for platelets to aggregate to close the artery puncture my point of view. The study's results showed a statistical significance between heart rate and bleeding done by (Pereira et al., 2019).

As for laboratory tests regarding the packed cell volume PCV 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. The researcher believes that the rate of packed cell volume PCV was within the normal upper limit due to the reason being that the majority of patients are elderly and smokers. A study by Qadir (2018) showed that older people are more likely to have an increase in the proportion of PCV. According to a study by Eisenga et al. (2018), smokers are more likely to increase PCV.

As for the platelet count, the results were within the normal range. 80% in the study group and 70% in control group. The study results done by Iliescu et al. (2021) showed that 98 patients underwent cardiac catheterization, and the proportion of participants was within the normal platelet range of 43%. The researcher thought the platelets

that were within the normal or more helped to prevent the occurrence of vascular complications. The normal rate and above of platelets count help prevent bleeding, while the opposite the decrease of the platelets count, the more at risk of bleeding supported by (Vinholt, 2019).

5.3. Discussion of bleeding, hematoma, ecchymosis, and pain levels among the experimental and control groups:

As shown in table (4-3), the result in the four measurements indicates the difference in the levels of bleeding, hematoma, ecchymosis, and pain 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. These findings are consistent with those of a study conducted by Çürük et al. (2018), in Turkey at the Heart Hospital of the Health Application and Research Center of Erciyes University to measure the effect of ice bag application on vascular complications in 104 patients, reported that 11.7 % bleeding rate after implementation.

The researcher mention states that using the ice bag with direct pressure to prevent bleeding after removing the femoral sheath leads to vasoconstriction, and a decreased blood flow, which leads to reduced bleeding. 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). Moinian et al. (2020), in Iran, Kermanshah, with 238 patients, used MC on the femoral artery to achieve hemostasis after removal of the femoral sheath in patients who underwent cardiac catheterization. The study's

results showed that MC effectively prevents bleeding after the removal of the femoral sheath.

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 conducted by Valikhani et al. (2020), in Mashhad, Iran, on 30 patients who underwent cardiac catheterization. After removing the femoral sheath, an ice bag was used for 15 minutes to reduce the hematoma. 6.7% in the experimental group and 20% in the control group had a hematoma. A study by Wei et al. (2020), to study achieving hemostasis in patients who underwent cardiac catheterization by accessing the brachial artery using a manual pressure (MC) or EXOSEAL vascular closure device (EVCD), the study showed a hematoma (8%) in the MC group and (3.7%) in the EVCD the group.

Direct pressure puts pressure on the wall of the punctured artery, resulting in less diffusion and accumulation of blood under the skin (the researcher). Hemostasis is the process of stopping blood flow immediately by vasoconstriction, platelet aggregation, and blood clotting make up the three essential parts of the hemostatic process (Zheng et al., 2020). Ice application reduces blood flow velocity while enhancing viscosity and coagulation. Through arterial vasoconstriction, elevated blood clotting, low capillary permeability, and reduced metabolic needs, it helps manage the bleeding and prevent ecchymosis and hematoma development (Kurt & Kaşıkçı, 2019).

Regarding ecchymosis, the study showed that in the fourth measurement after applying the protocol in the control group, 93.3% and in the experimental group was 13.3%, suffered from ecchymosis. A comparative study was conducted in Turkey on 298 patients by Çürük et al. (2017), to determine the effect of the Sandbag group's ice bag

group. In the compression dressing group, a patient underwent cardiac catheterization to reduce vascular complications after femoral sheath removal. The study's results showed that the ecchymosis was (ice bag group 19.2%, the Sandbag group 29.0%, and compression dressing group 47.9%).

The researcher believes that applying ice to the femoral sheath area helps reduce ecchymosis by narrowing blood vessels. Cold intervention decreases ecchymosis by promoting clotting by slowing blood circulation, increasing viscosity, decreasing capillary permeability, and producing vasoconstriction in the arterioles (Zaki et al. 2020). Cold therapy can reduce blood flow to the tissue and limit peripheral blood circulation, which helps prevent ecchymosis (Wang et al. 2020). The study finding of a that was conducted to assess the effect of cold application after subcutaneous injection of heparin. The results showed that using cold applications effectively reduces ecchymosis (Rupam et al., 2018).

Finally, this study showed that in the first measurement after applying the protocol, the pain intensity was 26.7% in the experimental group while 100% in the control group. An experimental study was conducted in Turkey on 200 patients (100 patients for the control group and 100 for the experimental group) to evaluate the effect of cold on pain intensity after removing the femoral sheath after performing a cardiac catheterization. Study results showed less catheter insertion pain and discomfort compared to14% in the experimental group and 34% in the control group done by (Kurt & Kaşıkçı 2019). The results of the study done by Isnaini et al. (2018), in Turkey on the effect of cold and deep breathing on pain relief in Arteriovenous Fistula Insertion The intervention group and control group differed significantly from one another. The results of the study by Mazloum et al., (2018), in Mashhad, Iran, on 51 patients who underwent open-heart surgery at the

Mashhad Heart Center. Applying ice bag 20 minutes after the chest drain removal relieves pain. The results of the study showed that the use of ice during Chest drain removal is effective in relieving pain.

The researcher believes that one of the non-pharmaceutical intervention methods for pain relief, the use of cold therapy, helps relieve pain and affects the transmission of nerve impulses. Non-pharmacological intervention pain relief is provided through the cold application. The pain sensitivity is increased, and the speed at which nerve fibers transfer pain sensations from the periphery to the central nervous system is slowed down by this method of therapy, which is the oldest and simplest Ibrahim & Deif (2021). An effective method to reduce pain is by applying cold. Pain and nerve conduction is less immediately produced by this technique (Mohammadi et al., 2021).

5.4. Discussion of the comparison significant between the mean of the readings of early complication, urinary retention, and back pain:

The use of an ice bag with direct compression for the participants in this study, as shown in tables (4-4), showed that it was very advantageous to use the application of the ice bag with direct pressure to prevent early complications that occur after removal of the femoral sheath. The result showed a significant difference between the means of the bleeding severity, hematoma size, ecchymosis size, pain intensity, urinary retention, and back pain in the control group.

There are no statistically significant differences in the experimental group's means of bleeding severity, hematoma size, urinary retention and back pain. These results are similar to those of a study done by Çürük et al., (2017), in Turkey at the Heart Hospital of the Health Application and Research Center of Erciyes University to find out how using an ice bag affected 104 patients with vascular problems such as severe bleeding, hematoma, ecchymosis, and pain.

The study conducted by Fathi et al. (2017), on 60 patients in Iran, reducing the duration of keeping a sandbag over the catheter insertion site from 6 to 3 hours did not affect the incidence of vascular problems such as (hematoma, hemorrhage, thrombosis, and ecchymosis) and decreased the incidence of groin pain, back pain, urinary retention, and increased patient comfort. The results of a study done by Rai et al., (2019) exposed that on 80 patients in India, early ambulation effective on decreases back pain, discomfort and fatigue without increasing vascular problems.

5.5. Discussion of the association between the effect of the application of ice bag with direct pressure in the prevention of early complications with their socio-demographic characteristics:

Table (4-9) 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 increase 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).

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

5.6. Discussion of the association between the effect of the application of ice bag with direct pressure in the prevention of early complications with their clinical data:

The results of this study exposed that there was a statistically significant association between the improvement in the bleeding with chronic diseases, heparin dose, systolic blood pressure, pulse rate, PCV, and platelet. In addition, the hematoma size and ecchymosis had a statistically significant association with chronic diseases, heparin dose, systolic blood pressure, PCV, and platelet conditions.

The result showed there is a relationship between early 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.

Regarding heparin dose, there was a significant relationship with bleeding, hematoma, and ecchymosis attributable to heparin work as it increased coagulation time, which will increase with dosing. This finding was compatible with a study conducted by Besli et al. (2021), that showed 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, and this finding is the same as a study done by Aguiar 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 and platelet count for the participant, both have 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 complications of the patient under cardiac catheterization with thrombocytopenia and low hematocrit.

Chapter Six

Conclusions & Recommendations

Chapter six

Conclusions and Recommendations

6.1. Conclusions:

This study's results conclude that:

1. Simple majority of the patients participating in this study were elderly and most sample were males.
2. Majority of the patients in the experimental group were smokers and one-fifth of them suffered from obesity class I.
3. Simple majority in the experimental group were suffering from hypertension and three-quarters of them used Aspirin and Plavix tablets.
4. Most of the participants in the study used heparin during cardiac catheterization, and therapeutic catheterization was a type of cardiac catheterization for them.
5. Majority of the participating patients had a femoral sheath size (6Fr) used.
6. Simple majority of the patients had increased systolic blood pressure, and Less than half had elevated diastolic blood pressure.
7. The application of an ice bag with direct pressure for 20 minutes had a positive effect on decreasing the level of bleeding severity, hematoma size, ecchymosis size, and pain intensity.
8. The application of an ice bag with direct pressure for 20 minutes has a positive effect on the early ambulation, and this has reduced the urinary retention and back pain.
9. A highly statistically significant association between the improvement in the bleeding with SBP and statistically significant association with chronic diseases, heparin dose, pulse rate, PCV, and platelet count.

10. The improvement of hematoma had highly statistically significant association with PCV and platelet and had a statistically significant association with chronic diseases, heparin dose, SBP.
11. Finally, the improvement in the ecchymosis had a highly statistically significant association with heparin dose and PCV and statistically significant association with chronic diseases, SBP, and platelet.

6.2. Recommendations:

According to the findings of this study and its' conclusions. This study suggests:

1. Instructed to perform the ice bag with direct pressure after removal of the femoral sheath to decrease the level of bleeding severity, hematoma size, ecchymosis size, pain intensity, urinary retention, and back pain.
2. Another study should be conducted to investigate the benefit of the applying an ice bag with direct pressure on other invasive procedures such as arterial-venous fistula, central venous line, and arterial line.
3. Suggest to implement the ice bag with direct pressure 20 minutes after the removal of the femoral sheath to get early ambulation to decrease the incidence of urinary retention, back pain, and decreased cost.

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Appendices

Appendix AI

Arrangement of University of Karbala \ collage of nursing

Republic of Iraq
Ministry of higher education & scientific research
University of Karbala
College of Nursing
Graduate studies Division

جمهورية العراق
وزارة التعليم العالي والبحث العلمي
جـــامعة كربلاء
كـلية التـمريـض
شعبة الدراسات العليا

العدد: ح ع/ 97
التاريخ: 14/ 11 / 2021

الى / دائرة صحة كربلاء / مركز التدريب و تطوير الملاكات /مركز كربلاء لأمراض و جراحة القلب

م/ تسهيل مهمة

تحية طيبة...

يرجـى التفضـل بالموافقـة علـى تسـهيل مهمـة السـيد (عبـاس بقـال حمـود) لغـرض أنجاز رسالة الماجستير الموسومة (Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after (Femoral Sheath Removal of Cardiac Catheterization (تـأثير تطبيـق كـيس الـثلج مـع الضـغط المباشـر فـي الوقايـة مـن المضـاعفات المبكـرة بعـد إزالـة الغمـد الفخـذي للقسـطرة القلبيـة) وهـو احـد طلبـة الدراسـات العليـا / الماجسـتير فـي كليتنـا / للعـام الدراسـي (2021-2020) و مستمر في الدوام في الوقت الحاضر.

... مع التقدير ...

أ.م.د. سلمان حسين فارس الكريطي
معاون العميد للشؤون العلمية و الدراسات العليا
2021 / 11 / 14

نسخة منه الى :-
- مكتب السيد المعاون العلمي المحترم.
- شعبة الدراسات العليا.

العنوان : العراق - محافظة كربلاء المقدسة - حي الموظفين - جامعة كربلاء
Mail: nursing@uokerbala.edu.iq website: nursing.uokerbala.edu.iq

Appendix AII

Arrangement of Ministry of Health / Karbala Health Department / Karbala center for cardiac & surgery

Karbala Health Directorate

Karbala Center for Cardiac Diseases & Surgery

محافظة كربلاء المقدسة

دائرة صحة كربلاء

مركز كربلاء لأمراض وجراحة القلب

الصادر

العدد: ١٧٦٤

التاريخ: ٢١/١٢/٢٠٢١

الى / قسم التدريب والتنمية البشرية /شعبة إدارة المعرفة/وحدة إدارة البحوث

م/ إجابة

السلام عليكم .....

إشارة الى كتابكم المرقم ٣٨٤٣ في ٢٠٢١/١١/٢٢

نود اعلامكم بأن لا مانع لدينا من تسهيل مهمة طالب الدراسات العليا (عباس بقال حمود) لإنجاز بحثه في مركزنا ويكون د. احمد حسين الميالي مشرف عملي على البحث .

للتفضل بالاطلاع .....مع الاحترام

الدكتور

احمد قاسم الحيدري

الطبيب الاختصاص

احمد قاسم الحيدري

مدير مركز كربلاء لأمراض القلب

٢٠٢١/١١/

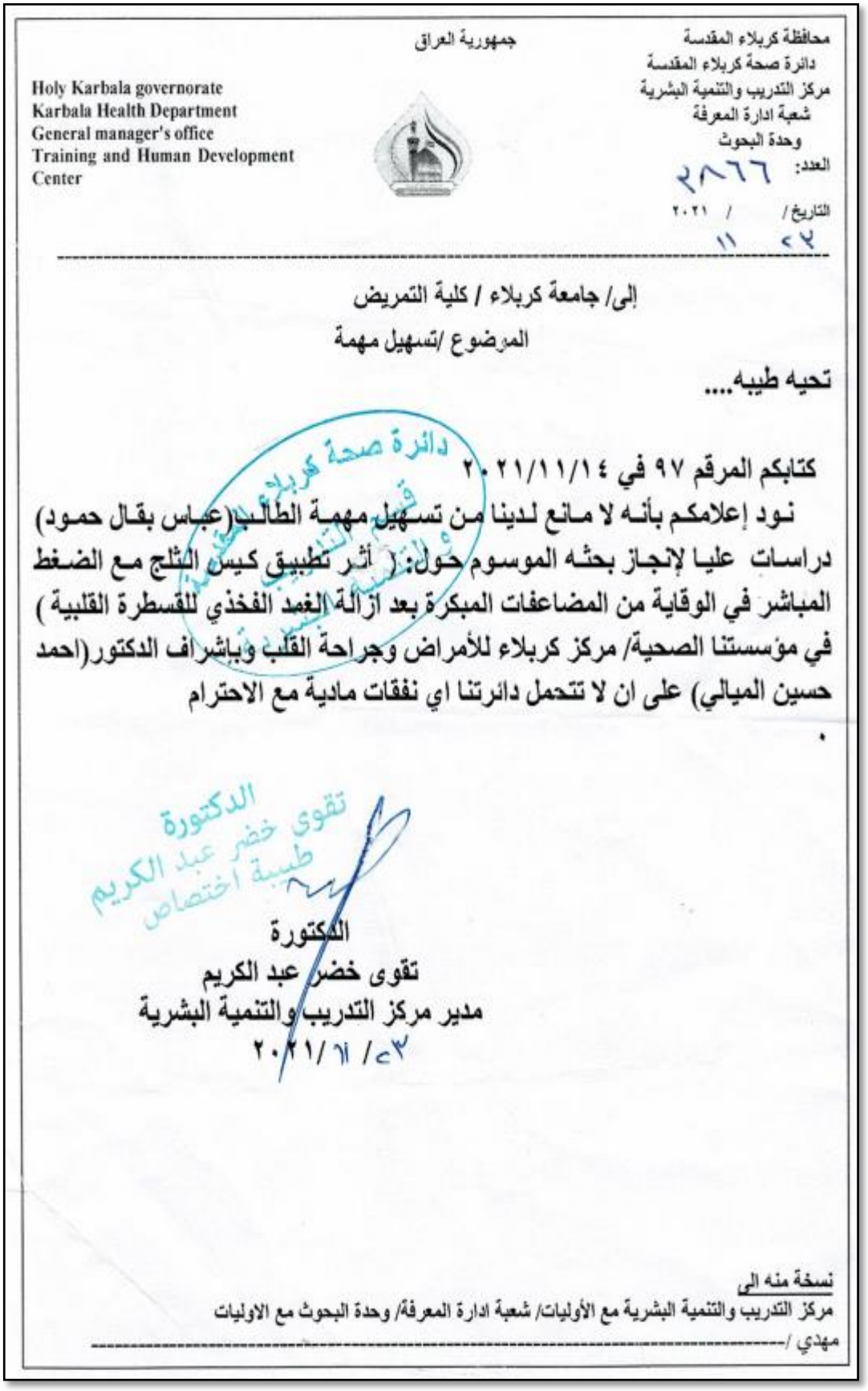
نسخه منه الى :

وحدة ادارة الموارد البشرية

٢١/١١/٢٢

Appendix AIII

Arrangement of Ministry of Health / Karbala Health Department / Training and Human Development Center



جمهورية العراق

محافظة كربلاء المقدسة
دائرة صحة كربلاء المقدسة
مركز التدريب والتنمية البشرية
شعبة ادارة المعرفة
وحدة البحوث
العدد: ٢٨٦٦
التاريخ / ١١ / ٢٠٢١

Holy Karbala governorate
Karbala Health Department
General manager's office
Training and Human Development Center

إلى/ جامعة كربلاء / كلية التمريض

المرضوع /تسهيل مهمة

تحيه طيبه....

كتابكم المرقم ٩٧ في ٢٠٢١/١١/١٤

نود إعلامكم بأنه لا مانع لدينا من تسهيل مهمة الطالب(عباس بقال حمود) دراسات عليا لإنجاز بحثه الموسوم حول: (أثر تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد ازالة الغمد الفخذي للقسطرة القلبية) في مؤسستنا الصحية/ مركز كربلاء للأمراض وجراحة القلب وباشراف الدكتور(احمد حسين الميالي) على ان لا تتحمل دائرتنا اي نفقات مادية مع الاحترام

دائرة صحة كربلاء المقدسة
قسم التدريب والتنمية البشرية

الدكتورة
تقوى خضر عبد الكريم
طبيبة اختصاص

الدكتورة
تقوى خضر عبد الكريم
مدير مركز التدريب والتنمية البشرية
٢٠٢١/١١/٢٣

نسخة منه الى
مركز التدريب والتنمية البشرية مع الأوليات/ شعبة ادارة المعرفة/ وحدة البحوث مع الاوليات
مهدي /

Appendix BI

Ethical consideration

Ministry of Higher Education and Scientific Research
University of Karbala / College of Nursing
Scientific Research Ethics Committee

وزارة التعليم العالي والبحث العلمي
جامعة كربلاء / كلية التمريض
لجنة اخلاقيات البحث العلمي

استمارة اخلاقيات البحث العلمي

عنوان مشروع البحث	
English	باللغة العربية
Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after Femoral Sheath Removal of Cardiac Catheterization.	تأثير تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد إزالة الغمد الفخذي للقسطرة القلبية.

بيانات عن الباحث الرئيسي			
الاسم الثلاثي	اللقب العلمي او العنوان الوظيفي	رقم الهاتف/ الموبايل	الايميل
عباس بقال حمود	طالب دراسات عليا \ ماجستير	07808434479	abbas.b@s.uokerbala.edu.iq

بيانات الباحث او الباحثين المشتركين			
الاسم الثلاثي	اللقب العلمي او العنوان الوظيفي	رقم الهاتف/ الموبايل	الايميل
فاطمة مكي محمود	ا.م.د.	07702934031	fatima.makki@uokerbala.edu.iq

(Importance of the research and its objectives) اهمية موضوع البحث واهدافه

Vascular access complications are the most common complications of diagnostic and interventional catheterization procedures performed via trans femoral approach. Vascular access complications increase morbidity and mortality. **This study aimed** to determine the Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after Femoral Sheath Removal of Cardiac Catheterization. And to Find out the relationship between the effects the application of ice bag with direct pressure in the prevention of early complications with patients' socio-demographic and medical information.

Time and Setting of the Research_ وقت ومكان اجراء البحث (الاماكن المقترحة لأجراء البحث فيها)

The study will be conducted in Karbala Center for Cardiac Diseases and Surgery from November 2021 to may 2022

(Methodology) منهجية البحث

Experimental research using of the application of ice bag with direct pressure for 20 minutes in the prevention of early complications (bleeding, hematoma, ecchymosis, and pain) after removal of the femoral sheath of cardiac catheterization. and then measuring the incidence and severity of early complications

Sample of the study عينة الدراسة

A random sample of 50 patients will be chosen using the (Systematic random sampling) approach.

(Ethical consideration during research) الاعتبارات الاخلاقية خلال اجراء البحث

التعهد

- انا الموقع ادناه (عباس بقال حمود) اتعهد بان اقوم بأجراء البحث وفقا لما ذكر في البروتوكول اعلاه وان التزم باتباع القوانين والتعليمات فيما يخص اجراء البحوث والالتزام بأخلاقياتها ، كما واتعهد بأخذ الموافقة من افراد العينة للمشاركة في الدراسة واخذ موافقة من ولي أمر المشارك الشرعي في حال كون عمر الشخص المشارك اقل من 18 سنة، او كونه غير قادر على الفهم ، وان اقدم الإيضاحات و المعلومات الخاصة بالدراسة لأفراد العينة للمشاركين في حال طلبها. وان اتعامل بسرية تامة مع بيانات افراد العينة.

اسم وتوقيع الباحث
عباس بقال حمود

توصية لجنة اخلاقيات البحوث في الكلية

نحن اعضاء اللجنة الاخلاقية نوصي بان موضوع الباحث : ذو قيمة علمية ومهم للمجتمع والمريض

رئيس اللجنة عضو عضو عضو عضو

Appendix BII

Consent form

موافقة خطية للمشاركة بالبحث

اني الموقع ادناه اوافق على ان اكون مشاركا كجزء من عينة البحث الموسوم (**اثـر تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد إزالة الغمد الفخذي للقسطرة القلبي**) بعد ان اطلعت من قبل الباحث (**عباس بقال حمود**) على فائدة البحث العلمية. وان مشاركتي طوعية ولي الحق برفض المشاركة او رفض الاجابة عن سؤال معين او الانسحاب من المشاركة باي وقت . كما تعهد الباحث بان تكون جميع المعلومات التي سوف ادلي بها سرية ولا يطلع عليها احد غيره وان هذه المعلومات سوف تستخدم للاغراض العلمية فقط .

ولأجل هذا وقعت على مشاركتي في هذا البحث

توقيع المشارك : ..... التاريخ ١٩ \ 1 \ 2022

توقيع الباحث : ..... التاريخ ١٩ \ 1 \ 2022

Appendix CI

Application of the interventional protocol

Appendix CII

Appendix CIII

After implementing protocol.

Appendix CIV

Dressing.

Appendix DI

The study instrument

Socio-demographic characteristics & medical information:

Age:

Gender: Male Female

Smoking: Yes No

Weight:

Height: BMI

Pre-existing conditions chronic diseases:

Antiplatelet medication:

Heparin dose:

Type of catheterization: diagnostic Therapeutic

Sheath size

4	5	6	7	8

Systolic blood pressure: hg mm

Diastolic blood pressure: hg mm

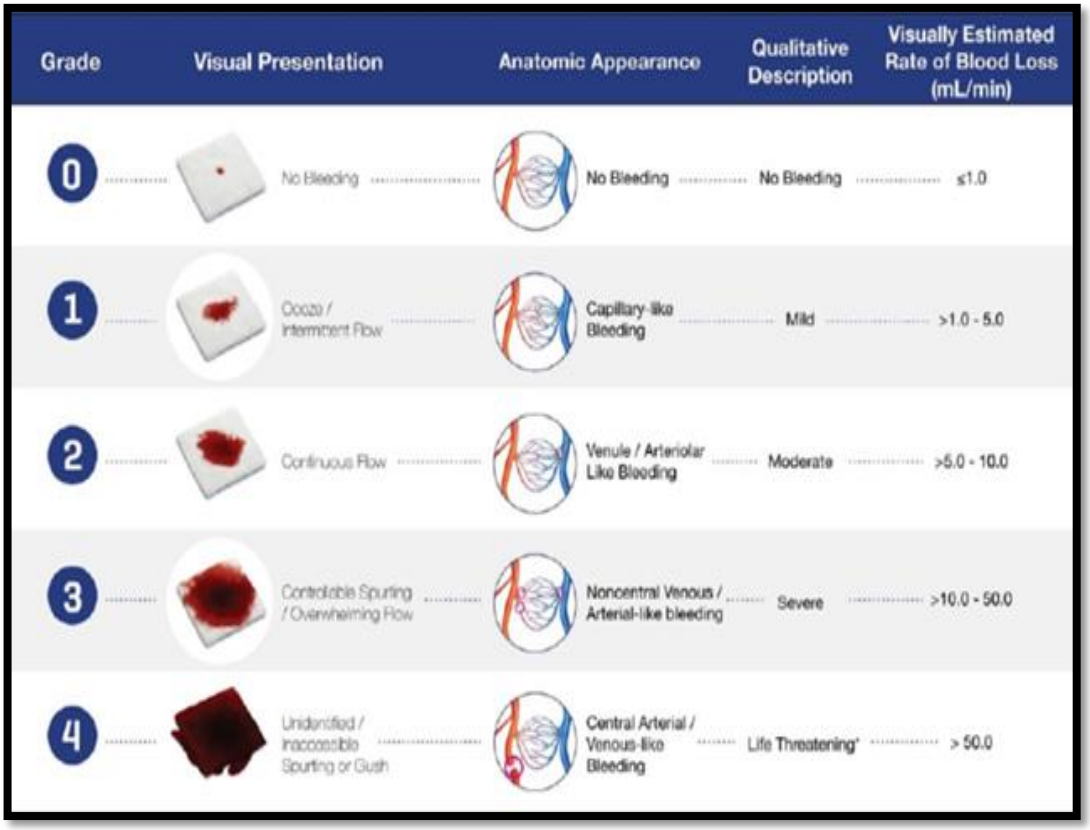
Heart rate : bpm

Laboratory finding :

- PCV :
- Platelet :

Appendix DII

Validated Interpretative Bleeding scale (VIBe SCALE)



Appendix DIII

Hematoma Scale

Hematoma	None < 2 cm	Small 2 - < 5 cm	Medium 5 - <10 cm	Large ≥ 10 cm
Grade	**0**	**1**	**2**	**3**

Appendix DIV

Ecchymosis scale

Ecchymosis	None < 2 cm	Small 2 - < 5 cm	Medium 5 - <10 cm	Large ≥ 10 cm
Grade	**0**	**1**	**2**	**3**

Appendix DV

Pain Observation Tool (POT)

Item	Description	Score
Facial Expression	Relaxed, neutral	**0**
	Tense	**1**
	Grimacing	**2**
Body Movements	No movement Absence of movements or normal position	**0**
	Protection	**1**
	Restlessness/Agitation	**2**
Vocalization	Talking in normal tone or no sound	**0**
	Sighing, moaning	**1**
	Crying out, sobbing	**2**
Muscle Tension	Relaxed	**0**
	Tense, rigid	**1**
	Very tense or rigid	**2**
TOTAL	**___ / 8**	

Appendix DVI

Urinary retention		After 1	After 2	After 3	After 4
	Yes				
Back pain	No				

Appendix EI

Permission

VIBe SCALE

(رسالتان) ٢

Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq> السبت، ٢٠ نوفمبر ٢٠٢١ في ١٠:١٣ م

إلى: kevinlewisdvm@gmail.com

My dear colleague

Good greeting...

I am the academic nurse Abbas Baqal Hammood, currently a master's student at the University of Karbala / College of Nursing in the city of Karbala - Iraq. One of the requirements for a master's study is a master's thesis. I have chosen to direct my research towards (reducing complications after removal of the femoral sheath after PCI). I read your research entitled (Development and validation of an intraoperative bleeding severity scale for use in clinical studies of
hemostatic agents) which includes Validated Interoperative Bleeding Scale (VIBe SCALE) Because I need this scale to conduct the research, and because of the ethical standards of scientific research, I ask for your consent to use this scale in collecting samples and conducting my research.

I wish you success in serving humanity

Kevin Lewis <kevinlewisdvm@gmail.com> الأحد، ٢٨ نوفمبر ٢٠٢١ في ١٠:٠٢ م

إلى: Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq>

Greetings,

Yes. You can use the scale. The scale is published in the public domain, so it is free to use. I am glad it will be a benefit to you.

If you have questions, you can email me. I wish you luck on your research project.

Kevin M. Lewis, DVM

Appendix EII

Permission

hematoma scale

Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq> الأحد، ٧ نوفمبر ٢٠٢١ في ١٠:٣٠ م

إلى: ahmedalsadia823@gmail.com

I am the academic nurse Abbas Baqal Hammond, currently a master's student at the university of Karbala / college of nursing in the city of Karbala - Iraq. One of the requirements for master's study is a master's thesis. I have chosen to direct my research towards (reducing complications after removal of the femoral sheath after percutaneous coronary intervention (PCI). I have carefully read the hematoma scale.

Because I need this scale to conduct the research, and because of the ethical standards of scientific research, I ask for my consent to use it in collecting samples and conducting my research

I wish you success in serving humanity

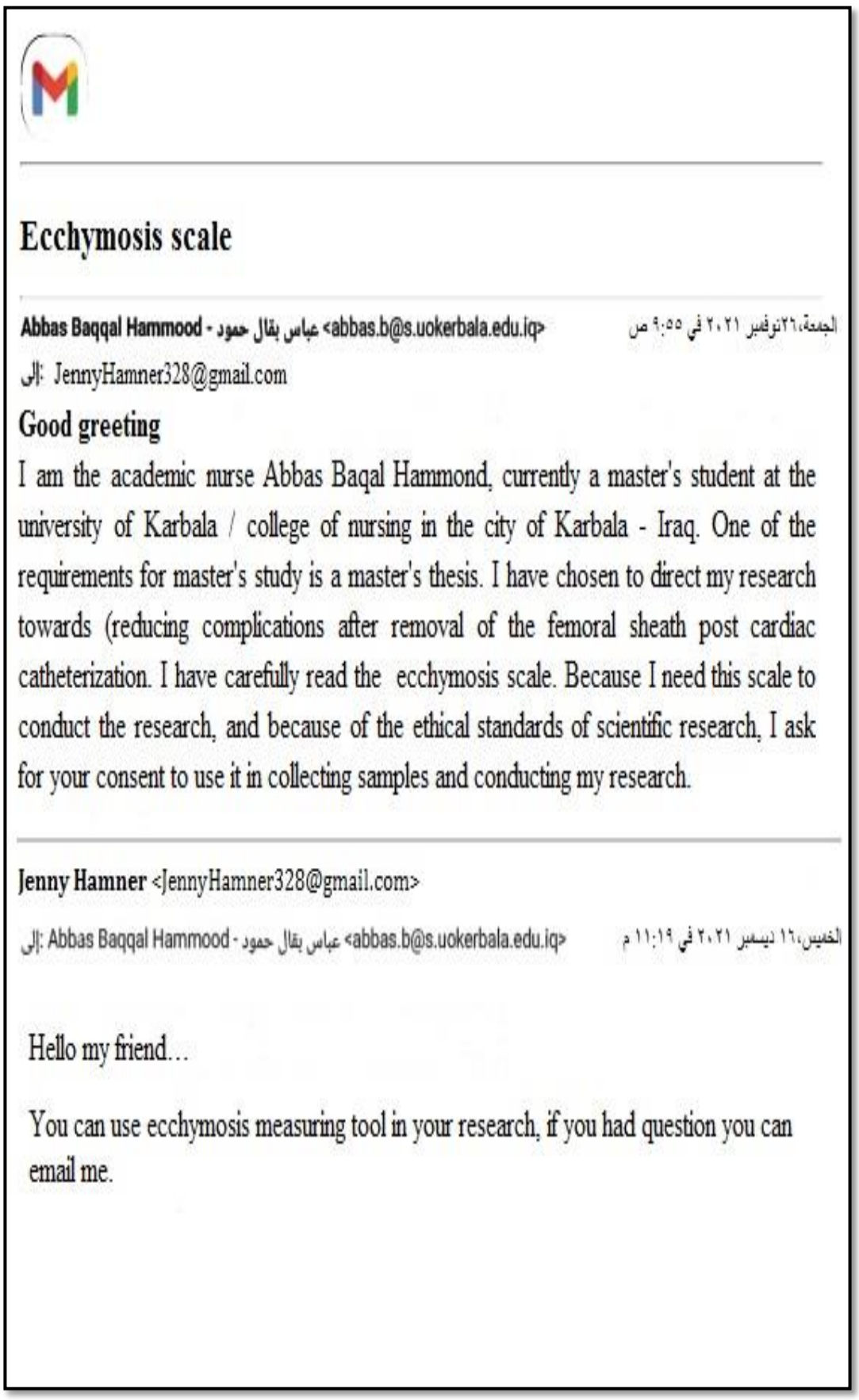
ahmedalsadia823@gmail.com الثلاثاء، ٩ نوفمبر ٢٠٢١ في ٨:٢١ م

إلى: Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq>

You can use the hematoma scale good luck my friend

Appendix EIII

Permission



Ecchymosis scale

Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq> الجمعة،٢٦نوفمبر ٢٠٢١ في ٩:٥٥ ص

إلى: JennyHamner328@gmail.com

Good greeting

I am the academic nurse Abbas Baqal Hammond, currently a master's student at the university of Karbala / college of nursing in the city of Karbala - Iraq. One of the requirements for master's study is a master's thesis. I have chosen to direct my research towards (reducing complications after removal of the femoral sheath post cardiac catheterization. I have carefully read the ecchymosis scale. Because I need this scale to conduct the research, and because of the ethical standards of scientific research, I ask for your consent to use it in collecting samples and conducting my research.

Jenny Hamner <JennyHamner328@gmail.com>

إلى: Abbas Baqqal Hammood - عباس بقال حمود <abbas.b@s.uokerbala.edu.iq> الخميس،١٦ ديسمبر ٢٠٢١ في ١١:١٩ م

Hello my friend…

You can use ecchymosis measuring tool in your research, if you had question you can email me.

Appendix EIV

Permission

CPOT Scale

Abbas Baqqal Hammood -عباس بقال حمود <abbas.b@s.uokerbala.edu.iq> الاربعاء، ١٠ نوفمبر ٢٠٢١ في ٦:٣٤ م

الى: Celine.gelinas@gmail.com

Good greeting...

I am the academic nurse Abbas Baqal Hammood, currently a master's student at the University of Karbala / College of Nursing in the city of Karbala - Iraq. One of the requirements for a master's study is a master's thesis. I have chosen to direct my research towards (reducing complications after removal of the femoral sheath after PCI). I read your scale entitled (The Critical-Care Pain Observation Tool (CPOT) . Because I need this scale to conduct the research, and because of the ethical standards of scientific research, I ask for your consent to use this scale in collecting samples and conducting my research.

I wish you success in serving humanity

Céline Gélinas < Celine.gelinas@gmail.com > الثلاثاء، ٣٠ نوفمبر ٢٠٢١ في ٢٢ : ٣ م

الى: Abbas Baqqal Hammood -عباس بقال حمود <abbas.b@s.uokerbala.edu.iq>

You have my consent. I wish you the best luck

Appendix F

Experts name

ت	اسم الخبير	اللقب العلمي	التخصص	سنوات الخبرة	مكان العمل	الغرض
1.	د. هدى باقر حسن	استاذ	تمريض صحة البالغين	34 سنة	كلية التمريض / جامعة بغداد	Content validity
2.	د. صباح عباس احمد	استاذ	تمريض صحة البالغين	34 سنة	كلية التمريض / جامعة بغداد	
3.	د. رجاء ابراهيم عبد	استاذ مساعد	تمريض صحة البالغين	25 سنة	كلية التمريض / جامعة بغداد	
4.	د. شذى سعدي محمد	استاذ مساعد	تمريض صحة البالغين	23 سنة	كلية التمريض / جامعة بابل	
5.	د. تحسين رجب محمد	استاذ مساعد	تمريض صحة البالغين	22 سنة	كلية التمريض / جامعة بغداد	
6.	د. حسن عبد الله عذبي	استاذ مساعد	تمريض صحة البالغين	19 سنة	كلية التمريض جامعة كربلاء	
7.	د. ضياء كريم عبد علي	استاذ مساعد	تمريض صحة البالغين	15 سنة	كلية التمريض جامعة العميد	
8.	د. صادق عبدالحسين حسن	استاذ مساعد	تمريض صحة البالغين	12 سنة	كلية التمريض / جامعة بغداد	
9.	د. حكيمة شاكر حسن	استاذ	تمريض صحة البالغين	33 سنة	كلية التمريض / جامعة بغداد	Face validity (response process validity)
10.	د. علي كريم خضير	استاذ	تمريض صحة نفسية وعقلية	30 سنة	كلية التمريض /جامعة كربلاء	
11.	د. حسين هادي خضير	استاذ	تمريض صحة البالغين	28 سنة	كلية التمريض / جامعة بغداد	
12.	د. خالدة محمد خضر	استاذ	تمريض صحة البالغين	20 سنة	كلية التمريض / جامعة بغداد	
13.	د. سعاد جاسم محمد	استاذ مساعد	تمريض صحة البالغين	42 سنة	كلية التمريض / جامعة بغداد	
14.	د. عبد صالح كميت	استاذ مساعد	تمريض صحة البالغين	14 سنة	كلية التمريض جامعة كركوك	
15.	د. نسيم سمير علي	استاذ مساعد	تمريض صحة البالغين	13 سنة	كلية التمريض / جامعة وارث الانبياء	
16.	د. جهاد جواد كاظم	استاذ مساعد	تمريض صحة البالغين	13 سنة	كلية التمريض / جامعة الكوفة	
17.	د. اياد ماجد موسى	مدرس	تمريض صحة البالغين	11 سنة	كلية التمريض / جامعة بغداد	
18.	د. علي حسين علك	مدرس مساعد	تمريض صحة البالغين	19 سنة	كلية التمريض / جامعة بغداد	
19.	د. احمد حسين الميالي	دكتوراه (بورد)	طبيب اختصاص دقيق قسطرة قلبية	30 سنة	كلية الطب /جامعة كربلاء	

Appendix GI

Content validity of bleeding scale

Expert / Item	1	2	3	4	5	6	7	8	ne	N	I-CVI	UA
Q1	1	1	1	1	1	1	1	1	8	8	1	1
Q 2	1	1	1	1	1	1	1	1	8	8	1	1
Q 3	1	1	1	1	1	1	1	1	8	8	1	1
Q 4	1	1	1	1	1	1	0	1	7	8	0.75	0
Q 5	1	1	1	1	1	1	1	1	8	8	1	1
Proportion relevance	1	1	1	1	1	1	0.8	**1**				
S-CVI/UA												**0.8**
S- CVI/Ave												**0.95**
Average proportion of items judged as relevance across the seven experts												**0.97**

I-CVI = CVR=(ne – N/2) / (N/2), S- CVI/Ave= (∑CVR/ N) , UA = Universal agreement, Content Validity Ratio CVR= I- CVI (item level content validity index), S-CVI\Ave scale-level content validity index, ne= number of experts in agreement , ne = The number = of experts who rated an item as "essential" , N = the total number of experts.

Appendix GII

Content validity of hematoma scale

Expert / Item	1	2	3	4	5	6	7	8	ne	N	I-CVI	UA
Q1	1	1	1	1	1	1	0	1	7	8	0.75	0
Q 2	1	1	1	1	1	1	1	1	8	8	1	1
Q 3	1	1	1	1	1	1	1	1	8	8	1	1
Q 4	1	1	1	1	1	1	1	1	8	8	1	1
Proportion relevance	1	1	1	1	1	1	0.75	1				
S-CVI/UA												**0.75**
S- CVI/Ave												**0.93**
Average proportion of items judged as relevance across the seven experts												**0.96**

I-CVI = CVR=(ne – N/2) / (N/2), S- CVI/Ave= (∑CVR/ N) , UA = Universal agreement, Content Validity Ratio CVR= I- CVI (item level content validity index), S-CVI\Ave scale-level content validity index, ne= number of experts in agreement , ne = The number = of experts who rated an item as "essential" , N = the total number of experts.

Appendix GIII

Content validity of ecchymosis scale

Item \ Expert	1	2	3	4	5	6	7	8	ne	N	I-CVI	UA
Q1	1	1	1	1	1	1	0	1	7	8	0.75	0
Q 2	1	1	1	1	1	1	1	1	8	8	1	1
Q 3	1	1	1	1	1	1	1	1	8	8	1	1
Q 4	1	1	1	1	1	1	1	1	8	8	1	1
Proportion relevance	1	1	1	1	1	1	0.75	1				
S-CVI/UA												0.75
S- CVI/Ave												0.93
Average proportion of items judged as relevance across the seven experts												0.96

I-CVI = CVR=(ne – N/2) / (N/2), S- CVI/Ave= (∑CVR/ N) , UA = Universal agreement, scale-=Content Validity Ratio CVR= I- CVI (item level content validity index), S-CVI\Ave level content validity index, ne= number of experts in agreement , ne = The number of experts who rated an item as "essential" , N = the total number of experts.

Appendix GIV

Content validity of pain scale

Item \ Expert	1	2	3	4	5	6	7	8	ne	N	I-CVI	UA
Q1	1	1	1	1	1	1	1	1	8	8	1	1
Q 2	1	1	1	1	1	1	1	1	8	8	1	1
Q 3	1	1	1	1	1	1	1	1	8	8	1	1
Q 4	1	1	1	1	1	1	0	1	7	8	0.75	0
Proportion relevance	1	1	1	1	1	1	0.75	1				
S-CVI/UA												**0.75**
S- CVI/Ave												**0.93**
Average proportion of items judged as relevance across the seven experts												**0.96**

I-CVI = CVR=(ne – N/2) / (N/2), S- CVI/Ave= (∑CVR/ N) , UA = Universal agreement, scale-=Content Validity Ratio CVR= I- CVI (item level content validity index), S-CVI\Ave level content validity index, ne= number of experts in agreement , ne = The number of experts who rated an item as "essential" , N = the total number of experts.

Appendix HI

Face validity of bleeding scale

Raters / Item	1	2	3	4	5	6	7	8	9	10	11	RA	UA	N	I-FVI
Q1	1	1	0	1	1	1	1	1	1	1	1	10	0	11	0.9
Q 2	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 3	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 4	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 5	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Proportion relevance	1	1	0.8	1	1	1	1	1	1	0.8	1				
S-CVI/UA															**0.8**
S-FVI/Ave															**0.98**
Average proportion of items judged as clarity and comprehension across the twelve experts															**0.96**

I-FVI = (agreed item)/ (number of rater), S-FVI/Ave = (sum of I-FVI scores)/(number of item), S-FVI/UA = (sum of UA scores)/(number of item), UA = Universal agreement = scale face validity.=raters in agreement, I-FVI = item face validity, S-FVI

Appendix HII

Face validity of hematoma scale

Raters / Item	1	2	3	4	5	6	7	8	9	10	11	RA	UA	N	I-FVI
Q1	1	1	0	1	1	1	1	1	1	1	1	10	0	11	0.9
Q 2	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 3	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 4	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Proportion relevance	1	1	0.75	1	1	1	1	1	1	1	1				
S-CVI/UA															**0.75**
S-FVI/Ave															**0.97**
Average proportion of items judged as clarity and comprehension across the twelve experts															**0.97**

I-FVI = (agreed item)/ (number of rater), S-FVI/Ave = (sum of I-FVI scores)/(number of item), S-FVI/UA = (sum of UA scores)/(number of item), UA = Universal agreement = scale face validity.=raters in agreement, I-FVI = item face validity, S-FVI

Appendix HIII

Face validity of ecchymosis scale

Raters / Item	1	2	3	4	5	6	7	8	9	10	11	RA	UA	N	I-FVI
Q1	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 2	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 3	1	1	0	1	1	1	1	1	1	1	1	10	1	11	0.9
Q 4	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Proportion relevance	1	1	0.75	1	1	1	1	1	1	1	1				
S-CVI/UA															**0.75**
S-FVI/Ave															**0.97**
Average proportion of items judged as clarity and comprehension across the twelve experts															**0.97**

I-FVI = (agreed item)/ (number of rater), S-FVI/Ave = (sum of I-FVI scores)/(number of item), S-FVI/UA = (sum of UA scores)/(number of item), UA = Universal agreement scale face validity.== raters in agreement, I-FVI = item face validity, S-FVI

Appendix HIV

Face validity of pain scale

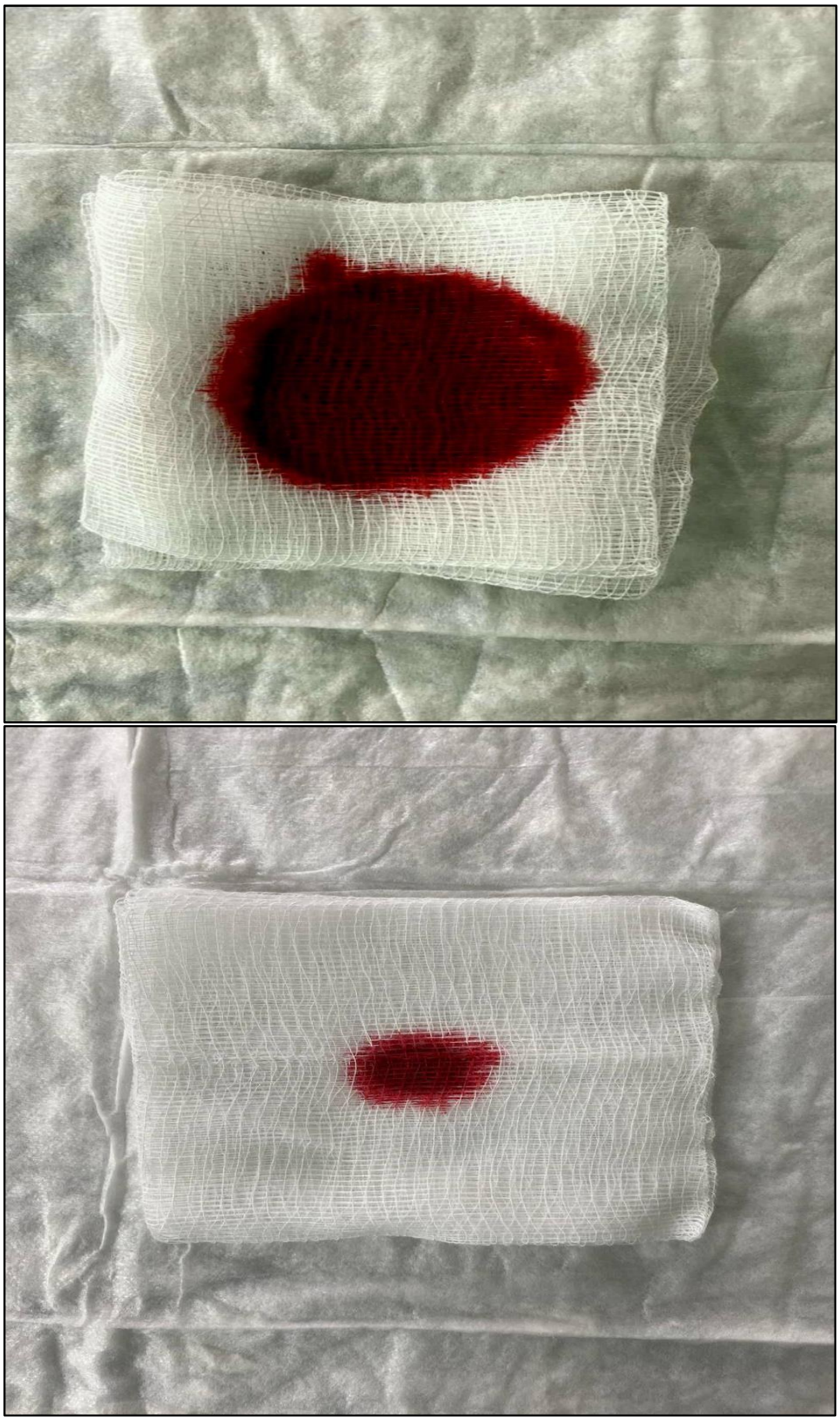
Raters / Item	1	2	3	4	5	6	7	8	9	10	11	RA	UA	N	I-FVI
Q1	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 2	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 3	1	1	1	1	1	1	1	1	1	1	1	11	1	11	1
Q 4	1	1	0	1	1	1	1	1	1	1	1	10	1	11	0.9
Proportion relevance	1	1	0.75	1	1	1	1	1	1	1	1				
S-CVI/UA															**0.75**
S-FVI/Ave															**0.97**
Average proportion of items judged as clarity and comprehension across the twelve experts															**0.97**

I-FVI = (agreed item)/ (number of rater), S-FVI/Ave = (sum of I-FVI scores)/(number of item), S-FVI/UA = (sum of UA scores)/(number of item), UA = Universal agreement scale face validity.== raters in agreement, I-FVI = item face validity, S-FVI

Femoral sheath

Manual pressure for 20 minutes followed by continuous pressure for 4 hours by using a gauze ball.

Ecchymosis in control group



Bleeding severity

Opinion of the statistician

Republic of Iraq
Ministry of higher education & scientific research
University of Kerbala
College of Nursing

جمهورية العراق
وزارة التعليم العالي والبحث العلمي
جامعة كربلاء
كلية التمريض
الدراسات العليا

اقرار الخبير الاحصائي

اشهد بان الرسالة الموسومة :

(اثر تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد إزالة الغمد الفخذي للقسطرة القلبية)

(Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after Femoral Sheath Removal of Cardiac Catheterization)

قد تم الاطلاع على الاسلوب الاحصائي المتبع في تحليل البيانات واظهار النتائج الاحصائية وفق مضمون الدراسة ولأجله وقعت.

توقيع الخبير الاحصائي:
الاسم واللقب العلمي: أ.د.
الاختصاص الدقيق:
مكان العمل: جامعة كربلاء / كلية
التاريخ: ١٤/ ٦ / 2022

Opinion of the Linguist's

Republic of Iraq
Ministry of higher education & scientific research
University of Kerbala
College of Nursing

جمهورية العراق
وزارة التعليم العالي والبحث العلمي
جامعة كربلاء
كلية التمريض
الدراسات العليا

اقرار الخبير اللغوي

اشهد بان الرسالة الموسومة :

(Effect of the Application of Ice Bag with Direct Pressure in the Prevention of Early Complications after Femoral Sheath Removal of Cardiac Catheterization)

(اثر تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد إزالة الغمد الفخذي للقسطرة القلبية).

قد جرى مراجعتها من الناحية اللغوية بحيث اصبحت بأسلوب علمي سليم خال من الاخطاء اللغوية ولأجله وقعت.

توقيع الخبير اللغوي:
الاسم واللقب العلمي:
الاختصاص الدقيق:
مكان العمل: جامعة كربلاء / كلية
التاريخ: 2022/7/15

الخلاصة:

خلفية البحث: تستخدم القسطرة القلبية بشكل شائع لتشخيص وعلاج متلازمة الشريان التاجي الحادة. عادة ما تؤدي المضاعفات المبكرة لهذا الإجراء إلى زيادة فترة الرقود في المستشفى والتكاليف.

الهدف: لتحديد اثر وضع كيس الثلج بالضغط المباشر لمنع حدوث المضاعفات المبكرة (نزيف ، ورم دموي ، كدمات ، ألم، احتباس الادرار، و الم الظهر) بعد إزالة الغمد الفخذي بعد القسطرة القلبية.

منهجية البحث: تصميم دراسة تجريبية ، اكتملت الدراسة بمشاركة 60 مريضاً (30 مريضاً في كل مجموعة ضابطة وتجريبية) خضعوا لقسطرة قلبية في مركز كربلاء لأمراض وجراحة القلب من 1 تشرين الأول 2021 إلى 17 تموز ، 2022

النتائج: وجدت هذه الدراسة أن ما يقرب من 40٪ من المشاركين كانوا في الفئات العمرية 60-69 سنة ، أكثر من 76٪ منهم من الذكور وأكثر من 53٪ كانوا مدخنين. أكثر من 20٪ تم تصنيفهم على أنهم سمنة من الدرجة الأولى في المجموعات التجريبية. أكثر من 33٪ من المجموعة التجريبية كانوا يعانون من ارتفاع ضغط الدم وأكثر من 56٪ كانوا يستخدمون الهيبارين أثناء قسطرة القلب. كانت هناك اختلافات في شدة النزيف وحجم الورم الدموي وحجم الكدمات وشدة الألم بين المجموعتين التجريبية والضابطة في القياسات الأربعة المختلفة. كان البروتوكول التداخلي (تطبيق كيس الثلج بالضغط المباشر) قادرًا على تقليل حدوث المضاعفات المبكرة والحصول على المشي المبكر بعد تطبيق البروتوكول.

الاستنتاجات: حسب نتائج الدراسة فإن كيس الثلج بالضغط المباشر فعال للحد من تطور المضاعفات المبكرة بعد إزالة غمد الفخذ.

التوصيات: تعليمات لعمل كيس الثلج بالضغط المباشر بعد إزالة غمد الفخذ لتقليل حدة النزيف والورم الدموي والكدمات والألم. يجب إجراء دراسة أخرى للتحقق من فائدة تطبيق كيس الثلج مع الضغط المباشر على الإجراءات التداخلية الأخرى مثل ازالة الناسور الشرياني الوريدي ,الخط الوريدي المركزي والخط الشرياني.

الكلمات المفتاحية: كيس الثلج ، المضاعفات المبكرة ، الغمد الفخذي ، القسطرة القلبية.

جامعة كربلاء/كلية التمريض

اثر تطبيق كيس الثلج مع الضغط المباشر في الوقاية من المضاعفات المبكرة بعد إزالة الغمد الفخذي للقسطرة القلبية

رسالة مقدمة الى مجلس كلية التمريض/ جامعة كربلاء وهي جزء من متطلبات نيل درجة الماجستير في علوم التمريض

كُتب بواسطة

عباس بقال حمود

بإشراف

أ.م.د.

فاطمة مكي محمود

محرم- 1444هـ **أب – 2022 م**