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The Effect of Using a High Heparin Dose versus a Standard Heparin Dose on the Quality and Safety of Cardiac Patients Following Diagnostic Trans-Radial Coronary Angiography at Palestine: An Experimental Study

By

Fekry Afeef Bsharat

Supervisor

Dr. Jamal Qaddumi

Co- Supervisor

Dr. Mohammad Rajab Abdel Qader Asia

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Thesis Approval

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This thesis was defended successfully on 6/12/2023 and approved by:

Committee members	**Signature**
1. Dr. Jamal Qaddumi: Supervisor	
2. Prof. Mohammad Asia: Co Supervisor	
3. Dr. Basmah Salameh: Internal Examiner	
4. Dr. Mohammed ALBashtawy: External Examiner	
5. Dr. Abdulla Alkhawaldeh: External Examiner	

Declaration

I declare that this thesis was composed by myself and that the work contained herein is my own, except where it states otherwise by references or acknowledgment, the work presented is entirely my own.

Name: Fekry Afeef Bsharat

ID: 202012622

Signature: Fekry Bsharat

Date: 20/5/2024

Dedication

To the dear one who gave his life and health so that his family could live a dignified life... One of the most important symbols of dedication and altruism... To the captain of the skillful ship that brought me to safety... To the source of my trust, pride and patience... To my dear father, I hope that Make you as proud of me as I am proud of you.

To the watchful eye... to the great epic that extended like its arms Land. The giver... to the inexhaustible source of tenderness... to those of us who try to enjoy comfort and security... to those who bow before its greatness, and in describing it, words feel ashamed and tremble. To the bright white heart, my dear mother….

To My deceased sister, Asmaa Your absence is felt deeply, yet your presence remains vivid in my heart and thoughts. As I pursue this doctorate, I find solace in knowing that your belief in me never wavers. Your belief that I'm capable of scaling heights, breaking barriers, and making a difference in this world keeps me motivated and focused.

I dedicate this journey and the success I achieve to the beautiful soul that you are, forever etched in my heart; my dear sons, with all the love and gratitude, thank you from my heart. لمن الهمت الالهام نفسه فكيف بالهام البشر..... زوجتي ايمان صديقة دربي

To my special friend Farid thank you for your support and for helping me with any problem faced me; you give me inspirational messages every time and encourage me to finish this important journey on time

To those with whom we shared the world and its joys... To those with whom I lived sincere love and giving... To the light of love in my life... Brothers and friends

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Abstract

Background: Cardiovascular disease (CVD) is the major cause of death worldwide, causing about 80%–86% of mortalities in low- and middle-income nations. Coronary angiography is the main method for the diagnosis of CHD and an invasive technique for the management of CHD with cardiovascular medications. Trans-radial coronary angiography (TCA) has the advantages of earlier recovery, a shorter time during a stay in the hospital, lower damage to the human body, and decreases postoperative complications. Trans-radial (TR) coronary angiography (CAG) and percutaneous coronary interventions (PCIs) are becoming increasingly popular worldwide, TCS might have some complication like radial artery occlusion (RAO); it may cause by thrombus formation, hematoma may appear in the puncture site.

Aim: This study aimed to investigate the effectiveness of using a high heparin dose (5000IU-7000IU or 100IU/kg) contrasted with a standard heparin dose (2000IU-3000IU or 50IU/kg) on the quality and safety of cardiac patients' post-trans-radial coronary angiography.

Methodology: A randomized controlled trial (RCT) was conducted between April and August 2023, including posttest, and follow-up to find a cause-and-effect association between an independent and dependent variable. The study conducted at Specialized Arab Hospital (SAH) with targeted participants, any patient admitted for cardiac catheterization in the SAH who met the inclusion criteria, the final sample was 289 participants, 143 participants received standard heparin dose and 146 received high heparin dose.

Result: the findings assured the quality and safety of care of using high dose of heparin among trans-radial catheterization as there are no statistically significant differences

between the dose of heparin (high vs. standard) and the Trans-radial Band (TRB) removal time, hospital stay, occlusion occurrence, occurrence of hematoma, abnormal sensation among standard dose group in compare with high heparin dose group. Moreover, statistical tests showed that there is a statistically significant relationship between the dose of the heparin and the occurrence of ischemia after the fourth hour and after a month of catheterization. (34.820 X2) (P: 0.001), (34.820 X2) (P0.001) respectively.

Although the average time of TRB removal time for patients taking the high dose of heparin was slightly higher than the average TRB removal time for patients taking the standard dose (3.36 versus 3.22 respectively). Also, the hospital stay rate was slightly higher among patients taking the usual dose of heparin compared to patients taking the high dose of heparin. As for the patient's feeling of pain, the feeling of pain a month after the catheterization procedure was higher among patients taking the high dose of heparin compared to patients taking the usual dose of heparin. While the pain average for patients taking the standard dose of heparin was higher than the pain average for patients taking the high dose of heparin after the second and fourth hours of the catheterization procedure.

Finally, the satisfaction (quality of care) rate among participants from the two categories (the usual dose and the high dose of heparin) is 4.06 out of 5, and this reflects a high level of satisfaction with the care provided.

Conclusion: Quality and safety of health care are a priority these days, which is also what this dissertation aims to achieve. Through this dissertation results, we find that the use of high doses can be adopted by hospitals that perform cardiac catheterization, as well as to be part of the instructions and guidelines. The administration of a high heparin dose during

TRA diagnostic procedures resulted in a striking reduction of early radial artery occlusion (RAO) rates compared with a standard anticoagulation regimen. The beneficial results produced by the use of high-dose heparin were found to be without an increase in major bleeding. Also, the current study confirmed that there is no statistically significant difference between patients taking the standard dose and patients taking the high dose of heparin with the occurrence of hematoma.

Key words: Cardiovascular disease, Coronary Angiography, Heparin, Trans-Radial, Occlusion, RCTs, Palestine.

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Abbreviation

No	Abbreviation	Meaning
1.	ACS	acute coronary syndrome
2.	AHA	American Heart Association
3.	AI	Artificial Intelligence
4.	AMI	acute myocardial infarction
5.	B.P.H	Benign Prostatic Hypertrophy
6.	C.V.A	Cerebral Vascular Accident
7.	CABG	coronary artery bypass graft
8.	CAD	coronary artery disease
9.	CAG	coronary angiography
10.	CDC	Center for Disease Control
11.	CHD	Coronary heart disease
12.	CHF	Congestive heart failure
13.	CI	confidence interval
14.	CQLI	Cardiac - Quality of Life Index
15.	CVD	Cardiovascular disease
16.	ECG	electrocardiograms
17.	ESC	European Society of Cardiology
18.	FMD	Flow-Mediated Dilatation
19.	H.F	Heart Failure
20.	HR	hazard ratio
21.	HRQOL	health-related quality of life
22.	IHD	ischemic heart disease
23.	IOM	Institute of Medicine’s

24.	KNN	K Nearest Neighbors
25.	LEAD	Lower Extremity Artery Disease
26.	LPNs	licensed practical nurses
27.	LR	Logistic Regression
28.	MAT	modified Allen's test
29.	MCS	mental health composite summary
30.	MI	myocardial infarction
31.	MOPH	maintenance of patent hemostasis
32.	Nas	nursing assistants
33.	NB	Naive Bayes
34.	OPD	Out-Patient Department
35.	PAD	Peripheral Artery Disease
36.	PCIs	percutaneous coronary interventions
37.	PSQ	Perceived service quality
38.	PTP	Pre-Test Probability
39.	RA	Radial artery
40.	RAO	Radial artery occlusion
41.	RAO	radial artery occlusion
42.	RAPL	radial artery pulsation loss
43.	RAS RCT	radial artery spasm randomized control trial
44.	RF	Random Forest
45.	RN	registered nurse
46.	SAH	Specialized Arab Hospital
47.	SCAD	spontaneous coronary artery dissection

48.	STEMI	ST elevation Myocardial Infarction
49.	SVM	Support Vector Machine
50.	TCA	Trans-radial coronary angiography
51.	TF	Trans Femoral
52.	TFA	Tran’s femoral access
53.	TFA	trans-femoral approach
54.	TQM	Total Quality Management
55.	TR	Trans-radial
56.	TRA	Trans-Radial Approach
57.	TRA	Trans-radial artery access
58.	TRB	Trans-Radial Band
59.	TRCA	trans-radial coronary angiography
60.	UN	United Nations
61.	V.H.D	Valvular Heart Disease
62.	WHO	World Health Organization

Chapter One

Introduction

1.1 Background

Cardiovascular Disease (CVD) is the major cause of death worldwide, causing about 80%–86% of mortalities in low- and middle-income nations. The overall mortality rate in developed nations has dropped due to the availability of non-invasive and invasive treatments as well as primary and secondary methods connected to CVD prevention (Saglietto et al., 2021). Coronary Heart Disease (CHD) is a significant global public health problem that affects people. The symptoms include hypoxia and myocardial ischemia brought on by insufficient blood flow through the coronary artery, include shortness of breath, chest discomfort, chest tightness, and other uncomfortable symptoms (Glovaci & Wong, 2019). Extreme conditions could lead to associated medical problems such cardiac rupture, malignant arrhythmia, and cardiogenic shock (Brown & Smith, 2020).

Coronary angiography is the main method for the diagnosis of CHD and an invasive technique for the management of CHD with cardiovascular medications. Most of the procedures are through the radial artery. Trans-radial artery access (TRA) was introduced in 1989 and has been universally used as an alternative approach to traditional trans-femoral access (TFA). Trans-radial coronary angiography (TCA) has the advantages of earlier recovery, a shorter time during a stay in the hospital, lower damage to the human body, and decreases postoperative complications (Adnan et al., 2020; Ford et al., 2020; Park et al., 2020).

Worldwide, percutaneous coronary interventions (PCIs) and trans-radial (TR) coronary angiography (CAG) are gaining popularity due to their extremely low incidence of significant bleeding and other local consequences. While more technically demanding than the trans-femoral (TF) technique, the TR access route has been linked to increased patient acceptability, shorter hospital stays, and more convenience (Catapano et al., 2020). Although blockage of the radial artery (RA) is virtually always asymptomatic, it is a major consequence of TR coronary operations. Occlusion of the radial arteries (RAO) is thought to be the most frequent and dangerous adverse effect of TRA. It has been referred to as the TR technique's "Achilles' heel" (Didagelos et al., 2021; Ziakas et al., 2018).

The possibility of RAO post-TCA is from 6 to 10 percent statistically because of the small diameter of the radial artery, when RAO is produced post-TCA. Consequently, discovering the risk factors of RAO and reducing or avoiding RAO have clinical and practical consequences (Pancholy et al., 2018).

The furthermost significant clinical complication is radial artery occlusion (RAO). Radial artery occlusion, caused by thrombus formation, is a common complication of trans-radial cannulation and catheterization. Iatrogenic vascular wall injury, often compounded by peripheral vasoconstriction or hemodynamic instability, likely contributes to the formation of thrombi (Aoun, 2019; Mangieri, 2023; Starke et al., 2020).

Common heparin as the furthermost classic anticoagulant, it is still the primary choice of anticoagulant in surgery. As far as simple coronary angiography is disturbed, whether the dose of heparin used through the surgical procedure would be calculated

affording to the patient's weight and further complete heparinization in batches has not been determined (Besli et al., 2019).

It has been discovered that heparinization works well to lower the risk of radial artery blockage, following trans-radial access, the patency of the radial artery may be significantly impacted by the compression pressure and length (Mason, 2018). Heparin dosages (2000IU-3000IU) and (5000IU-7000IU) are most frequently used to avoid the risk of RAO during coronary angiography. The high dose is 5000 IU-7000IU, or 100 IU/kg, whereas the typical dose is 2000 IU–3000 IU, or 50 IU/kg. Numerous studies show a correlation between RAO and heparin dose. In contrast to the group that got a high dose of UFH, RAO was found to be considerably greater in the group that received the standard dose of UFH (Besli et al., 2021; Wang et al., 2022; Zafarullah et al., 2022).

For medical and healthcare companies around the world, it is crucial to provide patients with a secure and comfortable atmosphere when receiving medical treatment. Total Quality Management (TQM) is receiving a great deal of attention from organizations and governments all over the world. In fact, it can be said that quality has taken the forefront in many organizations, and their management and lifestyle philosophies enable them to survive and prosper in the context of continual and quick environmental change as well as increasing awareness of t of the level of quality in the goods they receive (Almaamari et al., 2017; Al-Shdaifat, 2015).

Quality and safety improvement is a tactic used by health organizations to get a competitive edge in their market and enhance their long-term profitability and reputation. In order to thrive and satisfy patients, all hospitals have discovered that they must assess, track, and enhance the quality of their medical services. Healthcare administrators must have a solid grasp of the most feasible strategies for raising the

standard of care. Hospital administrators prioritize patient acquisition and customer loyalty in these situations by identifying the needs of their patients and making an effort to meet or exceed their expectations (El-Sherbiny et al., 2020; Jiang et al., 2019; Sodani, 2016). Therefore, the current study examines the effects on patient quality and safety of randomized controlled trials using conventional and high dosages of heparin to avoid radial artery blockage during trans-radial catheterization.

1.2 Problem Statement

Furthermost of the patients who experienced coronary angiography used heparin medication with a dose from 2000 IU to 5000 IU to avoid medical complications of RAO. Regarding the diverse countries, patients' individualization, and physicians' habits, the dose of heparin medication used in coronary angiography is generally conventional dose (2000 IU-3000 IU or 50 IU/kg) and high-dose (5000 IU-7000IU or 100 IU/kg). However, few scientific literatures are comparing the clinical impact of these two approaches of consuming heparin. Consequently, whether to use of high-dose heparin medication is improved and healthier than low-dose heparin in avoiding postoperative complications such as RAO, and whether the use of high-dose heparin is used in TCA to efficiently avert the incidence of RAO without growing the risk of bleeding and other related problems are still contentious (Degirmencioglu et al., 2015; Maden et al., 2016).

As the radial artery's simply superficial and compressible architecture, the radial route has become a popular alternative to the femoral method for catheterization. This has decreased entry location bleeding and enhanced patient comfort through early post-procedure movement. According to a current meta-analysis of numerous sizable randomized controlled trials, radial access enhances safety by reducing most important bleeding and vascular medical complications transversely to the range of CAD and

lowers all-cause mortality rate and foremost adverse cardiac procedures when compared to femoral access. One of these major limitations is radial artery blockage, which is thought to happen in 1%–10% of trans-radial cardiac catheterization instances. The radial artery cannot be used as an arterial conduit for coronary artery bypass surgery or renal dialysis fistulas when it has been blocked (Febres-Ramos & Mercado-Rey, 2020; Fernandez et al., 2018; Zaid et al., 2020).

Even with TCA's great safety benefits, the most common complications still arise. These include radial artery occlusion, nonocclusive radial artery injury, radial artery spasm, radial arterial perforation, radial artery pseudoaneurysm, arteriovenous fistula, granuloma formation, access-site bleeding, nerve damage, the development of a forearm hematoma, complex regional pain syndrome, and other infrequent consequences. Vascular problems with TRA may be influenced by several parameters such as body weight, gender, length of operation and compression, anticoagulant drug dosage, and number of catheters. 2019; Aoun et al.; Wang, 2011). However, it is still up for debate whether high-dose and standard-dose heparin can effectively prevent the incidence of RAO during trans-radial coronary angiography without raising the risk of bleeding or other related problems. In Pakistan, in a meta-analysis a comparison between the standard dose of heparin versus low dose for RAO, through searching in database of PubMed, EMBASE, CINAHL and CENTRAL for RCTs, the search revealed that there is decrease in RAO with using standard dose of heparin there is also a dearth of studies contrasting the clinical outcomes of these two heparin dosages (Dahal et al., 2018; Hammami et al., 2023).

The culture of healthcare must shift fundamentally in order to improve patient safety. Improving safety cultures to reduce injury is a top goal worldwide (Sodani,

2016). Total Quality Management (TQM) is a common approach that improves service quality and raises patient happiness, which is one of the primary metrics used to assess the caliber of care given in healthcare facilities. Improvements in perceived service quality (PSQ) increase patient satisfaction (Agyapong & Kwateng, 2018). Public health institutions now need to make a commitment to raising the standard of care they give their patients by figuring out what factors influence their greater level of satisfaction. Because patient feedback accurately reflects the performance of healthcare institutions, measuring the quality of healthcare services from the perspective of the patient is a crucial component in assessing the performance of this significant sector (Nguyen & Nagase, 2019).

1.3 Significance of the Study

This study assessed the effect of a high dose of heparin medication contrasted with standard heparin dose for decreasing the casual of radial occlusion subsequent to radial artery catheterization as a desirable way to prevent the femoral way subsequently. It has very associated complications such as lower aneurysm, ischemia, and large hematoma and it is further painful for the patient (Zafarullah et al., 2022). Also, this study assisted to simplify this procedure's assistance for the other cardiac catheterization health clinics to approve this way of involvement in Palestine. So, going deep into this new approach in radial catheterization methods helps in addressing the good outcome and little complication that enhances the other technicians to adopt this approach in Palestine (Zafarullah et al., 2022).

RAO was previously established to be significantly decreased when heparin is used. Heparin medication was administered intravenously in the initial study describing the influence of heparin on RAO. Numerous trans-radial invasive operatives currently

deliver heparin as a characteristic of the “radial cocktail” using an intra-arterial technique. The consequence of intravenous compared to intra-arterial heparin in preventing RAO is unidentified and unfamiliar. Therefore, most doctors here in Palestine used their knowledge in giving the dose of heparin regards the evidence base of this procedure so in many countries doctors start with giving a high dose of heparin like in Roma and Greece (Hahalis et al., 2018). Still here in Palestine, there is no clear protocol to give a high dose of heparin.

Quality is a multifaceted concept, and one of the most crucial aspects that reflects the caliber of services provided in a hospital environment is satisfaction with care. According to Ab Latiff, Din, and Ma'on (2013), patient satisfaction is defined as the degree to which patients feel that the treatments, they get match their requirements and expectations. It is also seen to be a trustworthy indicator of the value of services. The current study aims to determine the relationship between radial artery occlusion and increase heparin dose, as well as the effects of using 5000IU–7000IU or 100IU/kg of heparin instead of 2000IU–3000IU or 50IU/kg on quality and safety following cardiac catheterization. This is because it is important and necessary to evaluate the quality of health services, especially those provided in health facilities and hospitals. Finally, this study done as the he first study in Palestine.

1.4 Study Objectives

1.4.1 Main Objective

This study examined the effectiveness of using a high heparin dose (5000IU-7000IU or 100IU/kg) contrasted with a standard heparin dose (2000IU-3000IU or 50IU/kg) on the

quality and safety post-trans-radial coronary angiography to improve the health outcomes following radial artery catheterization at Palestine.

1.4.2 Specific Objectives

1. To evaluate the quality and safety of two different heparin doses during trans-radial coronary angiography.
2. To identify the main predisposing features and factors associated with quality and safety post radial artery catheterization.
3. To assess the effectiveness of using 5000IU-7000IU or 100IU/kg of heparin instead of 2000IU-3000IU or 50IU/kg to decline the radial artery occlusion post-cardiac catheterization.

1.5 Research Questions

1. What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on quality care and safety compared with 2000 IU-3000 IU or 50 IU/kg among patients at post-cardiac catheterization?

2. What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on decrease the radial artery occlusion compared with 2000 IU-3000 IU or 50 IU/kg among patients at post-cardiac catheterization?

3. What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on patients' satisfaction compared with 2000 IU-3000 IU or 50 IU/kg post-cardiac catheterization?

1.6 Study Hypothesis

H01. There will be no statistically significant difference in quality care and safety at post-cardiac catheterization between patients receiving 5000 IU-7000 IU or 100 IU/kg of heparin and 2000 IU-3000 IU or 50 IU/kg at $P \leq 0.05$.

H02. There will be no statistically significant difference in decrease the radial artery occlusion at post-cardiac catheterization between patients receiving 5000 IU-7000 IU or 100 IU/kg of heparin and 2000 IU-3000 IU or 50 IU/kg at $P \leq 0.05$.

H03. There will be no statistically significant difference in patients' satisfaction at post-cardiac catheterization between patients receiving 5000 IU-7000 IU or 100 IU/kg of heparin and 2000 IU-3000 IU or 50 IU/kg at $P \leq 0.05$.

1.7 Conceptual Framework

There are many parallels between human compassion and high-quality healthcare, despite their differences. Humans and health factors that impact the provision of healthcare are the focus of both. Above all, the goal of both approaches is to deliver the best possible treatment.

The conceptual framework of the current study is based on the Triad Model of Donabedian (Donabedian, 1980). The model composed of structure, process, and outcomes. The study utilized the process and the outcome components into consideration. The process focused on heparin high and standardized dose delivered by cardiologist to patients, and the outcome analysis focused on the effect of heparin on the status of the patients as measured by patient safety (pain, bleeding from the puncture site, bleeding from other sites, ischemia to the hand, and hematoma

grading) and quality of care (patient satisfaction and stay of hospitalization), as shown in Figure 1

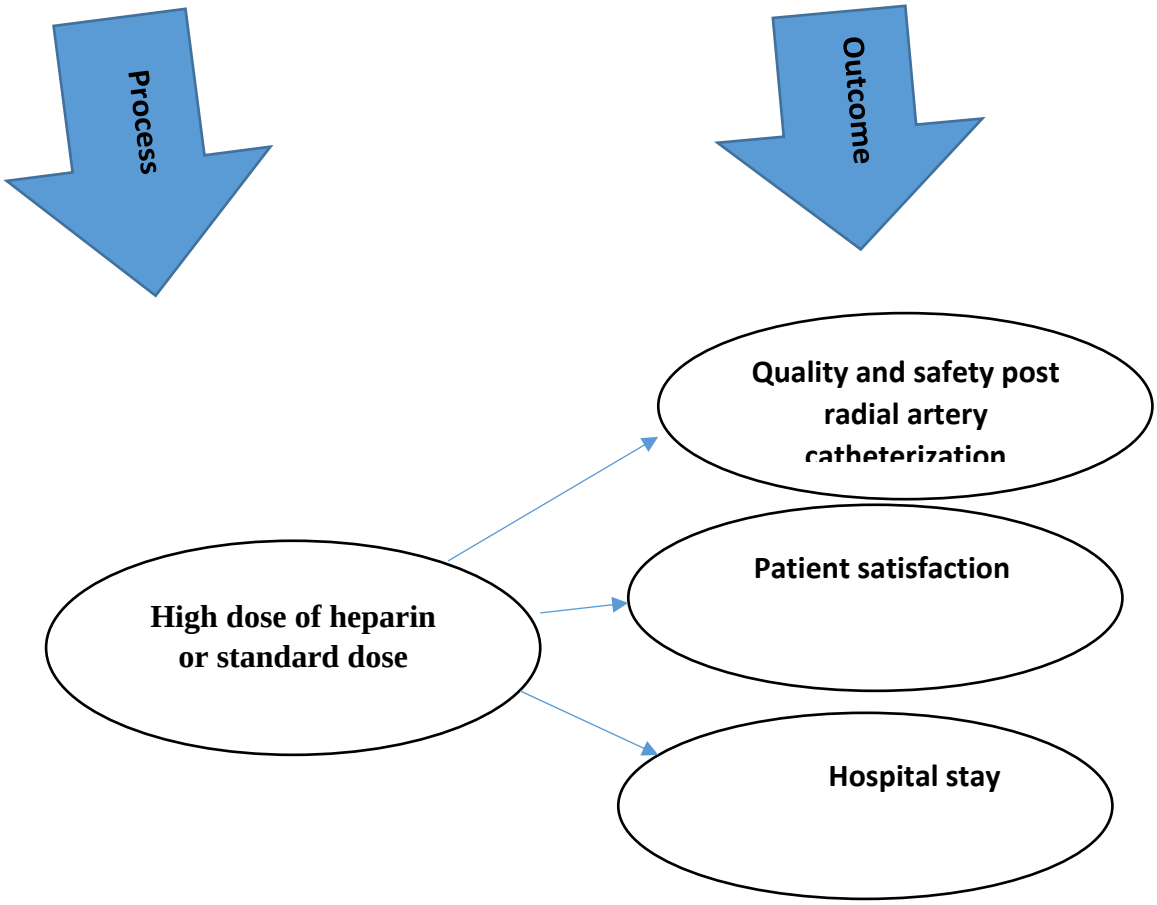

Figure 1 : Conceptual Framework of quality and Safety after removal of radial sheet on Patients Satisfaction of the quality of care

1.8 Operational Definitions

1. **Coronary Artery Disease (CAD): "**is a common heart condition that involves atherosclerotic plaque formation in the vessel lumen. This leads to impairment in blood flow and thus oxygen delivery to the myocardium" (Shahjehan & Bhutta, 2022).

2. **Trans-radial cardiac catheterization**: “is a procedure used to treat and diagnose certain heart conditions. It's also called **trans-radial** cardiac catheterization or angiography. During the procedure, a healthcare provider inserts a long thin tube (catheter) through the radial artery. The radial artery is a blood vessel in the wrist” (Cai et al., 2020).
3. **Radial artery occlusion**: “is a quiescent complication of trans-radial access (TRA) that rarely leads to critical hand ischemia requiring intervention because of the dual vascular supply of the hand from the palmar arch” (Rashid et al., 2016).
4. **Patient Safety:** “This is a healthcare discipline that emerged with the evolving complexity of healthcare systems and the resulting rise of patient harm in healthcare facilities. It aims to prevent and reduce risks, errors, and harm that occur to patients during the provision of health care. A cornerstone of the discipline is continuous improvement based on learning from errors and adverse events” (Jha, 2018).
5. **Quality of care**: “Quality health care can be defined in many ways but there is growing acknowledgment that quality health services should be Effective – providing evidence-based healthcare services to those who need them; Safe – avoiding harm to people for whom the care is intended; and People-cantered – providing care that responds to individual preferences, needs, and values” **(Busse et al., 2019).**

Chapter Two

Literature Review

2.1 Introduction

A literature review using Science Direct databases, Google Scholar, and PubMed was performed before the start of the study. Keywords used in the searches involved cardiac diseases, Trans-radial, Coronary Angiography, standard heparin dose, high heparin dose, and nurses. About 200 articles were searched on the topic, 18 of them was RCTs article, most of them are published in high impact journals. About 21 article was excluded because of language wise, 3 od studies was unpublished paper, 16 article was a systematic design(meta-analysis).

2.2 Previous Studies

A Thematic review approach was used to organize previous studies in the literature review.

2.2.1. Definition of cardiovascular diseases

The term "CVDs" refers to a group of chronic diseases, such as (CAD) that have a shared pathogenesis with atherosclerosis as heart attack, sudden death, myocardial infarction, and stable angina. Stroke as a hemorrhagic, ischemic, or transit ischemic attack is a cerebral vascular injury. Aortic aneurysm and Lower Extremity Artery Disease (LEAD) are examples of peripheral artery disease (PAD). Congestive heart failure (CHF), but both phrases are commonly used by medical practitioners. Sanchis-Gomar et al. (2016) define cardiovascular disease (CVD) as a group of disorders affecting the heart and blood arteries. Acute coronary syndrome (ACS), coronary artery

disease (CAD), and coronary heart disease (CHD) are among these conditions, although they are not the only ones. Furthermore, Lippi et al. (2016) found that whereas CHD is a CAD consequence, acute coronary syndrome (ACS) is a subgroup of CAD. While ACS nearly always manifests as a symptom, such as unstable angina, and is usually linked to myocardial infarction (MI) independent of the existence of CAD, CAD is defined by atherosclerosis in coronary arteries and can be asymptomatic (Lippi et al., 2016). Because of this, the terms "CAD" are typically used to describe several pathologic processes that impact the coronary arteries and CHD used to diagnoses of atherosclerosis, myocardial infarction (MI), and silent myocardial ischemia (Cervellin & Lippi, 2014).

Definition and epidemiology of coronary heart disease

Plaque accumulation in the arteries supplying the heart with oxygen-rich blood is the primary cause of coronary heart disease (CHD), often referred to as coronary artery disease (CAD). Over many years, deposits of calcium, fat, and cholesterol may combine to form plaque in the arteries. Atherosclerosis, a disorder that causes the coronary arteries to narrow and stiffen over time, can be brought on by this plaque (Bauersachs et al., 2019 & Liang et al., 2021).

Conditions involving impairment of coronary artery blood flow, which can lead to silent ischemia, angina pectoris, Acute Coronary Syndrome (ACS), or sudden cardiac death, are collectively referred to as Ischemic Heart Disease (IHD). According to He et al. (2017), Coronary Artery Disease (CAD) is a prevalent public health issue linked to high death rates and higher medical expenses. Regarding morbidity mortality indices, Zheng et al., (2023) stated that Coronary Heart Disease (CHD) is the major cause of death in most developed countries and many developing countries (Zheng et al.,2023).

Also, Dal Canto revealed that the clinical complications of CHD lead to substantial disability and are a main source of the rising cost of health care (Dal Canto et al., 2019)..

According to estimates, 32.7% of cardiovascular disease and 2.2% of the worldwide disease burden were attributed to CAD. It has an annual cost to the US health care system of more than $200 billion. The American Heart Association's (AHA) national health survey from 2009 to 2012 estimates that 5.0% of women and 7.6% of men in the US had CAD. Fifteen million and half of million Americans were affected by the illness over this period, according to Arun (2022) and Bauersachs et al. (2019). Even though the death rate from this illness has significantly decreased in Western nations over the past several decades, it still accounts for almost one-third of all fatalities in those over the age of 35. But whereas the incidence of CHD is rising sharply in central and Eastern Europe, as well as to some extent in Asia and Africa, it is falling in Western Europe, the US, and Australia (Kubra et al., 2021). The Framingham Heart Study provides crucial information on the goals for the primary and secondary prevention of CHD, summarizing the risk factors that lead to the development of the disease (Hajar 2017 & Khan et al., 2020). According to a research by Khan et al. (2020), IHD affects 126 million people worldwide (1,655 per 100,000), or around 1.72% of the world's population. Worldwide, IHD was the cause of nine million fatalities. Males were afflicted more frequently than females, and the prevalence rose with age, usually beginning in the fourth decade (Khan et al., 2020). Furthermore, they forecast that by 2030, the incidence rate—which is currently 1,655 instances per 100,000 people—may rise to 1,845 cases. The countries of Eastern Europe continue to have the greatest prevalence. Age-standardized rates, which account for population fluctuations over time, have decreased in a number of places. It is expected that aging populations, along with increased rates of obesity, diabetes, and metabolic syndrome, will contribute to the

ongoing rise in the incidence of IHD. Over the past 20 years, there has been a significant aging of the global population. According to UN estimates, the proportion of adults over 65 will rise from one in eleven in 2019 to one in six by 2050 (Khan et al., 2020).

Regarding the clinical manifestations of CHD, Jamee Shahwan., (2019) revealed that as the disease progresses, most people with CHD don't exhibit any symptoms for decades before their first symptoms, frequently a "sudden" heart attack, manifest. The symptoms and indicators of CHD were noted in the advanced condition of the disease. Some of these atheromatous plaques may rupture after years of advancement, which can trigger the blood clotting mechanism and start limiting blood flow to the heart, resulting in sudden death (Jamee Shahwan., 2019).

According to AHA Heart Disease and Stroke Statistics update, 15.5 million Americans aged 20 and over have (CHD). The prevalence of CHD is estimated to rise with age for both men and women, and one in every 42 seconds, an American is estimated to have a MI (Benjamin et al., 2018; Mozaffarian et al., 2016).

Data from 44 years of follow-up in the original Framingham Study cohort and 20 years of surveillance of their offspring have been used to determine the incidence of initial coronary events, including MI (whether clinically recognized or not), angina pectoris, unstable angina, and sudden and non-sudden coronary deaths. These data allowed the following observations to be made. First, the lifetime risk of getting CHD was 49% for males and 32% for women in persons aged 40, whereas the risk was 35% for men and 24% for women in people aged 70 (Gerloni et al., 2017).

However, it was also noted that the incidence more than doubled in men and tripled in women between the ages of 65 and 94 compared to the 35 to 64 age group, and that serious cardiac disease manifestations, such as MI and sudden death, were

uncommon in premenopausal women while the burden of CHD was significantly higher in postmenopausal women (Giang et al., 2013). According to Go, et al. (2006), there are other variables than gender that might affect whether an acute MI or stable angina is initially presented with congestive heart failure. According to a case-control study of persons whose initial clinical presentation of congestive heart failure was either acute MI (n = 916) or stable exertion angina (n = 468), the clinical presentation may be influenced by recent previous medication with beta blockers and statins (Go, et al., 2006).

On the contrary, CVD mortality has recently decreased in the US and areas with highly developed economies and healthcare systems, however, the situation varies considerably internationally. In fact, CHD ranks first among all causes of death for adults in low-, middle-, and high-income nations. According to predictions made by Gaziano et al. (2019), between 1990 and 2020, CHD mortality was expected to grow by around 29% for women and 48% for men in rich nations and by 120% for women and 137% for men in poor countries. Here are some instances of disparate findings from various geographical locations. Over 4 million fatalities per year were attributed to CVD in a 2014 research that used data from 49 European and northern Asian nations from the World Health Organization (WHO) (Nichols et al., 2014).

Clinical Presentation of Coronary heart disease:

The following are the characteristics of angina: location: retrosternal, or close to the sternum, however it can also be felt in the lower jaw or teeth, the epigastrium, or anyplace in between. The quality is characterized as being stifling, burning or constricting sensation, heaviness, pressure, and/or shortness of breath. Etiology: chilly weather, postprandial activity, or mental stress. Duration: 3 to 15 minutes (usually no

more than 10 minutes). Rest or sublingual nitroglycerin can induce remission (Gerloni et al., 2017).

The lack of triggering circumstances distinguishes atypical presentations. The discomfort is mild when you first wake up, gets stronger gradually, and lasts for up to fifteen minutes at its worst. Older individuals, women, and diabetics are more likely to have atypical pain. Women describe nebulous symptoms that respond differently to nitroglycerin, including palpitations, stabbing pain, and inflammatory discomfort that can linger for hours, days, or even seconds. Dyspnea or being asymptomatic are more common in diabetic individuals (Gerloni et al., 2017).

Despite having indications of (CHD), patients usually have no symptoms for years since atherosclerosis progresses over decades. The prognosis for individuals with non-obstructive heart failure (CHD) is lower when there is evidence of the disease, even in the absence of symptoms (Maddox et al., 2014). In a retrospective cohort study, the risk of MI increased significantly and progressively in parallel with the extent of both non-obstructive (at least one stenosis ≥20% but <70%) and obstructive (at least one stenosis ≥70%) and prior CHD events in 37,674 USA veterans (96% male) who underwent coronary angiography between October 2007 and September 2012 and were followed for a year. According to Chow et al. (2011), patients with non-obstructive CHD involving one vessel (hazard ratio (HR) 2.0; 95% CI: 0.8–5.1) and those with non-obstructive CHD involving two or three heart vessels (HR 4.5; 95% CI: 1.6–12.5) had a significantly higher risk of MI compared to those without CHD.

2.2.4. Risk factors of coronary heart diseases

There are two types of coronary artery disease risk factors: modifiable and nonmodifiable. 2019 research by Pencina et al. found that just a tiny percentage of

predictive performance was accounted for by modifiable risk variables, with age, gender, and race accounting for 63% to 80% of the total. However, the reduction of modifiable risk factors led to substantial decreases in the incidence of CAD (Pencina et al., 2019). According to Sanchis-Gomar et al. (2016), CAD prevalence rose in both men and women above the age of 35. This study also demonstrated the effect of age in CHD. The lifetime risk of developing CAD is 49% for men and 32% for women over the age of 40 years. Additionally, they discovered that men were more vulnerable than women (Sanchis-Gomar et al., 2016).

Another important risk factor is family history. Individuals under 50 years' old who have a family history of early heart disease are at higher risk of dying from CAD. According to a Hajar article on risk factors for CAD, having a mother or sister diagnosed before the age of 65 and a father or brother diagnosed before the age of 55 are both regarded as risk factors (Hajar, 2017). The two leading causes of mortality in 2019 research evaluating twelve modifiable risk variables were smoking and hypertension. However, only 54% of these people manage their blood pressure appropriately. Due to the oxidative and mechanical stress that hypertension puts on the artery wall, it has long been considered a significant risk factor for heart disease (Danaei et al., 2019).

The third most prevalent risk factor for IHD is thought to be hyperlipidemia. The WHO estimates that elevated cholesterol contributed to 2.6 million deaths. A recent cross-sectional investigation using the coronary calcium score found that the prevalence of low HDL-c, combination hyperlipidemia, and hypercholesterolemia was, respectively, 55%, 41%, and 20% higher. However, the connection between elevated triglycerides and CAD is more nuanced than that (Gebreegziabiher et al., 2021 & Nelson et al., 2013).

According to the Centers for Disease Control (CDC), prediabetes, which increases the risk of type 2 diabetes, heart disease, and stroke, affects more than one in three adult patients in the country. Adult patients with diabetes had a 2.5 times higher risk of heart disease in males and a 2.4 times higher rate in women than in non-diabetic individuals (Arnold et al., 2020). According to a meta-analysis, individuals with diabetes who had an A1C > 7.0 were 85% more likely to die from cardiovascular causes (hazard ratio 1.85, 95% CI 1.14-2.55) than patients whose A1C was < 7.0%. Additionally, research showed that individuals without diabetes who had an A1C > 6.0% were 50% more likely to die from cardiovascular causes (hazard ratio, 1.50, 95% confidence interval, 1.01-2.21) than patients with an A1C < 5.0%. Significant study heterogeneity was also noted by the researchers (American Diabetes Association, 2019; Cavero-Redondo et al., 2017).

Obesity raises the likelihood of acquiring other CAD risk factors such as hypertension, hyperlipidemia, and diabetes mellitus in addition to being an independent risk factor for CAD. After adjusting for demographics, smoking, physical activity, and alcohol use, a recent study found that obese people were twice as likely to have CHD (hazard ratio 2.00, 95% confidence interval 1.67-2.40) (Ades et al., 2017).

There have also been reports of the "obesity paradox". Even though there is evidence linking obesity to an increased risk of cardiovascular morbidity, some writers claim that patients who are overweight or obese have better results (American Diabetes Association, 2019). More evidence has demonstrated that trans-fat raises the risk of CVD by negatively affecting insulin resistance, inflammation, lipids, and endothelial function. A 23% increased risk of CAD was linked to every 2% of calories ingested from trans-fat (RR 1.23, 95% CI 1.11-1.37) (Al-Taraji et al., 2018).

2 In comparison to those who consumed less than 10% calories from added sugar, a prospective cohort study found that those who consumed 10% to 24.9% (adjusted hazard ratio 1.30, 95% CI 1.09-1.55) and 25% (adjusted hazard ratio 2.75, 95% CI 1.40-5.42) more calories from added sugar had a 30% and 175% higher chance of dying from CVD, respectively. There have also been reports that high fructose corn syrup, sucrose, and table sugar are major contributors to CAD (DiNicolantonio & OKeefe, 2017; Yang et al., 2014).

3 According to a meta-analysis, smokers with diabetes had a 51% higher risk of CHD (21 studies, RR 1.51, 95% CI 1.41.1-62). A different 2015 meta-analysis found that among individuals over 60, smoking increased the risk of CVD by 37% for past smokers and twice for current smokers. According to Pan et al. (2015), nonsmokers who are often exposed to secondhand smoke also have a 25% to 30% higher risk of CHD than non-exposure.

4 One preventive factor against the onset of CAD is exercise. A 2004 case-control research with 15,152 cases and 14,820 controls conducted in 52 countries across all continents showed that physical inactivity had a population-attributable risk of 12.2% on MI (Yusuf et al., 2014). Numerous observational studies have demonstrated that those who choose to exercise standard ly have lower rates of morbidity and mortality. Improved vasculogenesis, increased endothelial nitrous oxide generation, and more effective reactive oxygen species deactivation are some of the mechanisms underlying (Tana et al., 2019).

2.2.5 Diagnosis of coronary heart diseases

- The basis for determining the likelihood of IHD is the examination of pain characteristics, age, gender, prior cardiovascular illness, and other risk factors. Angina pectoris that is unstable; exercise produces the discomfort, which rests

rapidly relieves. After some time, the symptoms remain the same. Ischemic discomfort might be felt across the chest as a pressure, squeezing, burning, or heaviness. Although it usually appears retro-sternal, it can also occasionally come from the neck, lower jaw, or upper belly (Fang et al., 2016).

- **Physical examination**
- The physical examination is not very sensitive. While an irregular resting ECG raises the likelihood of a diagnosis, a normal ECG does not rule out the diagnosis. It is advised to perform routine laboratory testing to assess the severity of the variables. Every patient with suspected CAD should have evaluations for hyperglycemia, dyslipidemia, thyroid disorders, and renal failure (Task members of ESC et al., 2013). The levels of plasma cardiac troponin are not at normal (above 0–0.04 nanograms per milliliter (ng/ml). In order to determine left ventricular function, kinetic segments, and valve lesions (mostly mitral regurgitation), echocardiography should be carried out in all patients with spontaneous coronary artery dissection (SCAD), following ESC and Canadian recommendations (Gaziano et al., 2018).
- **Exercise ECG**

Exercise ECGs have a low sensitivity of less than 50% and a high specificity of more than 90%, with a significant likelihood of false positives, especially in females. The test is often performed using the Bruce protocol on a treadmill, going from rest to maximal effort. Modifications to ST segments are examined. Since five to ten percent of individuals with acute myocardial ischemia are known to have normal ECGs at hospital admission, a normal resting electrocardiogram does not rule out the condition. According to Ashley and Niebauer (2014), ST-segment alterations may occur over time and may not be captured on a single ECG recording.

- Myocardial ischemia initially manifests as abnormalities in the ST segment or T-wave. Acute myocardial ischemia is indicated by a new ST elevation in two adjacent leads that is > 0.2 mV in males or ≥ 0.15 mV in women in leads V2-V3 and/or ≥ 0.1 mV in other leads. Myocardial ischemia can also be indicated by a T-wave inversion of > 0.1 mV in two adjacent leads with a strong R-wave, or by a new horizontal or downsloping ST depression of ≥ 0.05 mV in two adjacent leads (Akbilgic et al., 2021). When compared to the treadmill test, stress echocardiography has a better predictive value. In addition to providing details on myocardial that is hibernating, it can distinguish between ischemia and non-ischemic myocardium based on differences in wall motion (Singh et al., 2020).

- **Novel techniques**

N2Genetic optimizer (a new genetic training) is a novel optimization approach presented by Abdar et al. (2019). Our research showed that N2Genetic-nuSVM predicted CAD outcomes among the patients included in a well-known Z-Alizadeh Sani dataset with an accuracy of 93.08% and an F1-score of 91.51%. According to Abdar et al. (2019), these outcomes are competitive and on par with the greatest outcomes in the field.

According to Mathur et al. (2020), artificial intelligence (AI) is important and may be used to diagnose a variety of illnesses, including cancer, diabetes, and heart disease. (AI) is a general phrase that refers to analytical algorithms that learn from data repeatedly, enabling computers to uncover hidden insights without explicit instructions on where to look. When traditional statistical methods fail, this group of operations—which includes terms like machine learning, cognitive learning, deep learning, and reinforcement learning—is used to integrate and interpret complex biological and healthcare data (Mathur et al., 2020).

A machine learning-based model for cardiac disease prediction was presented in a paper by Shorewala et al. (2021). Three machine learning techniques were employed, namely Support Vector Machine (SVM), Logistic Regression (LR), and Random Forest (RF). According to the findings, the RF algorithm outperformed other techniques (LR, SVM) in the prediction of cardiac disease. By selecting the most optimum model, hyperparameter optimization for the LR, SVM, and RF algorithms used to identify heart disease helped to generate models with greater performance. Stated differently, hyperparameter optimization is a crucial stage in developing the best possible machine learning model. Additionally, it outperformed the literature in predicting CAD (Shorewala et al., 2021).

The literature has a large number of research on the prognosis of cardiac conditions. Algorithms including J48, K Nearest Neighbors (KNN), Decision Tree, and Naive Bayes (NB) were employed for heart disease identification in a research by Bahrami and Shirvani (2015). J48 had the greatest accuracy (83.732%). In a different study, Ashari et al. (2013) used data mining classification approaches to predict the proportion of a person who has cardiac disease. The study assessed cardiac illnesses using the Decision Tree, KNN, and Naive Bayes (NB) algorithms. According to Ashari et al. (2013), NB had the best accuracy (73.7%) in the classification of cardiac disorders.

Mansoor et al. (2017) investigated the efficacy of LR and RF classification algorithms in determining the risk exposure of patients with CVD. They proved that the LR Model performed better than the RF classification method. According to Mansoor et al. (2017), the LR Model's accuracy was 89%, while the RF Model's accuracy was 88%. To categorize cardiac illness, a separate paper Random Forest technique was employed. In the test dataset, they had an accuracy of 84.448% when classifying new and unknown

patients (Buettner et al., 2019). As a result, the RF method may be suggested for future use in the creation of prediction models for various ailments, including the heart.

2.2.6 Coronary angiography as a diagnostic tool for coronary heart diseases

The radiographic imaging of the coronary arteries following the injection of radiopaque contrast material and captured in digital radiography pictures is known as coronary angiography. Most often, specialized intravascular catheters are used during the procedure. The process is often part of a cardiac catheterization, which may also include left ventricle and aortic angiography, among other arterial systems. Determining the coronary architecture and the level of luminal blockage in the coronary arteries is the aim of coronary angiography (Escudero et al., 2021).

It is most frequently used to examine the appropriateness and feasibility of different kinds of therapy, such as revascularization by percutaneous or surgical techniques, as well as the existence and severity of obstructive CAD. It is also employed in situations where the diagnosis of coronary disease is ambiguous and noninvasive methods are unable to conclusively rule out coronary disease (Writing Committee Members, 2022). The gold standard method for diagnosing CAD is coronary angiography. It is most frequently carried out using the trans-femoral approach (TFA). Because of its improved patient comfort and decreased incidence of vascular complications, the Trans-Radial Approach (TRA) has gained popularity in our nation in recent years (Aldoori et al., 2019).

The catheter inadvertently slid into the right coronary artery during Mason Sones' aortography by injection, providing the first direct angiographic picture of a coronary artery in a living patient. Melvin Judkins later used a percutaneous femoral approach, whereas Sones systematically developed the technique by brachial dissection

(Al-Hijji et al., 2019). Since then, coronary angiography has become one of the most popular clinical procedures for IHD due to significant advancements in technology, primarily in the radial artery approach, guidewire and high flow catheter technology, and digital imaging techniques (Brener et al., 2017).

This operation typically takes 20 to 40 minutes to complete and is fairly well tolerated. To put it briefly, a vascular catheter is placed into the radial or femoral artery using a 2 mm vascular introducer and a percutaneous approach under local anesthetic. According to Al-Hijji et al. (2017), premade catheters make it simple to engage the coronary arteries and acquire pictures by employing a contrast agent. Patients may require pretreatment with heparin 50–100 U/kg and intracoronary nitroglycerin as needed, and they may also be anesthetized. Digital radiography captures images of both coronary arteries at various angles. The catheters and introducers are withdrawn at the conclusion of the surgery or intervention, and external arterial compression is applied—ideally using pneumatic compressors (Escudero et al., 2021).

- **Indication of Coronary angiography**

The clinical condition of the patient will primarily determine the appropriateness of invasive coronary angiography. Determining the diagnosis, prognosis, and course of treatment—with or without coronary revascularization—is the aim in every situation. Acute coronary syndromes that are now present, chronic coronary syndromes, or a regular procedure for direct diagnosis are the three categories of indications (Ibanez et al., 2018 & Mintz et al., 2017). The most obvious reason to have invasive coronary angiography might be an acute coronary syndrome. In the treatment of coronary syndromes, the demonstrated value of arterial reperfusion therapy in this clinical situation and the significance of time have been shown to be crucial. International

recommendations clearly advocate early coronary angiography in the event of an ST-segment elevation myocardial infarction, whether as part of initial angioplasty or after fibrinolysis. Additionally, if the patient exhibits evidence of significant residual ischemia, is clinically unstable, or continues to be symptomatic, the surgery should be performed within the next 12 to 24 hours (Collet & Thiele, 2021).

For individuals with extremely high-risk non-ST-segment elevation myocardial infarction, prompt (within 2 hours) coronary angiography using an invasive approach is advised. For patients who are at high risk, such as those with cardiac biomarkers, signs of ischemia, ST-segment depression or dynamic EKG changes, or any other high-risk clinical variables (GRACE score > 140), coronary angiography should be performed within 24 hours.8 Following this time frame, the choice will be based on the degree of ischemia that has been generated, its progression, and the clinical state (Keykhaei et al., 2021).

Within the IHD diagnostic algorithm, chronic ischemic heart disease (also known as chronic coronary syndrome) presents a higher challenge for clinical decision-making. It becomes evident that an invasive coronary angiography with eventual subsequent revascularization is the appropriate course of action in high or very high-risk patients due to symptoms persistence (severe, progressive, or refractory angina) or severe ischemia with high-risk markers demonstrated by non-invasive tests (Knuuti et al., 2020).

A noninvasive CT coronary angiography is the suggested diagnostic procedure for patients with low-risk or low likelihood coronary atherosclerosis. Nonetheless, the patient has to be referred for an invasive coronary angiography if this diagnostic investigation reveals significant or widespread proximal high-risk illness. Similarly,

invasive coronary angiography is recommended for patients with documented ventricular dysfunction and a history or suspicion of chronic ischemic heart disease due to the likelihood of high-risk lesions and the benefit of revascularization in the majority of these cases (Heo et al., 2014).

The intermediate-risk category presents a more challenging decision, wherein factors such as the patient's desire, comorbidities, symptom characteristics, and the degree and duration of ischemia in each individual instance must be taken into account in addition to the risk profile (Pakkal et al., 2011). Also, there is a kind of tool can help in dealing with CAD patients to guide medical staff for the intervention with them as seen in Figure 2.

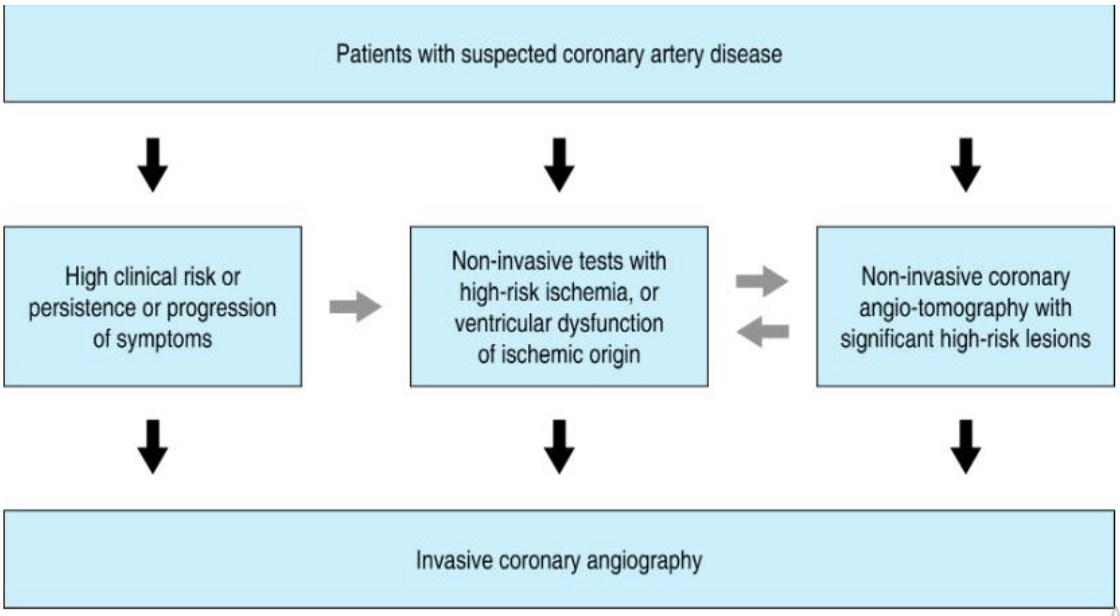

Figure 2: Diagnostic pathways in patients with suspected coronary artery disease. Solid black arrows show the preferred decision algorithm, and alternative personalized options in gray arrows"

A routine operation such as a direct coronary angiography may be indicated by some serious clinical circumstances. Among them are patients with proximal aortic disease with dissection or aneurysm subject to surgery, hypertrophic cardiomyopathy with persistent angina, asymptomatic Kawasaki disease with documentation of coronary aneurysms, and preoperative evaluation prior to cardiac surgery in heart valve disease, prior to cardiac or organ transplantation. Although some labor regulations in high-risk employment in some countries may suggest an intrusive treatment, in this case, non-invasive coronary angiography (CT) has emerged as the primary diagnostic method (Heo et al., 2014 & Knuuti et al., 2020).

- Randomized studies about the use of diagnostic techniques like coronary angiography are rare, although they are frequently accessible for reference in the establishment of treatment guidelines. The following classes (Escudero et al., 2021) compile the indications for coronary angiography:

Class I: “Conditions for which there is evidence and/or general agreement that this procedure is useful and effective”. “ACC/AHA Guidelines for Coronary Angiography: Executive Summary and Recommendations” was approved by the American College of Cardiology Board of Trustees in October 1998 and by the American Heart Association Science Advisory and Coordinating Committee in December 1998. Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of performing the procedure.

Class II: “Weight of evidence/opinion is in favor of usefulness/ efficacy. Class IIb: Usefulness/efficacy is less well established by evidence/opinion.”

Class III: “Conditions for which there is evidence and/or general agreement that the procedure is not useful/effective and in some cases may be harmful”.

The weight of evidence in support of the recommendation for each listed indication is presented as follows: Level of Evidence (Escudero et al., 2021).

- A: The presence of multiple randomized clinical trials. Level of Evidence
- B: The presence of a single randomized trial or nonrandomized studies. Level of Evidence
- C: Expert consensus.

❖ **Complication of Coronary angiography**

Less than 1% of patients experience cardiac problems during a diagnostic procedure. These consequences might include acute MI, stroke, unplanned revascularization, coronary dissection, pericardial effusion, or even death (0.01%). 1.3% of patients with a radical approach and 2.5% with a femoral approach had major bleeding, especially in patients receiving coronary surgery (Tavakol et al., 2012). The patient is often kept under observation in the hospital until the following day; however, in low-risk patients who do not have any problems from the treatment, an early 24-hour discharge according to "outpatient" protocol may be taken into consideration. According to Lun et al. (2021) the process of diagnostic coronary angiography is deemed safe and well-tolerated, resulting in few problems and brief hospital stays.

The likelihood of substantial problems is 2%; however, danger is greatly increased by the patient's state stability, shock, acute renal insufficiency, and cardiomyopathy (Lun et al., 2021 & Tavakol et al., 2012). To lower the risk of complications during coronary angiography, patients with preexisting renal failure—especially those with diabetes—and a history of previous allergic response to contrast medium should get extra care before the procedure (Lun et al., 2021).

In a study was held in Jordan regards RAO, and with 148 participants who underwent TCA, the study was a retrospective case-control design. the primary goal of this study was to assess the occlusion; the study revealed that, thirteen patients (8.8%) had RAO in a median follow-up time of 13 months. Hand disability as measured by Quick Dash score was significantly associated with RAO. This study gives an insight on late RAO after coronary catheterization in Jordan and the region (Al-Makhamreh et al., 2021).

2.2.7 Strategy diagnostic

The European and American recommendations (Joseph et al., 2018) as shown in figure 3, support a Pre-Test Probability (PTP) evaluation with the Duke clinical score and Diamond Forrest model prior to non-invasive testing. PTP for CAD is determined by symptoms, gender, and age. The ESC defines it as low at less than 15%, intermediate at between 15% and 85%, and high at more than 85%. According to Montalescot et al. (2013), the intermediate group is further divided into two categories: (a) 15-65% and (b) 66-85%.

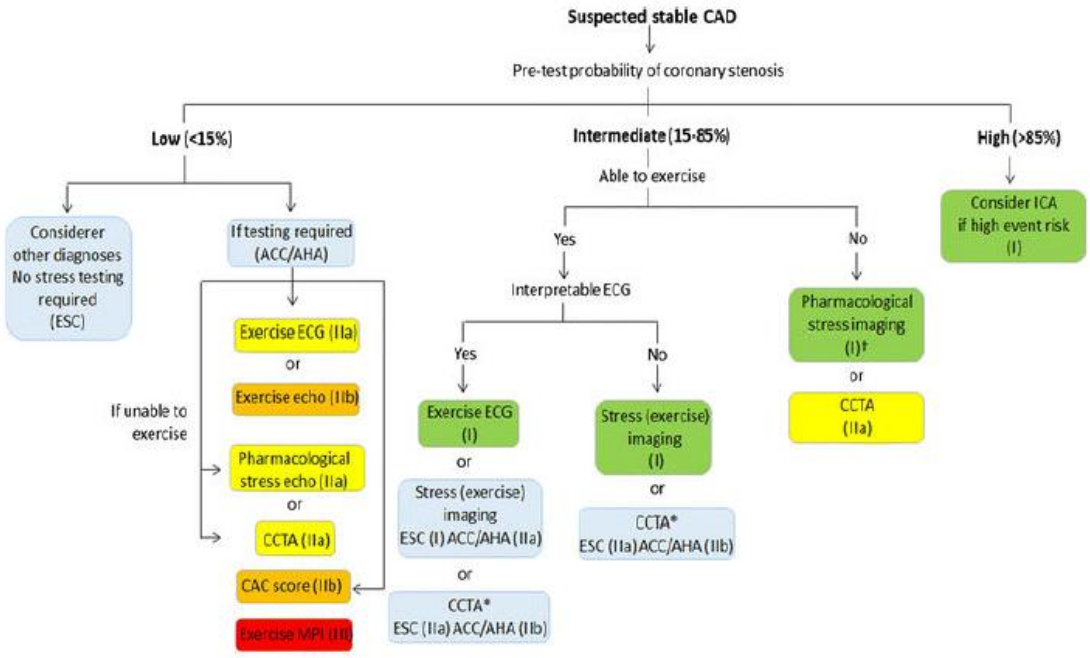

Figure3 : "ESC and ACC/AHA recommendations for stress testing and CCTA in the assessment of patients with suspected stable CAD according to pre-test probability of disease" (Joseph et al., 2018).

2.2.8 Trans-Radial Approach (TRA):

Access via the radial artery has now been shown to be superior to femoral access with less major bleeding and fewer vascular complications, to be more cost-effective with a decreased hospital stay, to improve patient satisfaction, and to reduce all-cause mortality. Trans-radial catheterization has therefore become the accepted standard of practice (Carvalho et al., 2015). The trans-radial approach is, however, not without challenges and complications. Cannulation of the radial artery is technically more challenging, with a steep learning curve to become proficient in the procedure and with higher cannulation failure rates compared to the trans-femoral approach (Alkholi, 2020 & Kolkailah et al., 2018).

Access difficulty may result in complications, with an increase in the number of radial artery puncture attempts being reported to increase the occurrence of radial artery spasm (RAS), radial artery pulsation loss (RAPL), radial artery occlusion (RAO), pain and discomfort (Aldoori & Mohammed, 2019). Bernat et al., (2018) reported one strategy to increase access success which includes dilating the radial artery before cannulation. Various strategies can be used to achieve dilatation including sublingual or subcutaneous nitrates, hand exercises, hand warming, and Flow-Mediated Dilatation (FMD). Flow-mediated dilatation is a physiological process whereby an artery is dilated by increasing the flow through it. This is usually achieved by inflation of a blood pressure cuff above the systolic pressure for some time, with subsequent deflation to restore flow and dilate the vessels (Bernat et al., 2018).

The survey was conducted by Bertrand et al., (2010) from August 2009 to January 2010 among 1,107 interventional cardiologists in 75 countries. Although pre-TRA dual hand circulation testing is not uniform in the world, >85% in the U.S. perform Allen or oximetry testing. The right radial artery is used in almost 90%. Judkins catheters are the most popular for left coronary artery angiographies (66.5%) and right coronary artery angiographies (58.8%). For percutaneous coronary intervention (PCI), 6-F is now standard. For PCI of the left coronary artery, operators use standard extra backup guiding catheters in >65% and, for the right coronary artery 70.4% use right Judkins catheters (Bertrand et al., 2010).

While heparin is still the standard antithrombotic drug worldwide, bivalirudin is widely utilized for PCI in the USA. More than 50% of cases of radial artery blockage go undiagnosed prior to hospital discharge. In all, about 50% of respondents said they will increase their use of TRA in the future (68.4% in the USA) (Aminian et al., 2022). As a result, TRA is already extensively utilized globally. It appears that customized radial catheters are not commonly employed since the diagnostic and guiding catheters used for TRA are comparable to those used for the conventional femoral route. However, there is a lot of diversity in practice when it comes to some elements of TRA, which implies that further information is required to figure out the best way to support TRA and maximize patency of the radial artery following catheterization (Aldoori & Mohammed, 2019).

2.2.9 Complications of trans-radial approach

There is a chance of both intra-procedural and post-procedural issues with the trans-radial technique, despite its reduced complication rates when compared to the transfemoral route. Technical difficulties in using the radial artery to execute operations

can result in complications, especially when accessing tiny, calcific, or morphologically variable arteries. These complications can cause considerable morbidity (Roy et al., 2022).

One of the most frequent side effects of trans-radial cardiac catheterization is radial artery spasm, thus operators need to be aware of the related therapeutic and preventative measures. There is no standard definition for radial artery spasm, which contributes to its varying reported incidence, which ranges from 4% to 20%. Many adreno-receptors in the radial artery wall are considered to play a role in the pathophysiology. These receptors are triggered by catheter manipulation, wall stretching, and local trauma, which increases vaso-reactivity and causes smooth muscle vasoconstriction. When radial arteries have a high (proximal) takeoff from the brachial or axial artery, for example, radial artery spasm is often linked to a tiny radial artery (Roy et al., 2022).

The main complications of TCA still occur despite its exceptional advantages in safety which are mostly manifested as radial artery occlusion, non-occlusive radial artery injury, radial artery spasm, radial arterial perforation, radial artery pseudo-aneurysm, arterio-venous fistula, granuloma formation, access-site bleeding, nerve damage, forearm hematoma development and complex regional pain syndrome along with other rare complications **(**Didagelos et al., 2021; Mangieri et al., 2023; Starke et al., 2020 & Ziakas et al., 2018).

- **Radial artery occlusion (RAO)**

Radial artery occlusion is the most frequent side effect of TRA (RAO). RAO following TRA is frequently not clinically evident because to the existence of dual circulation and significant collateralization via the interosseous arteries to the hand. To safeguard future vascular access, the optimal procedural approach necessitates methods

that permit RA patency (Alkholi, 2020). RAO is frequent; occurrence rates for early RAO within 24 hours are 7.7%, and after a month, they drop to 5.5%. Clinically speaking, an occluded artery is frequently defined as the lack of radial pulse; however, this might underestimate the actual prevalence of RAO.For instance, in one research, the incidence of radial artery flow obstruction (RAO) was determined to be 10.5% when there was no radial pulse, but 4.4% when there was. Therefore, it is advised to utilize an objective approach of radial flow measurement (RAO) utilizing ultrasonography. To bolster this argument, research on the RAO evaluation technique revealed that the incidence of RAO rose from 5.6% to 7.8% when ultrasonography was utilized to identify RAO (Pancholy et al., 2018).

The thrombotic phenomena behind acute arterial blockage is believed to be related to chronic occlusive alterations. The thrombogenic connective tissue is made visible during TRA because to endothelial injury caused by sheath insertion and instrumentation. Additionally, the nidus for thrombus development is provided by blood stasis while establishing hemostasis. Thus, lowering occlusion rates may be achieved by limiting endothelial damage by compression time reduction, employing a small introducer sheath size, and maintaining patent hemostasis (Saito et al., 2022). The frequency of blood flow decrease is much lower when the ratio of the radial artery inner diameter to the cannulated sheath outer diameter is less than 1.0 (artery/sheath diameter ratio >1), according to research on the association between arterial blood flow and sheath size outer diameter (Levine et al., 2011).

Numerous baseline patient attributes, including gender, age, and body mass index, as well as procedural factors including the ratio of the artery to sheath, the use of heparin, and the length of compression, have been linked to RAO (Pancholy et al.,

2018). The timing of the post-procedure evaluation of radial artery patency affects the occurrence of RAO. Acute RAO rates are greater in the short term and go down with time. The PROPHET trial found that the passage of 28 days (7%) nearly decreased the acute incidence of RAO (12%) (Masoudi et al., 2017).

Based on these findings, this study also points to a 28-day drop in the incidence of RAO, from 7.7% to 5.8%. The radial artery's natural recanalization can account for the gradual decrease in the incidence of RAO. Activation of initial fibrinolysis results in recanalization. By releasing tissue plasminogen activator and uro-kinase, the injured endothelium makes fibrinolysis possible (Rao et al., 2018). A previously published TRA consensus statement recommends total intra-procedural anticoagulation and MOPH during sheath removal since these therapies have been repeatedly shown to reduce RAO during TRA. Recent research shows that preventive simultaneous ipsilateral ulnar artery compression also lowers risk of radial artery disease (RAO; Mason et al., 2018).

Ulnar compression, as opposed to MOPH alone, decreased 30-day RAO from 3.0% to 0.9% in a Randomized Control Trial (RCT) involving 3000 patients having diagnostic angiography with 5F sheaths (P=0.0001) without demonstrating hand ischemia. In a different (RCT), ipsilateral ulnar compression (rather than MOPH alone) decreased RAO from 5% to 0% in 240 patients having diagnostic or interventional procedures with 6F sheaths (P=0.01) (Brunet et al., 2020). About 50% of RAOs that are detected early on following compression and hemostasis will recanalize in the next one to three months. According to certain research, restoring radial patency for one hour may be enhanced by ipsilateral ulnar compression. Recanalization may also be aided by administering systemic anticoagulation (such as low-molecular-weight heparin) for a month (Hulme et al., 2017).

After TRA, achieving hemostasis is very easy since the artery is shallow and easily compressed. In an effort to lower the incidence of RAO, the idea of patent radial artery hemostasis has lately gained popularity. The fact that 50% of TRA operators do not determine the occurrence of RAO prior to hospital release is a little unexpected. Because RAO is often asymptomatic and temporary, many operators are likely prejudiced (Hulme et al., 2017).

Hospitalized patients can be discharged or transferred to referring facilities the same day thanks to TRA's quick hemostasis and prompt ambulation following treatment, which makes it easier than with FA. Even in individuals with ACS, a few randomized trials have validated the safety of outpatient care following simple PCI. Even with established safety, same-day discharge or transfer may have a number of unfavorable motivations, and further study is needed to advance outpatient care (Romagnoli et al., 2012).

❖ **Bleeding complications**

Approximately, 1.2% to 16% of individuals experienced bleeding problems. Both significant and mild bleeding episodes were linked to an increased risk of both short- and long-term mortality, even if the definition of bleeding, the underlying patient risk, and the use of concurrent antithrombotic medications varied among studies. Slightly fewer than half of bleeding episodes in patients having PCI were due to the access site. Burzotta et al. (2021) found that both access site hemorrhage and non-access site bleeding were linked to higher fatality rates, despite the former having a better prognosis. Observational studies reported a lower rate of both minor and major bleeding complications associated with TRA compared with TFA, whereas RCTs demonstrated a reduction in bleeding events with TRA that was driven largely by lower rates of minor

bleeds (Iqbal et al., 2014; Généreux et al., 2011; Fefer et al., 2014 & Kadakia et al., 2015).

Radial Versus Femoral Access for Coronary Intervention, an international multicenter study, found no statistically significant difference between TRA and TFA for serious bleeding defined by protocol. On the other hand, the trial's major bleeding rate was very low overall (<0.5%), and the rate of bleeding attributable to the access site was also reduced. Major bleeds were less common with TRA (0.6% versus 1.0%; hazard ratio [HR], 0.53; 95% confidence interval [CI], 0.30–0.92), according to a post hoc analysis based on the access site utilized for procedure completion (Kadakia et al., 2015). However, the greater bleeding rate seen in individuals who transitioned from TRA to TFA casts doubt on this conclusion.

The ideal hemostatic pressure weaning procedure is not universally agreed upon. Less time spent compressing led to reduced rates of RAO in the CRASOC I, II, and III investigations (Compression of Radial Arteries Without Occlusion): 9.4% after 4 hours, 4.8% after 3 hours, 3.0% after 2 hours, and 2.3% after 1.5 hours. Shorter compression periods did, however, result in higher bleeding and recompression rates: 1.2% at 4 hours, 3.7% at 3 hours, 5.5% at 2 hours, and 8.4% at 1.5 hours (Dangoisse et al., 2017).

The majority of doctors advise RA compression for 120 to 180 minutes following PCI and for at least 60 minutes following a diagnostic procedure. For individuals receiving continuous intravenous or oral anticoagulation, somewhat longer compression periods can be taken into consideration. It is crucial to assess for wrist or forearm hematomas. If the hematoma is not rapidly found, acknowledged, or treated adequately, compartment syndrome may develop. Venous pooling can occasionally result in discomfort and aggravate compartment syndrome (Dangoisse et al., 2017).

2.2.10 Management of complications of trans-radial approach by heparin

To avoid RAO, procedural anticoagulation is essential. It should be used in conjunction with other procedural best practices, such as maintenance of patent hemostasis (MOPH). Activated clotting time and RAO rate have an inverse relationship. For diagnostic catheterization, the ideal dose of unfractionated heparin is 50 U/kg (up to 5000 U), and both intravenous and intra-arterial injection have comparable effectiveness. Comparable dosages of other anticoagulants, including enoxaparin or bivalirudin, have been shown to be just as effective in preventing RAO as unfractionated heparin (Bossard et al., 2017).

It is less known if warfarin or direct oral anticoagulants, either by alone or in conjunction with heparin, are sufficient for procedural anticoagulation and the prevention of RAO. Although none of the two observational studies showed indications of increased bleeding, they did show inconsistent results about the effectiveness of heparin (50 U/kg) in patients having TRA catheterization with therapeutic international normalized ratio values (Pancholy et al., 2014).

It doesn't appear that heparin usage affects arterial hemostasis when individuals on warfarin treatment undergo TRA catheterization. Therefore, it is appropriate to use supplementary heparin to prevent RAO in individuals with therapeutic oral anticoagulant levels; nevertheless, more research is needed (Bossard et al., 2017). Low Molecular Weight Heparin (LMWH) is another common procedure used to avoid thrombus development and occlusive vascular damage. Lefevre et al. shown in very early research on the function of anticoagulants that heparin injection into the radial artery dramatically decreased RAO (Feray et al., 2010).

Mason et al. (2018) found that lowering the intra-arterial heparin dosage increased the incidence of RAO. When compared to smaller dosages of 2000 to 3000 IU of heparin, they discovered that a dose of 5000 IU was particularly successful in maintaining the patency of the radial artery (risk ratio 0.36 95% CI 0.17–0.76). In the greater heparin arm, there was no observed increase in bleeding risk. Additionally, compared to a diagnostic coronary angiography context, the authors found that the rate of restenosis after percutaneous coronary intervention (PAI) was 4.5% as opposed to 8.8%. This finding may be related to the regular use of dual antiplatelet treatment and anticoagulants such heparin or bivalirudin during PCI procedures (Mason et al., 2018).

A research by Hahalis et al. (2018) examined 102 early RAOs (incidence 5.6%), which were discovered on ultrasonography. Without sacrificing safety, the risk of RAO in the high-dose heparin group was considerably lower than in the standard-dose heparin group (27 [3.0%] vs. 75 [8.1%]; odds ratio: 0.35; 95% confidence interval: 0.22 to 0.55; $p < 0.001$). The time it took for each group to reach hemostasis was comparable. In the high-dose heparin group, about 20 patients required to be treated in order to avert 1 RAO. Our updated meta-analysis of randomized controlled trials revealed a significant benefit of higher over lower anticoagulation intensity, and our integrated database confirmed these results, demonstrating an 80% reduction of forearm artery occlusions in high versus low heparin dose patients (Hahalis et al., 2018).

Also, 15 (3.3%) individuals have the RAO, according to Aykan et al. (2015). In comparison to the 5000 IU heparin group, the RAO in the 2500 IU heparin group was considerably greater (5.5% vs. 1.2%, $p = 0.010$). The independent predictors of RAO in multivariate regression analysis were female gender (Odds ratio (OR) = 66.135, $p = 0.002$, 95% confidence interval (CI) = 4.584–954.131), sheath removal time (OR =

1.496, p < 0.001, 95% CI = 1.254–1.784), and administration of 2500 IU heparin (OR = 9.758, p = 0.034, 95% CI = 1.195–79.695). In multivariate regression analysis, radial artery patency and the occurrence of hypertension were independently correlated (OR = 0.022, p = 0.005, 95% CI = 0.002–0.307) (Aykan et al., 2015).

In Isfahan, Iran, 441 patients who were at least eighteen years old participated in a prospective, randomized, double-blind controlled experiment conducted by Roghani et al. (2016). They were referred for radial access diagnostic coronary angiography. Initially, individuals were randomly assigned to receive a heparin injection of 2500 IU (group A) or 5000 IU (group B). Hemostasis, bleeding, and thrombosis were the three main study outcomes. The incidence of thrombosis was found to be 25.5% in group A vs. 2.3% in group B (P < 0.001), however there were no significant variations in the frequency of hematomas between group A and B. Not a single patient in either group experienced bleeding. After controlling for covariates, the risk of thrombosis was reduced by 95% when 5000 IU of heparin was used (odds ratio (OR): 0.05, 95% confidence interval (CI): 0.02-012). Thus, they came to the conclusion that, while hematoma and bleeding were unaffected, using a low dose of heparin (2500 IU) as opposed to the conventional dose (5000 IU) increased the risk of thrombosis during trans-radial diagnostic coronary angiography (Roghani et al., 2016).

According to Moody et al. (2013), individuals undergoing coronary angiography who received a greater dosage of heparin (100 IU/kg body weight) compared to 5000 IU had a lower incidence of RAO development. They suggested that the incidence of RAO was inversely correlated with the use of greater heparin dosages, with an average of 9000 IU. Furthermore, however, there was no difference in the incidence of RAO

between the two groups receiving 50 IU/kg and 5000 IU of heparin in the Manoukian et al.29 trial with TRA access (Moody et al., 2013).

In a 2017 research, Bossard et al. assessed the safety and effectiveness of brief homolateral ulnar artery compression to accomplish acute radial artery recanalization, as well as the incidence of RAO with two heparin dose regimens following trans-radial coronary angiography. Randomization was used to assign patients sent for coronary angiography to either low-dose heparin (5,000 IU) or very-low-dose heparin (2,000 IU). Hemostasis was achieved upon sheath removal by employing the TR band and a patent hemostasis approach guided by plethysmography.

In the case of RAO, as assessed by duplex ultrasonography 3 to 4 hours after hemostasis, immediate 1-hour ulnar artery compression was applied. Hematomas >15 cm2 were also assessed. The incidence of initial RAO was 5.9% in the 2,000-IU group and 2.9% in the 5,000-IU group ($p = 0.17$), with a compression time of 2.10 ± 0.78 hours and 2.25 ± 0.82 hours, respectively ($p = 0.051$). After ulnar artery compression, the final incidence of RAO was 4.1% in the 2,000-IU group and 0.8% in the 5,000-IU group ($p = 0.03$). The incidence of local hematoma was 2.3% and 3.7% in the 2,000- and 5,000-IU groups, respectively ($p = 0.42$) (Bossard et al., 2017).

In conclusion, acute RAO after trans-radial catheterization can be recanalized by early 1-hour homolateral ulnar artery compression. This simple nonpharmacologic method was effective and safe in patients with very low- and low-dose heparin. Nevertheless, the incidence of final RAO remained significantly lower after a higher anticoagulation level (Bossard et al., 2017). Although heparin administration has reduced the incidence of radial artery occlusion (RAO) during trans-radial coronary angiography (TRCA), the effective activated clotting time (ACT) value for guiding

unfractionated heparin dosing in patients undergoing TRCA is unknown (Bernat et al., 2018).

Therefore, Bernat et al., (2018) conducted a prospective study on four hundred thirty-two patients who were scheduled for elective TRCA in. All the patients received a standard dose of 5,000 IU unfractionated heparin. RAO was found in 29 patients (6.7%). A median ACT of 205 seconds in the RAO group and 265 seconds in the radial artery patent group was detected ($p < 0.001$). The mean procedure duration was significantly longer in the RAO group than in the radial artery patent group (18.55 ± 9.80 vs 11.24 ± 7.07 minutes, $p < 0.001$). There was a negative correlation between end-procedural ACT and procedure duration ($r = -0.117$, $p = 0.015$). In conclusion, shorter end-procedural ACT levels, longer procedural duration, and smaller radial arterial diameter were independently associated with RAOs after TRCA with standard-dose heparin. In prolonged procedures, ACT-based heparin dosing may be useful to overcome RAO (Bernat et al., 2018).

2.2.11 2.2.11 Nursing Considerations and Patient Safety and The Quality Care

In the setting of ACS, nurses who first respond to the patient must be aware of the institution's approach to TRA. Identification bands and peripheral intravenous access should not be placed near the potential puncture site; repositioning these items in the cardiac catheterization laboratory may cause unnecessary delay in door-to-reperfusion time (Gan et al., 2019).

Interventions to reduce RA spasms are important to procedural success and include maintenance of a comfortable temperature and quiet environment during the procedure. Although patient comfort is not always optimal on catheterization laboratory tables, the TRA technique also affords increased flexibility with patient positioning. For

example, the elevation of the torso with the use of a wedge and patient leg movement (knee flexion and hip rotation) are better tolerated with TRA than TFA. This may be of particular benefit in the ACS setting, especially in patients with pulmonary edema or sufficient ongoing chest pain that precludes them from lying flat or still (Wang et al., 2012).

The importance of nurse staffing to the delivery of high-quality patient care and reported that it was a principal finding in the landmark report of the Institute of Medicine's (IOM) Committee on the Adequacy of Nurse Staffing in Hospitals and Nursing Homes: "Nursing is a critical factor in determining the quality of care in hospitals and the nature of patient outcomes" (Karaca et al., 2019).

The rapidly changing health care system, together with recent advances in outcomes research, is stimulating the nursing profession to examine the quality of its services in an empirical, systematic manner. Providing quality health care is a professional responsibility and a patient's expectation. It has traditionally been defined in terms of the structure– process–outcomes health model developed by Donabedian. Nursing-sensitive outcomes reflect "an established or theoretical link to the availability and quality of professional nursing services and may include such variables as health status, patient safety, patient satisfaction, comfort, increased knowledge, and quality of life (Aiken et al., 2021 & Flaubert et al., 2021).

Increasingly, objective evidence is supporting that linkages exist between nursing care and patient outcomes. Most impressive is the beginning evidence of associations between the amount of professional nursing care and positive health outcomes (Needleman et al., 2012). Nurse staffing levels and selected patient outcomes have now been linked in several studies. Recently, in a retrospective study of 700

hospitals in 11 states, Needleman et al6 reported that increased amounts of registered nurse (RN) care were associated with better quality in hospitalized patients. Interestingly, no relationships were found between increased amounts of care provided by licensed practical nurses (LPNs) or nursing assistants (NAs). These staffing studies suggest that lower numbers of RNs are related to higher adverse outcomes in the acute care population (Manzoor et al., 2019).

Preliminary investigations have also suggested that the features or characteristics of nursing interactions with patients lead to improved health care outcomes. A study of 86 acute care medical-surgical patients, demonstrated a link between nurse caring and patient satisfaction. An RN telephonic case management intervention recently demonstrated lower hospital readmission rates and costs and higher patient satisfaction levels in heart failure patients (Manzoor et al., 2019). It is clear that linkages exist between professional nursing and patient outcomes; yet, what specifically accounts for those linkages is unknown. Nursing services are provided around the clock, across many settings, and throughout the health care continuum (Molina-Mula & Gallo-Estrada, 2020).

2.2.12 Patient satisfaction and quality of care

Patient satisfaction is one of the most important indicator of quality of care and it is considered an outcome of healthcare services. Patient satisfaction measurement provided crucial performance information thus contributing to total quality management (Goh et al., 2016; Shinde & Kapurkar, 2014). Total quality management TQM includes professional knowledge, competence, and application of appropriate technology, and the patients' perception of the type and level of care they have received (Özsoy et al., 2017; You et al., 2013).

In today's consumer-oriented healthcare markets, a patient-centered measure of satisfaction with the quality of nursing care received is a major component of hospital quality management systems (Laschinger et al., 2015). Patients need their problems diagnosed and treated properly, their function restored, and/or symptoms relieved. If the results are unsatisfactory, consumers will change the healthcare facility they applied for treatment and care. Patients who are more satisfied with their care are more likely to follow medically prescribed regimens and thus contributing to the positive influence on health (Buchanan, Dawkins & Lindo, 2015; Fröjd et al., 2011).

More satisfied patients are more liable to recommend the hospital to family and friends. Patients' opinions are the best source that can tell the providers what is important, that is why this information can be used in healthcare planning and evaluation. All these changes and developments in the healthcare field require restructuring of all healthcare services, including nursing, through questioning the quality of treatment services (Alsaqri, 2016; Merkouris et al., 2013 & Şişe, 2013).

Patient satisfaction is a concrete criterion for the evaluation of health care and therefore quality of nursing care. It provides crucial information for healthcare managers by providing important resources for processes such as those involved in measuring patients' expectations and satisfaction with nursing care quality, improving nursing service quality through the identification of areas of failure, and planning and implementing necessary training (Abdel Maqsood et al., 2012; Gadalean & Cheptea, 2011; Geçkil, Dündar & Şahin, 2018).

Nursing care is one of the major components of healthcare services. Patients' satisfaction with nursing care has become established as the most important predictor of overall satisfaction with hospital care and an important goal of any healthcare

organization (Goh et al., 2016; Mohanan et al., 2010 & Reck, 2013). Measuring patients' satisfaction with nursing care could be effective in improving nursing service quality by facilitating the creation of standards for care while monitoring both results and patients' perceptions of quality. The nurses have a central role in offering emotional and psychological support to patients and their families in all settings, such as supporting the patient through diagnosis and ensuring optimum care is given to them. Besides the provision of technical care, nurses must have the qualified professional knowledge, attitudes, and skills, to provide the informational, emotional, and practical support (Akhtari-Zavare et al., 2010; Buchanan et al., 2015 & Goh et al., 2016).

If healthcare organization managers can identify patient expectations, they could accordingly adjust the performance of services that they offer to meet these expectations. The surveys in health services concerning health satisfaction are carried out to evaluate patient satisfaction, to learn patient's expectations, suggestions and feedback, make the quality improvement constantly in all service periods, to search the effects of socio-demographic and treatment periods on patient satisfaction (Buchanan et al., 2015).

That is why patient satisfaction should be measured constantly using valid, reliable assessment instruments to assess care quality, identify variables that affect care, and determine which items should be prioritized and which require alteration in the service based on patients' responses (Buchanan et al., 2015 & Merkouris et al., 2013). A good assessment instrument measuring the factors that determine patient satisfaction should be developed to improve nursing service quality. Therefore, the findings of nursing management research should be used as an indicator of the contribution made by nursing to the patient care process and this could aid the advancement of the profession in terms of identification (Alsaqri, 2016; Freitas et al., 2014 & Goh et al., 2016).

Measures of patient satisfaction can assess communication in the consultation such as information transfer, patient involvement in decisions, and reassurance. Effective and continuous interaction and communication are critical determinants in patients' satisfaction, hospital stay, and recovery (Koç, Sağlam & Şenol, 2011). Health professionals' communication skills play a pivotal role in ensuring that patients feel valued and cared for. The allocation of sufficient time for talking and listening to patients and providing information is a prerequisite for patient satisfaction, as it ensures that patients are less stressed and more engaged and well-adjusted. There is evidence that health professionals are perceived as communicating well when the patient feels he/she shows individualized interest, understanding, and reassurance (Negarandeh et al., 2014).

A study by Abdel Maqsood et al., (2012) indicated that patients were more satisfied with having respectful communication whereas they were less satisfied with the professional information provided by the nurses about their disease, health status, investigations, and prognosis of their condition (Abdel Maqsood et al., 2012). In a meta-analysis conducted by Özsoy et al. (2017), patients expected favor, attention, understanding, kindness, and helpfulness from individuals providing care services. In our study, the highest level of satisfaction, represented by Patient Satisfaction with Nursing Care Quality (PSNCQQ) scores, was reported for the "Concern and Caring by Nurses" item. The results indicate that the nurses' communication style is to treat patients respectfully and be friendly toward them. However, the nurses were less interested in explanations about their interventions and communication with patients that did not meet their expectations (Özsoy et al., 2017).

Nurses and other healthcare professionals play a key role in providing support and information. Nurses care for patients on a 24-hr basis and should be empowered to provide requisite information and instructions to the patients. Patient education has been linked with positive clinical outcomes such as improved adherence to a therapeutic regime, reduced anxiety, and enhanced ability to cope with symptoms (Alhusban & Abualrub, 2019; Shinde & Kapurkar, 2014). It is known that receipt of adequate information affects patients' confidence and satisfaction and this is the most important factor in encouraging patients to participate in their health care. In addition, providing patients and their families with information about patients conditions is important in helping them overcome their fear of the unknown (Dzomeku et al., 2013; Koç et al., 2011 & Milutinovic et al., 2012).

Several studies have reported inadequacies in information provision. For example, Dzomeku et al. (2013) found that the type and amount of information provided by nurses about patients' conditions constituted one of the main causes of dissatisfaction. In a meta-analysis conducted by Özsoy et al. (2017), the patients' most important expectation concerning care quality was that they should be informed about medication and treatment. Patients reported that information played an important role in their satisfaction and they emphasized that information provided by nurses should be clear and concise. Therefore, nurses must realize that information provision and education are nursing responsibilities and that they should collaborate with other healthcare staff to provide complete and relevant information to patients (Dzomeku et al., 2013 & Özsoy et al., 2017).

Abdel Maqsood et al. (2012) indicated that the patients had low levels of satisfaction with information and instructions given by nurses and nurses had the

perception that “information giving” was the role of the physicians and the nurses may be fearful to provide information because of the power hierarchy between the nurses and the physicians. In this study, the lowest level of satisfaction, represented by PSNCQQ scores, was reported for the “Information You Were Given” explanations about tests, treatments, and what to expect” item. This result indicates that the explanations and information provided by nurses at the hospital were unsatisfactory in the nursing care (Abdel Maqsood et al., 2012).

Aiken et al., (2021) performed a cross-sectional survey and reported that patients’ perceptions of care were significantly eroded by lack of confidence in either nurses or doctors and by increases in missed nursing care. The average number of types of missed care was negatively related to six of the eight outcomes—ORs ranged from 0.78 (95% CI 0.68 to 0.90) for excellent care ratings to 0.86 (95% CI 0.77 to 0.95) for medications completely explained—positively associated with higher patient-to-nurse ratios (b=0.15, 95% CI 0.10 to 0.19), and negatively associated with better work environments (b=−0.26, 95% CI −0.48 to −0.04) (Aiken et al., 2021).

Manzoor et al., (2019) conducted a study to measure the health care services, like laboratory and diagnostic care, preventive healthcare, and prenatal care, to patient satisfaction in the public health sectors of Pakistan. A descriptive survey research design was used for this study. The target population was patients from the Out-Patient Department (OPD) of three public hospitals. The main results of the regression analysis validate that healthcare services, such as laboratory and diagnostic care, preventive healthcare, and prenatal care, have a significant and positive effect on patient satisfaction. Specifically, the study suggests that the physician’s behavior significantly moderates the effect of healthcare services on the satisfaction of patients. The overall

opinions about the satisfaction level of patients with the availability of health services in the hospitals were good. The degree of satisfaction was satisfactory concerning laboratory and diagnostic care, preventive healthcare, and prenatal care services. Based on the outcomes, the study confirms that the proposed hypotheses are statistically significant. Furthermore, the directions for future research of the study are offered (Manzoor et al., 2019).

2.2.13 The Impact of diagnostic angiography on patient satisfaction and Quality of life

The number of patients undergoing PCIs will continue to increase. After an angiogram, an important aspect of a positive diagnosis of CHD is the effect it may have on one's health-related quality of life (HRQOL). In the last decade, the effectiveness of cardiovascular therapies has frequently included the measurement of HRQOL. There is compelling and increasing evidence that HRQOL, which includes physical, psychological, and social domains, is associated with the diagnosis of CHD, its progression, and the outcomes of its treatment. Even when procedures, such as PCI or coronary artery bypass graft (CABG) surgery, provide effective revascularization of the heart, residual physical or psychosocial limitations and the diagnosis of CHD itself may alter patients' HRQOL (Spertus et al., 2014 & Safley et al., 2014).

Fernandez et al., (2017) reported several factors which are known to moderate HRQOL in the context of chronic disease, including CHD. After being diagnosed with CHD, patients experience lower levels of perceived control and higher levels of depression and anxiety. The uncertainty and change associated with the diagnosis of CHD are believed to threaten a patient's sense of control over health and life in general. In diverse populations, researchers have shown that this loss of control is associated with

impaired psychosocial adjustment, including more anxiety and depression, and diminished self-esteem (Fernandez et al., 2017).

Additional factors reported by Lee (2019) such as divorce or the loss of a loved one, are considerable life stressors and may negatively affect one's recovery and HRQOL. Although studies of HRQOL in patients with CHD have reported clinical endpoints of treatments, few studies have examined the role of the angiogram experience about HRQOL (Lee, 2019). Initial longitudinal studies of HRQOL in patients post-angiogram followed only patients with positive test results, that is, clinically significant CHD. Virtually nothing is known about the effects of the angiogram experience on HRQOL in individuals whose test results are negative, which in this study is defined as a finding of normal coronary arteries or clinically insignificant disease. Such individuals may remain symptomatic with chest pain but are left with no identified cause of their symptoms (Eastwood et al., 2017).

The findings regarding HRQOL indicate that differences between CHD-positive and CHD-negative patients are confined primarily to generic mental health aspects of HRQOL (MCS) and to the disease-targeted aspects of HRQOL, Cardiac - Quality of Life Index (CQLI). The mental health composite summary (MCS) responses of CHD-positive patients were consistent with population norms (Zaid et al., 2020). In contrast, despite improvements over time, CHD-negative patients remain below MCS population norms at all time points. Similar patterns were noted for the disease-specific HRQOL (CQLI). A possible explanation for these patterns is that younger patients, later found to be CHD-negative, may have questioned assumptions about their health more than older patients, in whom catheterization results were positive (Alshrbaji et al., 2022).

If CHD-negative individuals had symptoms before the angiogram, receiving negative results on the heart catheterization rendered them no definitive answers. Thus, CHD-negative patients may have interpreted their angiogram results as bad, rather than good news. In contrast, CHD-positive patients may have experienced a different trajectory because the solution to their symptoms was clear and definitive treatment was offered (Eastwood et al., 2011 & Mou, 2012).

It has been reported that patients undergoing revascularization treatments share the perception that the treatment is curative. It is possible that they did not understand the chronic nature of their illness. Between-group differences over time in the physical health component of HRQOL for CHD-negative and CHD-positive patients were not significant. Unlike previous studies, there was no significant improvement in physical health scores after receiving medical, interventional, or surgical treatment (Eastwood et al., 2011 & Mou, 2012).

This finding was surprising in light of previous studies. Most trials have shown a greater increase in physical health status in CABG compared with PCI; however, both procedures have been reported to improve physical function in patients with CAD. One of the most important determinants of physical health status is angina (Rafferty et al., 2017 & Zaid et al., 2020). Within the course of this study, drug-eluting stents were approved for use in the USA, so many of the patients had the benefit of newer technological advances. In addition, adjunctive medication is now on the market, which dramatically decreases the likelihood of angina and restenosis in patients who undergo PCIs. The interaction of age, hypertension, depression, and anginal symptoms may have played a factor in the low scores in the CAD-negative group (Lee, 2019).

Although there have been no previous studies that compare HRQOL in pre- and post-angiogram patients with and without diagnosed CHD, several large clinical trials testing specific treatments have evaluated changes in HRQOL over time. Although these studies were designed to test specific treatments (ie, revascularization by PCI vs CABG), they may inform the current findings. In these studies, investigators reported that pre-PCI appraisal of HRQOL predicted later post-PCI adverse outcomes (Griffiths et al., 2016).

2.2.14 The impact of TRA and related patient care on healthcare costs

There have been numerous developments in the field of medical care such as fitness and health bands. Furthermore, devices such as electrocardiograms and CT scans help in the detection of CHD. However, the high cost and infeasibility of these machines are major factors that have led to the death of 17 million patients due to CHD annually (Safley et al., 2013). The impact of TRA and related patient care pathways on healthcare costs is an evolving topic and the focus of active investigation but is also limited in data specific to the management of patients with ACS. Current data suggest that cost savings related to TRA are derived primarily from lower vascular and bleeding complication rates, shorter average intensive care unit and hospital lengths of stay, and minor differences in procedure costs (Safley et al., 2013).

A meta-analysis of 14 studies demonstrated that the benefits of TRA in terms of lower complication rates and shorter hemostasis time outweighed the potentially longer procedural time and higher crossover rates and resulted in an estimated direct cost saving of $275 per patient (Ratib et al., 2015). A subsequent retrospective analysis of a large national administrative hospital database showed that the use of TRA in PCI decreased overall costs by $533 (95% CI, 445–1010; P=0.033). Although “day of” costs

between TRA and TFA PCI were not different, costs from the procedure to hospital discharge were significantly lower for patients undergoing TRA. Furthermore, there was a graded increase in cost savings according to bleeding risk, with a $1621 cost savings with TRA (95% CI, 271–2971; P=0.039) in patients at high predicted bleeding risk such as those with ACS. In a small RCT of patients undergoing PCI for ACS, TRA was associated with a decrease of 1.5 days in hospital stay and a decrease from $23 389 to $20 476 in hospital charges (Amin et al., 2013).

In the RIFLE-STEACS trial, time spent in the intensive care unit and overall hospital length of stay was significantly lower in patients randomized to TRA compared with those randomized to TFA. Similarly, a small RCT in patients with ST elevation Myocardial Infarction (STEMI) in Poland demonstrated that compared with TFA the TRA approach was associated with shorter length of stay, lower cost of therapeutic success, and lower indirect patient costs (Mitchell et al., 2012). Finally, a recent analysis of patients undergoing PCI for stable and unstable CAD in the National Cardiovascular Data Registry demonstrated an adjusted cost difference of $916 (95% CI, 778–1035) in 2014 US dollars with TRA compared with TFA (Amin et al., 2017; Hess et al., 2015).

CHAPTER THREE

METHOD

3.1 Introduction

This chapter illustrates the research methods employed in the study, including the research design, questionnaire design phases, setting, population and sample, study instruments, data collection procedures, measures, data analysis and ethical consideration of the study. Research methods must address the research questions and subsequently lead to the achievement of the research objectives.

3.2 Study Design

The design was RCTs, including posttest, and follow-up to find a cause-and-effect association between an independent and dependent variable. The participants were assigned to groups based on simple random criteria of exposure between the given high doses of heparin contrasted with the standard dose.

Randomized controlled trial aim to evaluate interventions and to demonstrate causality between an intervention and an outcome. Randomized controlled trial studies can use both pre-intervention and post-intervention measurements as well as randomly selected control groups (Maciejewski, 2020).

3.3 Study Setting

This study was conducted at Specialized Arab Hospital (SAH). The SAH is considered one of the most important private and referral hospitals in the North West Bank and is located in the Nablus city in the Rafidia area. The hospital was established

in 1998 and was in rapid development with the opening of medical departments and the increase of subspecialties. The cardiology center at the SAH was opened in 2005 and contains a cardiac catheterization department and a cardiac care department, intermediate care, and an efficient and distinguished medical and nursing staff.

Currently, the cardiology center contains a cardiac catheterization operating room, an intensive and intermediate cardiac care department with 12 beds, an open-heart operating room, and a cardiac surgical intensive care department with 6 beds. The heart center consists of 35 nurses with advanced degrees and distinguished nursing experience, and it includes a staff of specialists in cardiac catheterization and cardiac surgery. The heart center receives patients 24 hours a day, seven days a week, with a monthly admission rate of 180 patients whose health condition ranges from moderate to good.

3.4 Population, sample, and sampling

The targeted participants of the study were any patient admitted for cardiac catheterization in the SAH between April and August 2023.

3.4.1 Inclusion and Exclusion Criteria

- **Inclusion criteria:**

1. Patients with clinical indications need coronary angiography;
2. The participants evidently showed that they were patients who experienced coronary angiography by the radial artery.
3. The intra-invasive operative heparin medication dose of the involved control group was lower heparin dose (2000IU-3000IU or 50IU/kg), the intervention group gave more heparin medication dose (5000IU-7000IU or 100IU/kg);

4. Allen's test was negative.
5. The patients with normal blood coagulation, liver, and kidney function tests.

- **Exclusion criteria**

1. A significantly growing risk of bleeding such as severe liver and kidney inadequacy, and peptic ulcers or active bleeding.
2. Medical history of inadequate radial artery access and severe peripheral vascular disease.
3. Allen's test positive.
4. The patients with a chronic malignant tumor or wasting disease.
5. The patients with an allergy to contrast media or iodine substances.
6. The patients with uncontrolled severe arrhythmia (rapid atrial fibrillation, ventricular arrhythmia, etc.).
7. The patients used other anticoagulants previously and through the invasive operation.

In this study, sample of targeted patients who met the study criteria enrolled in the study. Random assignment used to ensure that each participant has an equal chance to be assigned to any group (an intervention or control groups) according to the admission number. Therefore, the head nurse of the department prepared admission numbers list for the patients and assign randomly the first number in the number' list to the intervention group and then the second one to the control group in an alternative process. The same process repeated until the desired sample size was achieved.

3.4.2 Sample Size Calculation

The sample of the study was calculated using G*Power that allowed for determining the sample size required to obtain adequate power to detect differences

between the groups. Sample size depends on power, alpha, and P level of significance, confident interval and effect size determinations. Power used to estimate the sample size needed to obtain significant results between the two groups (Polit &Beck, 2014).

The high-power values are desirable; at least 80% is preferable. Power proportionately increases as the sample size for the study increases. The P value defined as "the statistical significance testing, that evaluates differences between what we expect on basis of our hypothesis and what we observe" (Munro, 2005, p. 91). While, confidence interval defined as "the degree of confidence expressed as a percent and indicates the likely range of values for the true effect in the population" (Munro, 2005, p. 95). The effect size is the difference between two groups or more based on some treatment or intervention (Polit &Beck, 2014).

The G*power version 3.0.10 used to estimate necessary sample size to obtain significant results between the two groups (Munro, 2005). Using a calculated medium effect size of 0.5 based on nursing research (Polit &Beck, 2014) for Mann- Whitney test to determine the differences between means of the two groups, an alpha of 0.05, and power of 0.95 which is recommended (the higher desired power the more subjects required) based on the assumption of an expected difference resulted in a sample of 64 participants per group (Munro, 2005). The total sample required was 220 participants. To overcome the attrition rate and who refuse to participate, the final sample was 289 participants, 143 participants received standard heparin dose and 146 received high heparin dose. Random by assignment done to choose intervention group and control group, this done by using Excel sheet before collecting data; Then, the patient file numbers were transcribed into an Excel file that had been previously prepared and the file contained patient name sent to the doctor to start the procedure. The heparin dose

given by the physician and evaluation done blindly without knowing participants from control or intervention.

3.5 Tool Instrument

The data were collected through questionnaire (Appendix 3). The study instrument was designed by the researcher after critical literature review, it consists of 66 items. The questionnaire contained four parts as follows:

The first part was regarding sociodemographic data it consists of 9 items (age, gender, residency, marital status, sedentary life style as smoking and physical activity, type of diet, and information regarding weight, height, and Body Mass Index BMI).

The second part consists of 34 items includes (patient health history includes past medical history, using of medications, and lab test such as Hgb, cholesterol level, PT, PTT, INR, and RBS).

The third part consists of 14 items includes (the angiography procedure includes an indication of angiography, access site, previous stage access sites, heparin dose, puncture duration, fluoroscopy duration, and the number of catheters).

The fourth part consists of 17 items includes (quality and safety after removal of the radial sheet that include site complications of the current procedure as RAO, (TRB) removal time, length of hospital stay (days), and patient's satisfaction with the quality of care).

3.6 Validity

Face and content validity was applied in this study, The initial draft of the questionnaire was validated by sending it to five professions, three were cardiologists

and two researchers and professionals from nursing and medical background to give their expert opinion with respect to its simplicity, relativity and importance. Suggestions were incorporated into the instrument and the needed modifications were completed.

3.7 Intervention

The researcher used an experimental design, the data was collected through a post-test measurement. The researcher applied examinations on a patient who had cardiac catheterization, and radial artery investigation by using the Allen test which is accomplished with physiological testing by using manual pressure on the radial artery and documents the outcome on the time of the blood backflow. Assessment of collateral circulation to the hand is essential for previously invasive procedures or the gathering of the radial artery. A modified Allen's test (MAT) is frequently used to measure palmar arch collaterals. A variety of non-invasive approaches contain digital pressures (Habib, Baetz & Satiani, 2012). Then palpation documentation for the pulse was completed and the researcher examined the artery blood flow and radial artery occlusion posttest through an ultrasonography scan for artery patency and the existence of any obstruction or occlusion.

3.8 Ethical Consideration

Before the beginning of the research study, ethical approval was obtained from the Arab American University With archived no. (2023/C/112/N) as well as from the Ministry of Health. Written permission (informed consent) for participation was obtained from each participant. All ethical issues of research were continued and participation was voluntary. Participant confidentiality was assured. Ethical principles incorporate the avoidance of deception and confidentiality. This procedure was

anonymous and Participant identification was not presented during the study stages (data collection, analysis, or reporting of study findings). The procedures have been explained to the participants and voluntary issue explained withdrawal allowed any time during study period. Moreover, all information was stored and kept securely and was only accessible to the study team.

3.9 Pilot study:

In a pilot study, the questions are: can things be carried out? Can the investigators move on with it? If yes, how? A pilot study, on the other hand, also has a unique design characteristic; it is carried out on a smaller scale than the primary or full-size investigation. Stated differently, the purpose of the pilot study is to enhance the effectiveness and caliber of the primary investigation. Furthermore, the study aims to evaluate the safety of treatments or interventions, potential recruits, investigate randomization and blinding procedures, enhance the researchers' familiarity with study methodologies, medications, and interventions, and furnish estimates for sample size computation (In, 2017). On the department of cardiac care 10 participants who met the criteria for the study was chosen, questionnaire given to them after the procedure done.

3.10 Study Procedure

The participants were divided into two groups for giving heparin dose: intra-invasive operative use of high-dose (5000IU-7000IU or 100IU/kg) of unfractionated heparin was injected intrathecally for protective anticoagulation as the intervention group, but intra-invasive operative use of standard doses (2000-3000IU or 50IU/kg) of unfractionated heparin was injected intraradial artery for protective anticoagulation as the control group. All patients were evaluated concerning radial artery occlusion

occurrence by using vascular doppler ultrasonography at 30 days' post cardiac catheterization. In whole cases, a 6 F sheath (Terumo, Germany) was located in the right (mostly) or left radial artery subsequently local anesthesia with xylocaine 2%. An altered Allen test with pulse oximetry was accepted out to assess ulnar artery patency previously the radial puncture.

3.11 Data Analysis

Data analysis was executed by using SPSS v 23. Descriptive analysis was conducted and data were reported as percentage, frequency, mean and standard deviation. Significance was set at $p \leq 0.05$ and 95% confidence interval. The Mann–Whitney U, Fisher, chi square tests were used to compare the differences between study variables.

Chapter Four

Results

Introduction

This study examined the effectiveness of using a high heparin dose (5000IU-7000IU or 100IU/kg) contrasted with a standard heparin dose (2000IU-3000IU or 50IU/kg) on the quality and safety post-trans-radial coronary angiography to improve the health outcomes following radial artery catheterization at Palestine.

4.1 Sociodemographic data

The total number of the participants was 289. Looking at the first table (4-1), we find that the age group from 40 to 60 years is the largest age group among the patients participating in the study (67.9%). As for gender, the majority of them are males (71.4%), from Jenin (53.8%), and married (86.2%).

Table 1 : Sociodemographic data

Sociodemographic data

		Frequency	**Percent**
Age (years)	Less Than 40	20	6.9
	40-60	197	68.2
	More Than 60	72	24.9
Gender	Male	207	71.6
	Female	82	28.3
Residency	Jericho	12	4.1
	Salfeet	11	3.8
	Ramallah	14	4.8
	Qalqilia	25	8.6
	Nablus	49	16.9
	Tubas	8	2.8
	Bethlehem	1	.3
	Tulkarm	11	3.8
	Jenin	156	53.8
Marital status	Single	29	10.0
	Married	250	86.2

	Other	6	2.1

4.2 Sedentary Life Style

Table 2 shows that the percentage of smokers among the study patients' participants was high (85.3%), as the average number of cigarettes was 17 and average duration of smoking was 15.8. As for physical activity, unfortunately, few of the study patients' participants practiced daily physical activities (13.4%) at a rate of 3 times a week for a mean period of 152.9 minutes.

As for the weights of the study participants, the majority of them weighed between 60-80 kilograms (71.7%) with a body mass index between overweight and obese that reached (46%). As for the nature of their diet, the majority of them ate a regular meal (76.7%), while a few of them, they adopted low-salt or low-sugar meals (5.2% & 11.7% respectively).

Table2 : Sedentary Life Style

Sedentary Life Style

		Frequency	**Percent**
Smoking	**No**	121	41.7
	Yes	169	58.3
	Smoking Duration	**M (SD):** 15.80 (6.58)	**MIN-MAX**: 2-40
	Cigarette Number	17.05(9.62)	1-40
Physical activity	**No**	251	86.6
	Yes	39	13.4
	Times weekly	**M (SD):** 3.07 (0.80)	**MIN-MAX**: 1=4
	Duration (minutes)	152.97 (107.45)	20=360
Weight	< 60kg	22	7.6
	60-80	208	71.7
	> 80	48	16.6
BMI	Normal	77	55
	Overweight	46	32.9
	Obese	17	13.1
Type of diet	Low Salt	15	5.2
	Low Sugar	34	11.7

	Regular	222	76.6
	Other	19	6.6

4.3 Past Medical History

Regarding the past medical history of the study participants, Dyslipidemia (59.9%), hypertension (52%), and diabetes (28.8%) were the most common, while other diseases such as those related to the kidneys, liver, and organs were Gastrointestinal disorders are the least common among the patients participating in the study, as seen in (table 3).

Table 3: Past Medical History

		Frequency	**Percent**
	None	**12**	**4.5**
1	Dyslipidemia	160	59.9
2	Arterial Hypertension	139	52.0
3	Diabetes	77	28.8
4	Ischemic Heart Disease (I.H.D)	47	17.6
5	Arrhythmia	40	14.9
6	Thyroid Disease	37	13.8
7	Heart Failure (H.F)	26	9.7
8	Respiratory Disease	17	6.3
9	Cancer	12	4.5
10	Liver Disease	12	4.5
11	Kidney Disease	10	3.7
12	Valvular Heart Disease (V.H.D)	9	3.3
13	Gastrointestinal Disease	8	2.9
14	Benign Prostatic Hypertrophy (B.P.H)	6	2.2
15.	Pulmonary valve disease	6	2.2
16	Blood Disorder	5	1.8
17.	Cerebral Vascular Accident (C.V.A)	3	1.1
18	Miscellaneous	11	4.11

4.4 Use of Medications

As for the medications used by patients participating in the study, ASA (81.1%) and statin (56%), followed by ACE (46.1%) and Beta Blockers (35.7%) were the most frequently used by patients participating in the study, as seen in (table 4).

Table 4: Use of Medications

Medications	Frequency	Percent
None	12	4.4
ASA	220	81.1
Statins	152	56.0
ACE	125	46.1
Beta Blockers	97	35.7
Clopidogrel	49	18.0
Prasugrel	35	12.9
Ticagrelor	11	4.0
Anticoagulant	8	2.9
Thrombolytic	3	1.1
Others	173	63.8

4.5 Lab Test Result

As for the laboratory results of the patients participating in the study, Table (5) shows that their cholesterol result was high at (21.7%), while blood Hb was at a mean of 14.16. Also, the average laboratory results for blood coagulation was 14.97 for PT, 24.03 for PTT, and the mean for INR was (1.30). As for random blood sugar, the mean was 118.55 with range between 75 -300 mg/dl.

Table 5: Lab Test Results

		Frequency	Percent
Cholesterol	Normal	221	76.2
	High	63	21.7
	Mean	**SD**	**MIN- MAX**
HB	14.16	1.73	7.12-18.00
PT	14.97	3.33	10.00-28.00
PTT	24.03	4.44	16.00-40.00
INR	1.30	.630	.70-9.00
RBS	118.55	27.90	75-300

4.6 Angiography Procedure

Figure (4) shows that unstable angina is the most common indication (73.7%) for cardiac catheterization, followed by STEMI (13.1%). This is followed by NSTEMI

(9.3%), while stable angina (3.8%) is the least common indication of catheterization of the heart coronary arteries.

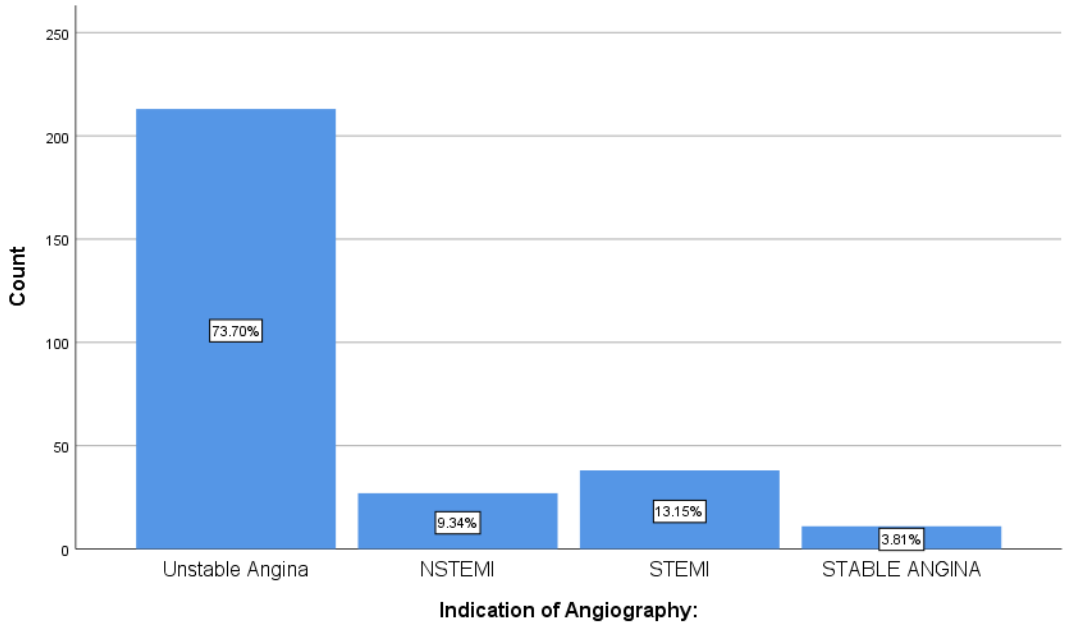

Figure 4: Indication for Angiography

Figure (5) reflects that the right radial artery is the most (94.8%) commonly used as an access site for cardiac coronary catheterization. Followed by femoral arteries and left radial (2.7% & 2.4% respectively)

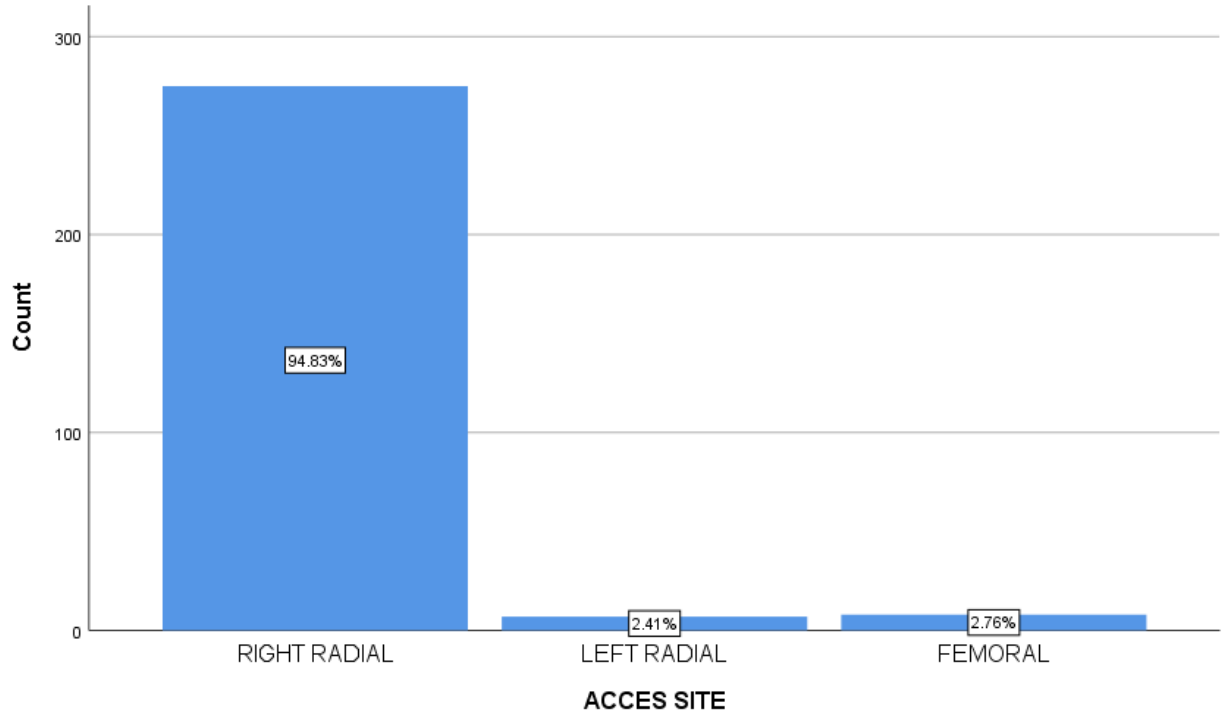

Figure 5: Access Site

Table (6) displays the characteristics of previous cardiac catheterization, which shows that 37.6% had previously performed cardiac coronary catheterization and that 14.5% of them had developed radial occlusion due to the catheterization.

Table 6: Angiography Procedure

		Frequency	**Percent**
Previous Stage Access Site	**No**	178	61.4
	Yes	109	37.6
Radial artery occlusion from previous cardiac catheterization & intervention	**No**	142	49.0
	Yes	42	14.5

Figure (6) shows that the majority (51.2%) of study participants used two catheters. Followed by 36.5 % of them used one catheter.

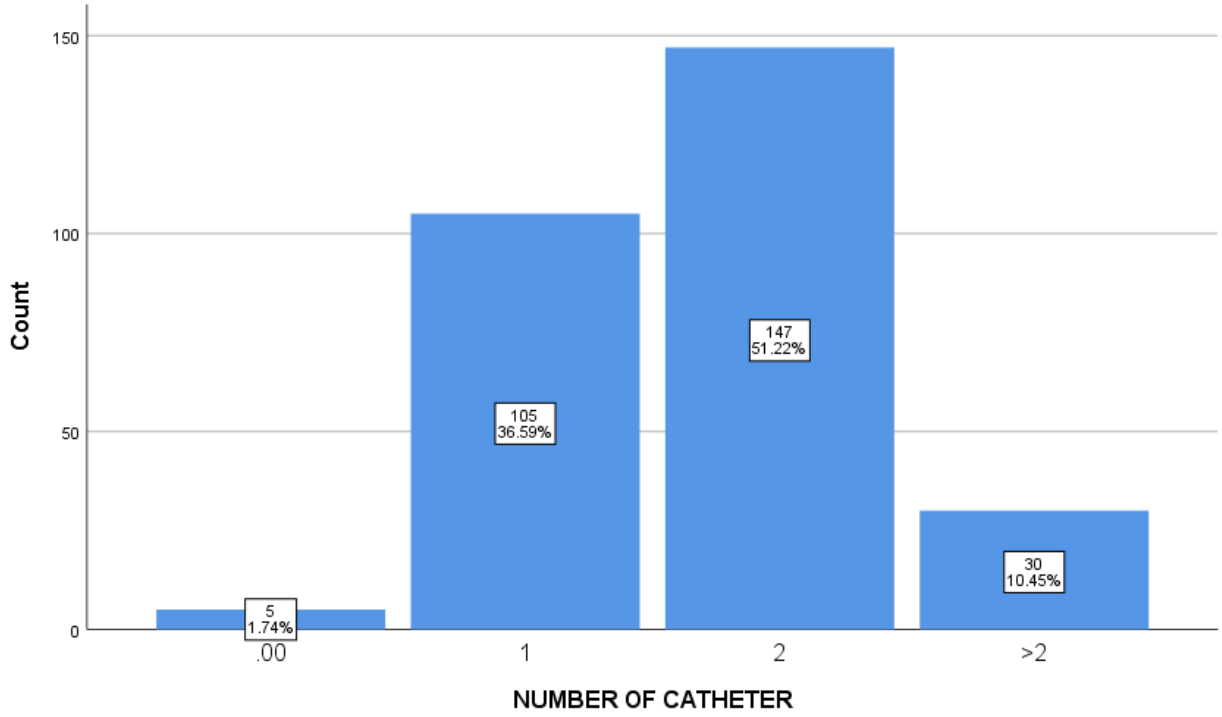

Figure 6: Number of Catheter

4.7 Quality and safety of care

To answer the 1st Research question "What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on quality care and safety (length of the patient's stay, TRB removal time, & patient's feeling of pain) compared with 2000 IU-3000 IU or 50 IU/kg among patients at post-cardiac catheterization?" The Mann-Whitney U statistical test was used.

Table (7) shows the relationship between the dose of heparin (high vs. standard) with the length of the patient's stay in the hospital, the TRB removal time, and the patient's feeling of pain. The Mann-Whitney U statistical test showed that there are no statistically significant differences between the dose of heparin (high vs. standard) and the TRB removal time, although the average time of TRB removal time for patients taking the high dose of Heparin was slightly higher than the average TRB removal time for patients taking the standard dose (3.36 versus 3.22 respectively).

Also, the hospital stay rate was slightly higher among patients taking the usual dose of heparin compared to patients taking the high dose of heparin, and this difference was not statistically significant (*p* value = .095).

As for the patient's feeling of pain, the feeling of pain a month after the catheterization procedure was higher among patients taking the high dose of heparin compared to patients taking the usual dose of heparin, and this difference was statistically significant (*p* value = .011).

While the pain average for patients taking the standard dose of heparin was higher than the pain average for patients taking the high dose of heparin after the second and fourth hours of the catheterization procedure, this difference did not have any statistical significance (*p* value > 0.05).

Table 7: Heparin dose and length of hospital stay, TRB removal time, and pain

	Heparin dose	**N**	**Mean**	**Std. D**	**Mean Rank**	**M-W U**	**Z**	***P* value**
Length of Hospital Stay (Days)	50u/kg (2000-3000 u)	143	1.46	.722	151.18	9139.5	-1.887	**.059**
	100u/kg (5000-7.000u)	146	1.35	.692	136.03			
TRB Removal Time	50u/kg (2000-3000 u)	143	3.22	.988	138.74	9544.5	-1.248	.212
	100u/kg(5000-7.000u)	146	3.36	.734	150.18			
Pain 2hrs	50u/kg (2000-3000 u)	143	4.23	2.284	.191	1.842l®	286	**.066**
	100u/kg(5000-7.000u)	146	3.77	1.924	.159			
Pain 4 hrs	50u/kg (2000-3000 u)	143	1.16	1.710	146.57	10214.0	-.345	.730
	100u/kg(5000-7.000u)	146	.952	1.211	143.46			
Pain Month	50u/kg (2000-	143	.007	.083	140.99	9866.0	-2.548	**.011**

	3000 u)							
	100u/kg(5000-7.000u)	146	.102	.435	148.92			

M-W U: Mann-Whitney U TRB: Trans-radial band

Statistical tests using exact Fisher Test showed that there is no statistically significant (*p* value > .05) relationship between patients taking the usual dose of heparin and high-dose heparin with the occurrence of bleeding from the site of the catheter insertion or from other places, as seen in (table 8).

Table 8: Heparin dose and Bleeding from the puncture site and Bleeding from other sites

		Bleeding from the puncture site 2hrs			
Heparin dose	**Total**	**No**	**Yes**	**X^2**	***P* Value**
50u/kg (2000-3000 u)	143	116	27	2.514	.113
	49.5%	52.0%	40.9%		
100u/kg(5000-10.000u)	146	107	39		
	50.5%	48.0%	59.1%		
		Bleeding from the puncture site 4 hrs			
50u/kg (2000-3000 u)	143	138	5	1.650	.199
	49.5%	50.4%	33.3%		
100u/kg(5000-10.000u)	146	136	10		
	50.5%	49.6%	66.7%		
		Bleeding from other sites 2hrs			
50u/kg (2000-3000 u)	143	142	1	.316	.574
	49.5%	49.7%	33.3%		
100u/kg(5000-10.000u)	146	144	2		
	50.5%	50.3%	66.7%		
		Bleeding from other sites month			
50u/kg (2000-3000 u)	143	142	1	1.025	.311
	49.5%	49.3%	100.0%		
100u/kg(5000-10.000u)	146	146	0		
	50.5%	50.7%	0.0%		

Fisher Exact Test

As for the occurrence of ischemia, statistical tests showed that there is a statistically significant relationship between the dose of the heparin and the occurrence of ischemia after the fourth hour and after a month of catheterization, where the

incidence rate was higher among patients taking the standard dose compared to patients taking the high dose, as seen in (table 9).

Table 9: Heparin dose and Ischemia to the Hand

		Ischemia to the Hand 2hrs						
Heparin dose	**Total**	**None**	**Pale**	**Coldness**	**Weakness**	**Pulseless**	X^2	
50u/kg (2000-3000 u)	143	36	102	80	46	42	16.869	.263
	49.5%	40.4%	40.0%	66.7%	25.0%	50.0%		
100u/kg(5000-10.000u)	146	53	84	60	31	21		
	50.5%	59.6%	60.0%	33.3%	75.0%	50.0%		
		Ischemia 4hrs						
50u/kg (2000-3000 u)	143	68	66	43	32	27	34.820	**.001**
	49.5%	41.5%	36.4%	0.0%	25.0%	75.0%		
100u/kg(5000-10.000u)	146	96	43	24	11	5		
	50.5%	58.5%	63.6%	100.0%	75.0%	25.0%		
		Ischemia Month						
50u/kg (2000-3000 u)	143	105		14	8	25	36.574	**.000**
	49.5%	42.7%		75.0%	66.7%	100.0%		
100u/kg(5000-10.000u)	146	141		4	1	1		
	50.5%	57.3%		25.0%	33.3%	0.0%		

To answer the 2nd Research question "What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on decrease the radial artery occlusion (safety) compared with 2000 IU-3000 IU or 50 IU/kg among patients at post-cardiac catheterization?" Chi-square statistical test was used.

Table (10) shows the occurrence of occlusion post trans-radial cath. While at the 2nd hour both groups (standard & high heparin dose) had no significant difference in occlusion occurrence but the percentage of occlusion was higher among standard dose group in compare with high heparin dose group (22.4% vs. 14.4%). On the other hand, the occurrence of occlusion was significantly differed and higher among standard dose group in compare with high heparin dose group (18.9% vs. 3.4% respectively) at the 4th post Cath (p value <0.001) and (17.5% vs. 0.0%respectively) at one month (p value <0.001).

Table 10: Heparin dose and RAO

			Heparin dose			
		Total	50u/kg (2000-3000 u)	100u/kg(5000-10.000u)	X^2	*p*
Occlusion 2hrs	No	236(81.7%)	111 (77.6%)	125(85.6%)	3.083	.079
	Yes	53(18.3%)	32(22.4%)	21(14.4%)		
Occlusion 4hrs	No	257(88.9%)	116(81.1%)	141(96.6%)		
	Yes	32(11.1%)	27(18.9%)	5(3.4%)	17.528	.000
Occlusion Month	No	264(91.3%)	118(82.5%)	146(100.0%)		
	Yes	25(8.7%)	25(17.5%)	0(0.0%)	27.942	.000

As for the relationship of the dose of heparin with the occurrence of hematoma, statistical tests (Fisher's exact test analysis) showed that there is no statistically significant difference between patients taking the standard dose and patients taking the high dose of heparin with the occurrence of hematoma, as seen in (table 11).

Table 11: Heparin dose and Hematoma Grade

		Hematoma Grade 2 hrs						
Heparin dose	**Total**	**None**	**1.00**	**2.00**	**3.00**	**4.00**		
50u/kg (2000-3000 u)	143	101	36	1	4	1	7.253	.123
	49.5%	53.2%	45.6%	14.3%	33.3%	100.0%		
100u/kg(5000-10.000u)	146	89	43	6	8	0		
	50.5%	46.8%	54.4%	85.7%	66.7%	0.0%		
		Hematoma Grade 4hrs						
Heparin dose	**Total**	**None**	**1.00**	**2.00**	**3.00**	**4.00**		
50u/kg (2000-3000 u)	143	114	26	0	2	1	3.974	.553
	49.5%	49.8%	49.0%	0.0%	40.0%	50.0%		
100u/kg(5000-10.000u)	146	115	27	3	3	1		
	50.5%	50.2%	51.0%	100.0%	60.0%	50.0%		
		Hematoma Grade Month						
Heparin dose	**Total**	**None**		**1.00**	**3.00**	**4.00**		
50u/kg (2000-3000 u)	143	139		2	1	1	3.096	.377
	49.5%	48.9%		100.0%	50.0%	100.0%		
100u/kg(5000-10.000u)	146	145		0	1	0		
	50.5%	51.1%		0.0%	50.0%	0.0%		

Statistical tests (Fisher exact test) showed that there was a statistically significant difference between the dose of heparin (usual vs. high) and the feeling of abnormal sensation, as the percentage of patients who felt an abnormal sensation was higher, 86.5%, than that of patients taking the high dose of heparin, 13.5%, after the second

hour of the catheterization procedure. However, this difference disappeared after four hours, as tests showed that there was no difference between the two groups in terms of abnormal sensation, as seen in (table 12).

Table 12: Heparin dose and abnormal sensation

		Abnormal sensation 2 hrs			
	Total	**No**	**Yes**	X^2	
50u/kg (2000-3000 u)	143	111	32	23.245	**.000**
	49.5%	44.0%	86.5%		
100u/kg(5000-10.000u)	146	141	5		
	50.5%	56.0%	13.5%		
		Abnormal sensation 4hrs			
50u/kg (2000-3000 u)	143	143	0	.983	.321
	49.5%	49.7%	0.0%		
100u/kg(5000-10.000u)	146	145	1		
	50.5%	50.3%	100.0%		

To answer the 3rd Research question "What is the effect of 5000 IU-7000 IU or 100 IU/kg of heparin on patients' satisfaction (quality of care) compared with 2000 IU-3000 IU or 50 IU/kg post-cardiac catheterization?" the mean, SD, and histogram figure were used.

Figure (7) shows that the satisfaction (quality of care) rate among participants from the two categories (the usual dose and the high dose of heparin) is 4.06 out of 5, and this reflects a high level of satisfaction with the care provided. This high level of satisfaction did not have any statistically significant difference between the two groups.

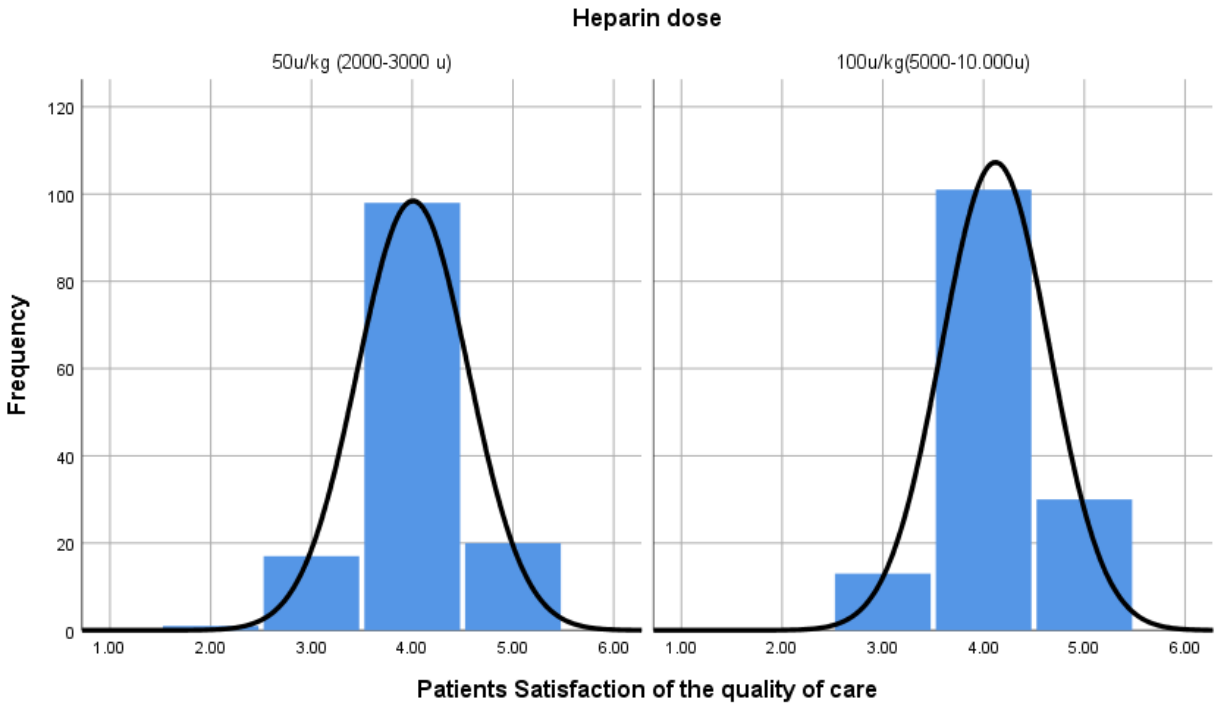

Figure 7: Patients Satisfaction of the quality of care between two groups

Chapter Five

Discussion

5.1 Introduction:

In this chapter, discussion, conclusions, and recommendations were explained. The conclusion was formulated according to the purpose of the study. The purpose of this study was to examine the effectiveness of using a high heparin dose (5000IU-7000IU or 100IU/kg) compared with a standard heparin dose (2000IU–3000IU or 50IU/kg) on the quality and safety of post-trans-radial coronary angiography to improve the health outcomes following radial artery catheterization in Palestine.

5.2. Results of the study and the proposed conceptual framework

Based on the conceptual framework, a high heparin dose was proposed as an effective method of preventing RAO, bleeding, and hematoma. The results of the study were confirmed by the Triad Model of Donabedian (Donabedian, 1980), which argued that high-dose heparin as a process improves the quality, safety, and satisfaction of patients after catheterization through TRA as an outcome. The clinical effectiveness and safety of this study will provide a theoretical basis for the early prevention and treatment of RAO, which will be costly on health expenditure and alter the quality of life of patients. Moreover, our study supports benchmarking our results with international evidence.

Patients who received high-dose heparin were able to meet the conceptual framework outcomes. They didn’t develop bleeding or hematoma, and RAO after one month of catheterization was zero. Consequently, this approach improves the quality and safety of the patients.

5.3. Discussion

On a global scale, TRA is gaining popularity as the strategy of choice for cardiac catheterization due to its comfort level for patients, early discharge and mobilization for the patients, low bleeding at the site of access, and simple achievement of an effective hemostasis. Modern guidelines emphasize TRA as the first approach for cardiac catheterization as it is linked with better clinical outcomes (Neumann et al., 2018). TRA access occlusions are often asymptomatic and consequently underdiagnosed; thus, it seems logical that anticoagulant therapy should be used to decline these events (Moody et al., 2013).

The current study found that the average TRB removal time for patients taking the high dose of heparin was slightly higher than the average TRB removal time for patients taking the standard dose. Also, the hospital stay rate was slightly higher among patients taking the standard dose of heparin compared to patients taking the high dose of heparin. However, these differences were not statistically significant between the standard and high doses of heparin injection. The obtained results pertaining to the use of a high dosage of heparin were consistent with the results of prior studies, which outline the benefits of high-dose heparin for the prevention of RAO in patients who are undergoing cardiac catheterization (Hahalis et al., 2018; Zafarullah et al., 2022). Thus, it can be considered that the use of a high dose of heparin in patients undergoing cardiac catheterization is a reasonable choice.

As for the patient's feeling of pain, the feeling of pain after two and four hours was similar. However, the pain a month after the catheterization procedure was higher among patients taking the high dose of heparin compared to patients taking the usual dose of heparin, and this difference was statistically significant.

Also, the current study found that there is no statistically significant relationship between patients taking the standard dose of heparin and those taking high-dose heparin and the occurrence of bleeding from the site of the catheter insertion or from other places. These results were supported by a prospective, randomized, double-blind controlled trial carried out on 441 patients aged ≥ 18 years old in Isfahan, Iran, referred for diagnostic coronary angiography with radial access. None of the patients in both groups had hemorrhage from high- and standard-dose heparin (Roghani et al., 2016). A recent Cochrane meta-analysis of 31 randomized trials comparing trans-radial and trans-femoral approaches found lower rates of bleeding for the trans-radial approach (Kolkailah et al., 2018). Also, randomized controlled trials comparing radial versus femoral access for percutaneous coronary intervention have shown that local vascular complications and major bleeding episodes are reduced by as much as 68% with radial access (Jolly et al., 2011; Valgimigli et al., 2018). However, the results of a study indicated that higher-dose heparin was found to be an independent predictor of bleeding (Degirmencioglu et al., 2015).

As for the occurrence of RAO, statistical tests showed that there is a statistically significant difference between the dose of heparin and the occurrence of RAO after the fourth hour and after a month of catheterization, where the incidence rate was higher among patients taking the standard dose compared to patients taking the high dose. Adequate procedural anticoagulation and patent hemostasis are the most important reported strategies for the prevention of RAO (Pacchioni et al., 2019). Spaulding et al.

(1996), in a non-randomized study, diagnosed RAO in 71% of patients who did not receive heparin, 24% of patients who received 2000–3,000 IU of heparin, and 4.3% of patients who received 5,000 IU of heparin ($P<0.05$). Bernat et al. (2011) studied the incidence of RAO in patients treated with either 2,000 or 5,000 IU of unfractionated heparin. A lower dose of heparin was associated with numerically double rates of RAO (5.9% vs. 2.9%, $P = 0.17$). In the same study, when patients with RAO were treated with compression of the ipsilateral ulnar artery for 60 minutes, the incidence of RAO was reduced from 5.9% to 4.1% in the low-dose heparin group and from 2.9% to 0.8% in the high-dose heparin group ($P = 0.03$). The current study finding was supported by a study in which, in the high-dose heparin group, the rate of RAO was significantly lower compared with the standard-dose heparin group without compromising safety (Hahalis et al., 2018). Additionally, high-dose heparin was independently associated with a lower rate of radial artery RAO (Besli et al., 2021). Another study indicated that RAO was significantly higher in the standard heparin group than in the high-dose heparin group (Aykan et al., 2015). Furthermore, a meta-analysis showed a trend toward a reduction in the risk of RAO with the use of standard-dose heparin (Dahal et al., 2018). In a systematic review and meta-analysis, it was found that the most significant measure that decreased RAO was higher doses of heparin (risk ratio 0.36, 95% CI: 0.17–0.76)(Rashid et al., 2016). The recommended dose of unfractionated heparin is at least 50 IU/kg, up to 5,000 IU (Rao et al., 2014).

Regarding hematoma, the current study revealed that there is no statistically significant difference between patients taking the standard dose and patients taking the high dose of heparin with the occurrence of hematoma. Similar results were reported by Roghani et al. (2016) study, which found that the frequency of hematoma had no significant differences between high-dose and standard-dose heparin. However, the

current study reported that high-dose heparin patients experienced fewer hematomas per month than standard-dose patients.

The findings of the present study were in line with those of the study conducted by Aoi et al. (2019). In the study by Aoi et al. (2019), hematoma was observed in only 7 out of 202 patients (3.5%). Also, a study conducted by Khanna et al. (2019) indicated that trans-radial angiography has a very low incidence of hematoma.

According to the patients, satisfaction in the two categories (the usual dose and the high dose of heparin) is 4.06 out of 5, and this reflects a high level of satisfaction with the care provided. This high level of satisfaction did not have any statistically significant difference between the two groups. The trans-radial angiography approach decreased access site complications and bleeding, reduced hospital stays, and reduced health care costs, and these will contribute to increasing patient satisfaction with this approach (Arora, Patel, & Shroff, 2015). Also, routine use of patent hemostasis, a higher dose of anticoagulation, and a shorter post-procedure compression time have been shown to reduce the risk of radial artery occlusion, thus increasing patient satisfaction (Avdikos et al., 2017).

5.4 Strength and limitations of the study

This study was the first study in this field of cardiac patients and heparin use also, it was examining three events at the same time, including occlusion, hematoma, and bleeding. Second, this study was an RCT. Third, this study used two heparin doses for all patients with consideration of their weights.

However, this study had some limitations. First, this was a single-center trial. Second, the study didn’t assess activated clotting time upon sheath removal. Activated clotting times would probably have enabled us to calibrate more precisely the needs of our study

patients in terms of anticoagulation intensity for a more robust reduction of incident RAO. Third, ultrasonography was not used to assess the incidence of artery occlusion after catheterization in patients.

5.5 Recommendations of the study

- Applying evidence-based best practices in health care should be considered an important aspect of the starting point in the process of improving the quality of cardiac care and improving health outcomes.
- Further studies in multi-centers with a larger study population are required to confirm our observations.
- Also, further study is needed to assess activated clotting time upon sheath removal.
- Policies and protocols should be revised and updated over time.

5.6 Implication for nursing:

Nursing Practice

Nurses should use various methods to assure good assessment regards cardiac patients regards quality and safety also comfort during patient hospitalization periods. The approach of dealing and giving care to cardiac patients who wait the CAG is quite stressful for patient more particularly the post procedure outcome. These emotional and also physical bears affect the family of the patients, so there is a lot to do regards these situations. Follow up and training program for nurses can applied in this field to assure quality and safety. Also arrange with the nurses leaders

to have training sessions on identify risks of RAO and ensure the outcome for the patency of the RA for upcoming procedures if indicated and to go through updated conferences.

Nursing Education:

The nurse educators should involve the nurses and nursing students in various home care practices to manage RAO through have knowledge about signs of occlusion and the techniques used to follow up patient in home care-based treatment, also the practice on using TRB for patients before discharge also to observe the ischemic signs and how to report it to the physician to prevent complication. To assist patients in dealing with health changes, nurses can get education on a variety of management techniques. In nursing education, the integration of theory and practice is essential and crucial. Nurses must have and work in developed some protocols in dealing with cardiac patient waiting for CAG. Finally, nurse educators must establish and should take the initiative to organized continuing nursing education program for the nurses in this field.

Nursing Administration:

Health challenges, the health care needs or demands and the increase of health concerns especially in the critical ill patients has been growing up day by day with the more technological advances material and tool so the administrators have the high responsibilities to give the chance for nurses to go through different type of treatment and follow up and assessment approach in the giving car for cardiac patients. This also must be with nurse ability to be update in all skills in this field. Not also locally wise but also nurses administrators should have the international look in having policies and protocols. Finally to have guide lines to create special health education program for the inpatient waiting for CAG.

Nursing Research:

The demands and needs are looking for the evidence based to support the assessment and interventions with cardiac patients so there is a need to go deep and intensive research in the field of using heparin and the protocols of this anticoagulant and to go create more database. Research can identify the opportunity to go through these tasks and conduct more and more studies in the field. Student of nursing have also impact in adding more through making research in this field to generate more scientific data. Finally, Dissemination of findings through seminars, conferences and publications in professional international journals worldwide is highly recommended so more theories regard this field can be generated**.**

5.7 Conclusion

The administration of a high heparin dose during TRA diagnostic procedures resulted in a clear reduction of early RAO rates compared with a standard heparin dose. The beneficial results produced by the use of high-dose heparin were found to be without an increase in major bleeding. Also, the current study confirmed that there is no statistically significant difference between patients taking the standard dose and patients taking the high dose of heparin with the occurrence of hematoma. Furthermore, the study indicated a high level of satisfaction with the care provided.

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Appendix 1

Arab American University- Palestine
Deanship of Scientific Research
IRB committee
Tel: 04-241-8888, ext 1196
E-mail: irb.aaup@aaup.edu

الجامعة العربية الامريكية- فلسطين
عمادة البحث العلمي
لجنة أخلاقيات البحث العلمي
تلفون: 1196 04-241-8888 ext
البريد الالكتروني: irb.aaup@aaup.edu

IRB Approval Letter

Study Title: The Impact of Using High Heparin Dose Versus Standard Heparin Dose on Quality and Safety of Cardiac Patients After Diagnostic Trans radial Coronary Angiography at Palestine: Experimental Study.
Submitted by: Fekry Afif Bsharat

Date received: 12th May 2023

Date reviewed: 12th June 2023

Date approved: 6th September 2023

Your Study titled "**The Impact of Using High Heparin Dose Versus Standard Heparin Dose on Quality and Safety of Cardiac Patients After Diagnostic Trans radial Coronary Angiography at Palestine: Experimental Study**" with archived number 2023/C/112/N was reviewed by the Arab American University IRB committee and was approved on the 6th September 2023.

Ahmad Ayed, PhD
IRB Committee Member
Arab American University of Palestine

Sajed Ghawadra, PhD
IRB Committee Vice-chairman
Arab American University of Palestine

Reham Khalaf-Nazzal, MD, PhD
IRB Committee Chairman
Arab American University of Palestine

General Conditions:
1. Valid for 1 year from the date of approval.
2. It is important to inform the committee with any modification of the approved study protocol.
3. The committee appreciates a copy of the research when accomplished.

IRB
ARAB AMERICAN UNIVERSITY

لجنة أخلاقيات البحث العلمي في الجامعة العربية الامريكية

IRB at Arab American University

Appendix 2

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Faculty of Graduate Studies

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كلية الدراسات العليا

6/6/2023

الموضوع: "تسهيل مهمة بحث لطلاب الدراسات العليا – تخصص دكتوراة بالتمريض "

تهديكم الجامعة العربية الأمريكية أطيب تحياتها ,,,,,

إشارة إلى الموضوع أعلاه, وتماشيا مع سياسة كلية الدراسات العليا /**الجامعة العربية الأمريكية** المتعلقة بتعزيز التعاون بين المؤسسات **والمستشفيات بالوطن** بإتاحة فرص الإثراء العلمي للطلبة والخريجين في المؤسسات الوطنية وإسهامها في تنمية قدراتهم وخبراتهم ونرجو من حضرتكم التكرم بالإيعاز للجهات المعنية لتسهيل مهمة الطالب **فكري عفيف بشارات**ي الدراسات العليا تخصص دكتوراة بالتمريض لاستكمال بحثه العلمي بعنوان:

The Impact of Using High fteparin Dose Versus Standard heparin Dose on Quality and Safety of Cardiac Patients after Trans radial Coronary Angiography at Palestine

وذلك في مشفاكم الموقر والذي لديه الخبرة بالعناية بمرضى القلب وعمليات القسطرة, وذلك لأغراض البحث العلمي حيث سيكون الهدف من الدراسة :" تأثير استخدام جرعة عالية من الهيبارين مقابل جرعة الهيبارين القياسية على جودة وسلامة مرضى القلب بعد تصوير الأوعية التاجية الشعاعية حيث انه سيتم توزيع استبيانات ذات علاقة بهذا الموضوع وذلك من تاريخ 2023/6/15 الى تاريخ 2023/12/15 , وهذه الدراسة تحت اشراف الدكتورجمال القدومي .

كما أود التنويه بأن الطالب فكري عفيف بشارات سوف يقوم بجمع الاستمارات وذلك بعد الحصول على موافقة رسمية من

مع فائق الشكر والتقدير

د.نوار قطب

كلية الدراسات العليا
FACULTY OF GRADUATE STUDIES

Jenin Tel: +97 2 18888 Ext:1471,1472 Fax: +9704-2510810 P.O. ox:240
Ramallah Tel: +97P- 2- 2941999 Fax: +970-2 2941979 Abu Qash - Near Alrehan
E-mail: FGS@aaup.edu ; PGS@aaup.edu

Appendix 3

Questionnaire

The Impact of Using High Heparin Dose Versus Standard Heparin Dose on Quality and Safety of Cardiac Patients Transradial Coronary Angiography at Palestine: Experimental Study

Part I: sociodemographic data

A. Sociodemographic data

1. Age: 1-less than 40 years 2- 40-60years 3- more than 60 years
2. Gender: Male ------ Female =--------
3. Residency …….
4. Marital status: single---- Married =--- Other----
5. Hospital name: …… Hospital type …….
6. sedentary life style
   A. . Smoking: Yes……. No……
      If yes duration……. How many cigarette……...

   B. . Physical activity: Yes……No……

      If yes, how many times weekly……. Duration per minutes……
7. Weight: 1-less than 60kg 2- 60-80kg 3- more tha80kg
8. Height: ……. BMI ……
9. Type of diet
   A. Low salt
   B. Low sugar
   C. Regular
   D. Others

Part II: Patient health history

A. Past Medical History

1. Arterial Hypertension
2. Dyslipidemia
3. Diabetes
4. Arrhythmia
5. Ischemic Heart Disease (I.H.D)
6. Valvular Heart Disease (V.H.D)
7. Heart Failure (H.F)
8. Cerebral Vascular Accident (C.V.A)
9. Kidney Disease
10. Thyroid Disease
11. Cancer
12. Benign Prostatic Hypertrophy (B.P.H)
13. Respiratory Disease
14. Pulmonary valve disease
15. Gastrointestinal Disease
16. Blood Disorder
17. Liver Disease
18. Miscellaneous

B. Use of Medications

1. ASA
2. ACE
3. Beta Blockers
4. Clopidogrel
5. Statins
6. Anticoagulant
7. Ticagrelor
8. Thrombolytic
9. Prasugrel
10. Others

C. Lab test result

1. Hgb
2. Lipid profile
3. PT
4. PTT
5. INR
6. RBS

Part III: Angiography Procedure

A. Indication of Angiography:

1. Unstable Angina
2. NSTEMI
3. STEMI
4. Stable Angina

B. Access Site

1. Rt. Radial
2. Lt. Radial
3. Femoral

C. Previous Stage Access Sites: yes no? please move to Part II

if yes, Rt. Radial Artery …… Lt. Radial Artery ……

4. Radial artery occlusion from previous cardiac catheterization and intervention: yes no

D. Heparin dose

1. 50u/kg (2000-3000 u)
2. 100u/kg(5000-10.000u)

E. Puncture Duration (sec) …….

F. Fluoroscopy duration …….

G. Number of catheters 1 , 2 or more than 2

Part IV: Quality and Safety after removal of radial sheet

A. Site complications of current procedure

Variable		**2 hrs**		**4 hrs**		**One month?**	
		Yes	**No**	**Yes**	**No**	**Yes**	**No**
Pain 1-10 Scale							
Bleeding from the puncture site							
Bleeding from other sites							
Ischemia to the Hand	Pale						
	Coldness						
	Weakness						
	Pulseless						
Hematoma	Grade 1.						
	Grade 2						
	Grade 3.						
	Grade 4.						
	Grade 5.						
Abnormal sensation							

B. Transradial band (TRB) removal time:

1. 30 minutes

2. 60 minutes

3. 90 minutes

4. 120 minutes

5. Others?

C. Length of Hospital Stay (Days) _____

D. Patients Satisfaction of the quality of care

1. Very Satisfied
2. Satisfied
3. Neither Satisfied nor Dissatisfied
4. Dissatisfied
5. Very Dissatisfied

الملخص

امراض القلب هي السبب الرئيسي للوفاة في جميع أنحاء العالم، حيث تسبب حوالي 80٪ -86٪ من الوفيات في الدول المنخفضة والمتوسطة الدخل. تصوير الأوعية التاجية هو الطريقة الرئيسية لتشخيص أمراض القلب التاجية وتقنية جراحية لإدارة أمراض القلب التاجية باستخدام أدوية القلب والأوعية الدموية. يتميز بمزايا الشفاء المبكر، ووقت أقصر أثناء الإقامة في المستشفى، وتقليل الأضرار التي تلحق بجسم الإنسان، وتقليل مضاعفات ما بعد الجراحة. أصبح تصوير الأوعية التاجية عبر الشعاعي ذات شعبية متزايدة في جميع أنحاء العالم بسبب انخفاض معدل حدوث النزيف الكبير والمضاعفات الأخرى..

هدف الدراسة: تهدف هذه الدراسة إلى التحقق من مدى فعالية استخدام جرعة عالية من الهيبارين (5000 وحدة دولية – 7000 وحدة دولية أو 100 وحدة دولية / كجم) مقارنة بجرعة الهيبارين القياسية (2000 وحدة دولية – 3000 وحدة دولية أو 50 وحدة دولية / كجم) على جودة وسلامة مرضى القلب بعد تصوير الأوعية التاجية.

المنهجية العلمية: تم اجراء تجربة عشوائية بين أبريل وأغسطس 2023، بما في ذلك الاختبار البعدي والمتابعة للعثور على علاقة السبب والنتيجة بين متغير مستقل وتابع. أجريت الدراسة في المستشفى العربي مع مشاركين مستهدفين، أي مريض تم قبوله لإجراء قسطرة القلب في المستشفى العربي التخصصي والذي استوفى معايير الاشتمال، وكانت العينة النهائية 289 مشاركًا، تلقى 143 مشاركًا جرعة الهيبارين القياسية و146 تلقوا جرعة عالية من الهيبارين.

النتيجة: اكدت النتائج جودة وسلامة الرعاية عند استخدام جرعة عالية من الهيبارين مقابل الجرعة القياسية من حيث الوقت, الاقامة في المستشفى و الورم الدموي, حيث لا توجد فروقات ذات دلالة احصائية.

كما أظهرت الاختبارات الإحصائية أن هناك علاقة ذات دلالة إحصائية بين جرعة الهيبارين وحدوث نقص التروية للمرضى الذين ياخذون الجرعة القياسية. وأخيرا، بلغ معدل الرضا (جودة الرعاية) بين المشاركين من الفئتين (الجرعة المعتادة والجرعة العالية من الهيبارين) 4.06 من 5، وهذا يعكس مستوى عال من الرضا عن الرعاية المقدمة.

الخلاصة: تعتبر جودة الرعاية الصحية وسلامتها من الأولويات هذه الأيام، وهو أيضًا ما تهدف هذه الأطروحة إلى تحقيقه. ومن خلال نتائج هذه الأطروحة نجد أن استخدام الجرعات العالية يمكن أن تعتمده المستشفيات التي تجري عمليات قسطرة القلب، كما تكون ضمن التعليمات والإرشادات.