An-Najah National University

Faculty of Graduate Studies

Comparison of Compressive Dressing with Gauze and Elastic Crepe Bandage Versus Transradial Band in the Management of the Radial Approach for Cardiac Catheterization and Interventions. A Prospective, Randomized, Controlled Observational study

By

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Dedication

I dedicate this study to Dr. Aidah Abu Elsoud Alkaissi and the Cath lab team at An-Najah National University Hospital, who have helped me a lot during my nursing career, both at university and throughout my studies, in order to professionalize this wonderful profession and elevate it to the highest level. Thank you so much for all your support.

I'd also like to express my gratitude to my parents and wife for their unwavering love and willingness to stand by my side.

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First and foremost, I give all credit to God, my source of power, for providing me with the health and well-being that enabled me to complete this monumental mission.

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Finally, but certainly not least, I want to express my gratitude to my parents, my lovely young sister, and my wife for their sacrifice, affection, understanding, and encouragement.

الاقرار

أنا الموقع أدناه، مقدّم الرسالة التي تحمل العنوان:

Comparison of Compressive Dressing with Gauze and Elastic Crepe Bandage Versus Transradial Band in the Management of the Radial Approach for Cardiac Catheterization and Interventions. A Prospective, Randomized, Controlled Observational Study

أقر بأن ما اشتملت عليه هذه الأطروحة إنما هو نتاج جهدي الخاص، باستثناء ما تمت الاشارة إليه حيثما ورد. وأن هذه الرسالة كاملة، أو اي جزء منها لم يقدم من قبل لنيل اي درجة او لقب علمي او بحثي لدى أي مؤسسة تعليمية أو بحثية أخرى.

Declaration

The work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

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Date: 08.08.2021 **التاريخ:**

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List of Abbreviations

Abbreviation	Meaning of Abbreviation
2LB	Two- layer system
ACS	Acute Coronary Syndrome
AV	Arteriovenous
CABG	Coronary Artery Bypass Grafting
CM	Centimeter
IRB	Institutional Review Board
Lt.	Left
NIS	New Israeli Shekel
NNU	An-Najah National University
NNUH	An-Najah National University Hospital
RAO	Radial Artery Occlusion
RCT	Randomized Controlled Trials
Rt.	Right
TRA	Transradial approach
TTW	Time to Wean
USG	Ultrasonography
AF	Atrial fibrillation
Fr.	French
H	Hour
Mins	Minuets
Sec	Seconds
Inj	Injection
Ml	Milliliter
Mg	Microgram
Kg	Kilogram
BPM	Beats per minute
IU	International unit
MAP	Mean Arterial Pressure

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Abstract

Introduction: TR BAND® Radial Compression Device like bracelet designed to assist hemostasis of the radial artery after the transradial cardiac catheterization. The crepe bandage is a medical material that is essential for wound dressing, but theoretically, bandage can compromise peripheral circulation. Both of these methods are used for maintaining the hemostasis of the puncture site of the radial artery. So, comparison between these methods in reference to hemostasis, vascular complications such as bleeding, hematoma, Acute radial artery occlusion (RAO) and the cost effectiveness in term of Price of these methods are warranted.

Aim: This study aims to determine the differences between TR Band and compressive dressing with gauze swab and elastic Crepe bandage after cardiac catheterizations and interventions in terms of benefits, complications, and cost effectiveness concerning the price of these methods.

Methodology: A prospective, randomized, and observational study at An-Najah National University Hospital (NNUH). A number of 400 patients who would be admitted at NNUH for cardiac catheterization and interventions, and whom would voluntarily accept to participate. They were randomly allocated according to the randomization list generated by the GraphPad® software, developed by GraphPad Software Inc, San Diego, California, USA.

Results: of the 417 patients, 200 were randomized to the TR band group and 200 to the gauze swab and crepe bandage group.17 patients were excluded due to different exclusion criteria. Demographic and Procedural characteristics were similar. Both hands were equally effective in fulfilling hemostasis, incidence of hematoma and Acute RAO was higher in the TR band group (2.50% vs. 0.5%; $p = 0.100$), also time to hemostasis was less in the gauze swab and TR band group (1.67 h vs. 1.11 h ; $p = 0.000$).

Keywords: TR Band, Crepe bandage, Radial artery**.**

Chapter One
Introduction

1.1. Introduction

Transradial approach (TRA) has evolved to become one of the most important approaches used to reduce bleeding episodes and other vascular complications among patients who undergo invasive diagnostic and/or therapeutic interventions for coronary artery disease. This technique was shown to reduce mortality, notably, among patients with acute coronary syndrome (ACS) in comparison with femoral artery access technique (Valgimigli et al., 2015).

This transradial access to the coronary artery was shown to be the safest approach for the percutaneous coronary interventions (PCI) (Hamon, Martial, et al 2013). Also it has been widely applicable in various clinical situations, so it has become the first choice access for Cardiac Catheterization and interventions in many countries (Feldman et al., 2013).

Radial artery occlusion is an important and challenging problem for transradial catheterization because it limits the reuse of the radial artery access(Rashid et al., 2016) which is resulted from catheterization related injury to the Radial vessel wall, another challenging problem for the operator to use the Radial Artery access its small diameter.

Radial artery entry for cardiac catheterization has three potential sources of the vascular complications: the first one, is the needle which has been

overcome with new puncture technique (Seto et al., 2015) and dedicated needles (Dangoisse et al., 2017) which may minimize the initial vessel damage, the second cause, is the “dilator-sheath” unit which has been overcome with improving and innovating more “slender” sheaths (Aminian et al., 2014), which should decrease stress on the wall of the radial artery. And the third source, is the compression or hemostasis step after sheath removal, our available compression devices are the elastic crepe bandage with gauze swab which is safe, cheap, easy to use and popular, the second one is the TR band which is also easy to use and well-studied.

It has been shown that interrupting the flow of the radial artery whole compressing has the potential to impact the rate of occluding the radial artery at follow up (Sermsathanasawadi et al., 2018).

Lately, many compressive hemostatic devices were invented. It has been demonstrated that these devices were effective and safe in ensuring hemostasis (Rathore et al., 2010).

Bandages are medical materials that are essential for wound dressings, but theoretically, bandages can compromise the external circulation (Midttun et al., 2010).

In compression therapy, two or more layers of dressing are required. Performance qualities of each layer are different. In practice, acceptance of continued graded compression depends on the pressures that distribute uniformly to the different layers of the bandage. Additionally, structure of

the bandage and textile fibers are also important (Rajendran & Anand, 2006).

Bandage thickness should be considered. The attainment of a pressure between 35 and 45 mm Hg was defined as an adequate quality (Sermsathanasawadi et al., 2018).

Compression bandages come in two main types: elastic and inelastic. Elastic type is further categorized based on their pressure level that they generate on the angle of an average leg. Of these bandages: 1) Class 3a provides low compression pressure in the range of 14-17 mmHg, 2) Class 3b provides moderate pressure in the range of 18-24 mmHg, 3) Class 3d provides high pressure in the range of 25-35 mmHg, and 4) Extra high pressure 3d provides very high pressure of up to 60 mmHg. However, the extra high pressure 3d class is seldomly used because the high pressure can reduce blood flow to the skin tissues (Sermsathanasawadi et al., 2017).

A previous study by Hanna et al (2008) suggested that a two layer system (2LB) can provide the necessary pressure while managing ulcers of venous legs (Hanna, Bohbot, & Connolly, 2008). The study suggested that this type has the property of ease of application, therefore, it can be a good alternative to the multilayer systems. The 2LB system can provide a pressure of 30–50 mmHg.

A previous study by Ghosh (2008) showed that the pressure profile that is generated by bandages can be greatly affected by friction behavior, crepe behavior, and bonding angle during application. Further analysis suggested

that the sliding in a multilayer system can be limited by the surface friction. Additionally, the pressure provided by a bandage can be affected by the dimensions of the limb and the amount of stretch during application. It has been demonstrated that addition of elastomeric ingredients provides higher durability and allows provision of homogenous distribution of pressure. To the best of our knowledge, the literature reported little on the impact of compression with an adapted bandage on hemostasis and incidence of vascular complications (Cong, et al., 2015). On the other hand, many previous studies compared mechanical devices that were developed by industry to provide pneumatic or rotary compression in the shape of bracelets (Pancholy 2019).

In developing countries, customized compression dressings with hemostasis gauze bandages are commonly used on the radial access site due to economic reasons. In the absence of standardization and formal recommendations, clinical experience and institutional protocols are used to inform the technique and time of radial artery compression. In the current practice, scientifically-based evidence is still lacking.

At An-Najah National University Hospital, over 90% of diagnostic and interventional cardiac catheterizations are done using the transradial route. Immediately after the intervention, the vascular sheaths are removed and pressure-device hemostasis using a TR Band and air bladder–based compression device, and gauze with crepe bandage are used. Conventionally, the TR band pressure is weaned down gradually at 2 hours

after the vascular sheaths are removed. The time to wean (TTW) of 2 hours after the vascular sheaths are removed is the accepted time frame to permit the intraprocedural anticoagulants/antiplatelets effect to wear off.

This study aims to determine the variations between TR Band and compressive dressing with gauze swab and elastic Crepe bandage after cardiac catheterizations and interventions in terms of benefits, complications, and cost effectiveness in term of price of these methods.

1.2 Background

1.2.1 TR

is a transparent compression device like bracelet applied to the puncture site of the radial artery after cardiac catheterization and interventions. It is applied to achieve hemostasis at the puncture site. The transparency allows visual observation and control of the puncture site for hematoma or bleeding. For a precise fit and optimized comfort for the patients, 2 brand lengths are available: regular (24 cm) and long (Velcro® 29 cm). The TR band helps maintain the potency of the radial artery at the time of hemostasis. This prevents occlusion of the artery in the future (Rathore, Stables et al. 2010).

The brand name of the TR band in catheterization lab at An-Najah National University Hospital (NNUH) is Terumo Corporation and its cost is 65 NIS for both sizes.

Regarding hemostasis after cardiac catheterization and intervention with using TR band, some blood is withdrawn to make sure that there is no thrombus inside the sheath then align the green marker of the TR band that is placed in the central part of the compression balloon (1 cm proximal to the site of puncture). The strap is then fixed on the wrist with the adjustable fastener, rotation and direction of the TR band is different from Rt.to Lt. radial artery, recording SpO2 in the finger thumb of the affected hand following that 15cc of air injected in the band balloon with using special syringe while withdrawing the sheath from the radial artery, then deflate the balloon slowly till the fresh blood is seen in the puncture site then inject 2cc of air till the blood stopped, another SpO2 record in the finger of thumb of the affected hand during compression should be obtained, finally evaluating the patient's comfort with using visual analogue scale.

TR band compression duration is one hour for patients underwent diagnostic cardiac catheterization and two hours for those underwent interventional procedures, the TR band will be relieved regularly every 15 minutes with withdrawing 2 to 3cc air, if we observe fresh blood goes out from radial entry after removal of this amount of air from TR band, we inject 2 cc of air in the balloon and wait for the next 30 minutes again.

1.2.2 A crepe bandage

is a long strip of stretchable bandage that can be wrapped around the target site. It's also called an elastic crepe bandage, the main function of the crepe bandage is reducing blood flow to a specific area with applying localized

and stable pressure, crepe bandage is designed to deliver graduated compression from one site to another.

The contemporary elastic bandages are made from polyester, cotton, and yarns that is free from latex. There are many uses for the crepe bandage used in muscle strain and sprain, chronic vein insufficiency, lymphedema, bone fracture and as a compression therapy for the vascular access of the catheterization, there are three sizes of the crepe bandage 8cm, 10cm and 12cm, the 10cm bandage is used for all our patients.

1.2.3 A gauze swab

made from accomplished cotton yarn to achieve higher tending capacity and absorption rate, less allegiance to healing tissue, and there're many uses for the gauze swab, one of them, for swabbing and cleaning wounds especially dressing low exudates wounds, another use, for the gauze swab is hemostasis and absorbing the blood, the used gauze swab at NNUH is from Medi-Care Medical supplies company and it consists of 13 threads to achieve 10cm x 10cm-8ply, also the used gauze is sterile by using gamma radiation.

The cost of one piece of the sterile gauze is 0.25NIS.

In regard to hemostasis, with using gauze swab and elastic crepe bandage, first of all, some blood is withdrawn to make sure that there is no thrombus inside the sheath, one piece of 10cm x 10cm-8plygauze (thin, translucent fabric with a loose open weave) is rolled into a small square to get a height

of 1cm gauze swab then apply it 1cm proximal to puncture site and before wrap it with crepe bandage, recording SpO2 in the finger thumb of the affected hand then applying first wrap of crepe bandage which should be with enough pressure and relieved gradually in the next wraps, another SpO2 record in the finger of thumb of the affected hand during compression should be obtained, finally evaluating the patient's comfort with using visual analogue scale. The incidence of hemostasis is often evaluated after 15 min.

When bleeding occurs, further tension will be applied in the dressing and additional 30-minute intervals of compression will be performed.

A re-evaluation of the site will be done every 15 minutes until a complete hemostasis is achieved. The cost of 10cm crepe bandage is 3.10 NIS.

Local vascular complications will be documented as:

Oozing, ecchymosis, bleeding, hematoma, aneurysm, wound infection, time to a complete hemostasis, occlusion of radial artery at discharge, incidence of radial artery spasm during the intervention.

Palpation, inspection, and Doppler Ultrasonography (USG) are used for the assessment of late postoperative complications after removal of the compressive dressing.

Hematoma is evaluated on the basis of its diameter as in the classification disseminated in the EASY (Early Discharge after transradial Stenting of Coronary Arteries) study as: 1) type I: ≤ 5 cm, 2) ≤ 10 cm, 3) type III > 10

cm if the hematoma did not reach the elbow, 4) type IV: when the hematoma extends beyond the elbow, and 5) type V: a hematoma that is accompanied by ischemic injury to the hand (Bertrand, Olivier F., et al 2009).

1.2.4 The introducer radial sheath and the puncture needle

There are two type of 6Fr radial introducer sheaths were used from Terumo and Merit medical companies for all patients whom underwent cardiac catheterizations and interventions but with specific characteristics that were summarized in **table 1** below:

Table 1: The introducer radial sheaths and the puncture needles characteristics.

Hydrophilic Coated Introducer Sheath 6F: **GLIDESHEATH SLENDER® From Terumo**		Hydrophilic Coated Introducer Sheath 6F: **Prelude IDeal™ From Merit**	
Item Code	60-1065	**Item Code**	PID6F11018SC
Sheath	A-Kit – 6F 10cm	**Sheath**	6F - 11cm
Dilator	0.025	**Dilator**	0.018 , 17cm
Guide Wire	**Diameter** / 0.025 , 45cm **Material** / Hydrophilic **Tip Configuration** / Straight Hydrophilic Tip	**Guide Wire**	**Diameter**/ 0.021 , 45cm **Material**/ Stainless Steel **Tip Configuration** / Straight Floppy Tip Spring Coil
Needle	20G	**Needle**	21G

1.3 Problem statement

Transradial access to the coronary artery was shown to be safe, efficient, and versatile in a variety of interventional settings (Grinfeld, Berrocal, Matas, Magni, & Belardi, 1996; Schneider, Mann, Cubeddu, & Arrowood,

1997), and opposed to the femoral approach, the radial route was shown to minimize the vascular complications relevant to the access site (Agostoni et al., 2004; Kiemeneij, Laarman, Odekerken, Slagboom, & van der Wieken, 1997), another benefit is the ability to move quickly and discharged from hospital earlier.

There have been many compressive hemostatic devices developed that were proven safe and efficient in maintaining hemostasis (Ochiai et al., 2000). However, no studies have compared between the effects of various hemostatic products, such as the TR-Band, gauze swab dressing, and elastic crepe bandage, on comfort to the patients, the time needed to maintain hemostasis, and complications to the local vasculature.

These techniques allow applying selectively regulated pressure on the radial artery, allowing for continued arterial and venous flow. Following transradial procedures, we regularly use the TR band compression unit at our center. Our study's goals are to compare the effects of gauze swab with elastic crepe bandages, and TR bands on the comfort to the patients, the time needed to maintain hemostasis, and complications to the local vasculature.

1.4 Significance of the study

In the current study, we are comparing two methods of hemostasis including TR

Band and gauze swab with crepe bandage in reference to cost effectiveness in term of price to prevent local complications such as bleeding, RAO or hematoma.

One of the most common complications of TRA is radial artery occlusion (RAO). About 10% of patients develop this complication, which is poorly diagnosed and often comes with no symptoms. Presence of RAO in the radial artery renders this artery useless for additional interventions like free transplantation of patients undergoing revascularization procedure following myocardial infarction. Predictors of RAO include incompatibilities between the diameters of the induction mantle and the diameter of the radial artery (RA), insufficient anticoagulation, and interruption of RA flow neither during nor after the procedure. Furthermore, patent hemostasis in the radial artery is a necessary component of RAO prevention, which includes controlling blood pressure during compression, maintaining anterograde flow, and using hemostatic devices to compress the puncture site (Rashid et al., 2016; Wagener & Rao, 2015).

As far as we know, few studies were reported in the literature to have addressed use of compression with tailored dressings to achieve hemostasis and assess the incidence of vascular complications (Cong et al., 2016; Neto, de Freitas Jr, Berti, Costa Jr, & Zbeid, 2015). A considerable percentage of the previous studies compared the use of various mechanical devices that were developed by different manufacturers. These devices

were comprised of rotary or pneumatic compression systems in the shape of bracelets (Lavi et al., 2017).

In developing countries, custom compression bandages with gauze bandages for hemostasis at the radial access point are used commonly due to the added value of the cost associated with their use. In the absence of standardization and formal recommendations, clinical experience and institutional protocols are used to inform the technique and time of radial artery compression. In the current practice, scientifically-based evidence is still lacking.

Therefore, this investigation aimed to compare 2 radial artery compression times after elective coronary angiographies with compression bandage with regard to hemostasis and incidence of vascular complications.

1.5 Aim of the study

This study aims to determine the differences between TR Band and compressive dressing with gauze swab and elastic Crepe bandage after cardiac catheterizations and interventions in terms of benefits, complications, and cost effectiveness in term of price of these methods.

1.6 Objectives of the study

- To identify the significant difference at a level of 0.05 related to hemostasis between groups of gauze swab with crepe bandage and TR band.

- To determine the significant difference at a level of 0.05 related to incidence of vascular complications (pseudoaneurysm, local hematoma, compartment syndrome, bleeding, and immediate and late radial artery occlusions) between groups of gauze swab with crepe bandage and TR band.

- To determine the significant difference at a level of 0.05 related to cost effectiveness in term of price between groups of gauze swab with crepe bandage and TR band.

1.7 Study hypothesis

a. Null hypothesis:

- There is no significant difference at a level of 0.05 related to homeostasis between groups of gauze swab with crepe bandage and TR band.

- There is no significant difference at a level of 0.05 related to the incidence of vascular complications (pseudoaneurysm, local hematoma, compartment syndrome, bleeding, and immediate and late radial artery occlusions) between groups of gauze swab with crepe bandage and TR band.

- There is no significant difference at a level of 0.05 related to cost effectiveness in term of price between groups of gauze swab with crepe bandage and TR band.

b. Alternative hypothesis:

- There is a significant difference at a level of 0.05 related to homeostasis between groups of gauze swab with crepe bandage and TR band.
- There is a significant difference at a level of 0.05 related to incidence of vascular complications (pseudoaneurysm, local hematoma, compartment syndrome, bleeding, and immediate and late radial artery occlusions) between groups of gauze swab with crepe bandage and TR band.
- There is a significant difference at a level of 0.05 related to cost effectiveness in term of price between groups of gauze swab with crepe bandage and TR band.

1.8 Research question

What are the differences between the gauze swab with crepe bandage and TR band in the management of the Radial approach for cardiac catheterization and interventions in terms of benefits, complications and cost effectiveness in term of price?

The primary endpoints of this study: Are homeostasis and acute radial artery occlusion.

The secondary endpoint is incidence of vascular complications (pseudoaneurysm, local hematoma, compartment syndrome and bleeding) and cost of the used compression devices in term of price.

Chapter Two
Literature Review

2.1 Introduction

A literature search of hemostasis of radial artery entry after percutaneous cardiac catheterization and intervention with using different compression methods, vascular complications and cost effectiveness was performed with using Pub-Med, Google Scholar and Sci hub in searching for articles related to the research topic (Comparison of compressive dressing with gauze swab and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions).

2.2 Previous studies

Fernandez and Lee (2017) conducted a systematic review of the published evidence was conducted by the researchers to compile the best available evidence of the effects on rates of RAO following percutaneous coronary intervention of the methods for achieving hemostasis. This study recruited patients who were adults (≥ 18 years) and who underwent coronary angiographies or revascularization interventions using the radial artery route. The study excluded the patients who underwent percutaneous coronary procedure through the brachial or femoral arteries. Several interventions were used, the comparison group consisted of patients who received traditional compression, such as bandages, elastic bands, tourniquets, etc. The study included 7 trials, there was a trial that showed significant decrease in the rate of RAO in the clients whose mean arterial

pressure (MAP) that was used to guide the transradial band (TR band) to the conventional TR band (OR= 0.08, 95% confidence interval of 0.02, 0.37). There was statistically significant decrease in the occurrence of RAO that was witnessed between the clients who received Chitosen (biopolymer dressing) when compared to the clients who received the TR band (OR= 2.20; 95% confidence interval 1.20, 4.02). There is no difference in the occurrence of RAO as documented among the clients who received the TR band as well as the clients who received the P ¼ 0.08 elastic bandages or the P ¼ 0.76 TR band. Simultaneously, there were differences in the incidence rates of RAO among clients who received pro-coagulant dressings when compared to the clients who had a long or short manual compression. The TR band was compared to a MAP-guided TR band in a clinical trial. No statistically significant differences were found between the two groups in terms of the time taken for hemostasis to be maintained (P ¼ 0.61). In comparison with the TR band, the hemostatic biopolymer dressing (Chitosen) kept hemostasis for significantly less time. Hemostasis achieved with pneumatic compression or traditional compression did not lead to a statistically significant difference in hematoma incidence.

Sanghvi et al (2018) conducted a prospective, single center, randomized, blinded clinical trial that compared between 2 devices for radial compression hemostasis in terms of their effect on the RAO (Sanghvi, Montgomery, & Varghese, 2018). It was performed in an Academic Teaching Hospital for Tertiary Care with extended experience in trans-arterial catheterization (TRC). In their study, the TRC rate was 67%. In this

study, 314 patients agreed to take part and were selected for a post-radial intervention. The patients were treated randomly with wither Safeguard Radial (Merit Medical) or Transradial band (TR band) (Terumo Corporation). But the patients who have heparin intolerance, Reynaud's phenomenon, scleroderma, Barbeau's type D response, and active use of anticoagulation were excluded from the study. One hundred and fifty-five patients among 314 patients were included in the analysis and randomly assigned to the TR band group, while 159 patients were assigned to the Safeguard Radial (SGG) group. The demographics and the characteristics of the intervention were comparable in for the two groups. The interventional characteristics (diagnostic only/interventional, access time (measured as the time from lidocaine injection to sheath insertion in minutes), heparin ≥ 50 u/kg, percentage of posterior/anterior puncture technique, mean number of exchanged coronary catheters, time of fluoroscopy, number of attempts for access, use of contrast, time taken to achieve hemostasis, time to achieve hemostasis, percentage of patent hemostasis, usage of 5fr./6fr. coronary catheters, usage of radial vasodilator medications, and incidence of radial spasms were similar in the 2 groups with the exception that an increased percentage of patients in the TR band group were subjected to coronary interventions (SGG 28.30% vs. TRG 40.6%, p=0.03). This could have impacted the incidence of RAO as larger doses of unfractionated heparin. The incidence of acute RAO at discharge was higher among the patients on whom Safeguard band was used compared to the TR band (TRG 3.8% vs. SGG 6.28%, p=0.5). After a

follow up of 30 days, the odds of chronic RAO were comparable in the 2 groups (SGG 2.5% vs. TRG 1.9%, p=0.10). In both groups, achieving patent hemostasis was comparable (TRG 86% versus SGG 87%, p = 0.52). When the air volumes required to achieve hemostasis were compared, the Safeguard band required less volume (TRG 11.6 ml versus SGG 4.8 ml, p = 0.001). Incidence of hematoma of (> 2 cm was higher in the DG group) (3.1% in SGG versus 1.25% in TRG, p = 0.046). On the other hand, the incidence of minor bleeding was comparable in the 2 groups (6.2% in SGG versus 5.8% in TRG, p. = 0.75). Additionally, the time to achieve hemostasis was comparable between the two groups (SGG 84.21 min vs. TRG 79.30 min, p = 0.39) and between interventions (SGG 141.20 min vs. TRG 132 min, p = 0.43). During the study, none of the patients reported severe discomfort. However, patients in the TR band reported more mild to moderate discomfort compared to the patients in the Safeguard band group (TRG 18.7%vs. SGG 10.6%, p= 0.04). Among all patients, 6 Fr. slender sheaths were used. With regard to the other factors that affect the incidence of RAO like the use of 5Fr. /6Fr. catheters, spasmolytic cocktails, incidence of spasm, and rate of successfully completing the intended action were comparable in the 2 groups.

Ognerubov et al. (2019) conducted a study including 392 patients who underwent diagnostic transradial coronary angiography and not receiving anticoagulant therapy by dividing them into 2 groups, group 1 including 221 patients that their bandage removal was done from puncture site in four hours after the procedure with the radial artery patency protocol by using

the existence of pulse metric curve while compressing the ulnar artery. The number of patients in group 2 was 171, the compression band removal was achieved after twenty-four hours after the procedure. The control of radial artery patency was done in both groups after twenty-four hours of using the reverse Barbeau test. Ultra sound imaging of the forearm arteries was done for detection the presence of radial artery occlusion (RAO). All of these done for investigating complication rates at early removal of compression bandages by comparing between the rates of complications in the access site at early (after four hours), and traditional (after 24 hours) removal of a compression bandage post diagnostic transradial coronary angiography in patients not receiving anti-coagulants. This study found that the RAO in group 1 wasn't detected while its detection in group 2 was found with 15%. The incidence rates of hematomas at the puncture site were not statistically significant. The bleeding at the puncture site after the removal of band and needs recurrent application of band happened in one patient in group 1 (0.6%); There were no registration for this cases in the group 2. So, this study shows that the rate of radial artery occlusion (RAO) is minimal after early withdrawal of compression crepe bandages post transradial coronary angiographies in comparison with the traditional method.

A prospective, randomized study is done by (Dangoisse et al., 2017) between 2009 and 2016 involving 3616 patients underwent TRA cardiac catheterization and interventions, which aimed to study durations intensities of hemostasis occurred with TR Band of the radial artery entry

after cardiac catheterization and interventions, the patients in the TRA group were randomized to TR Band hemostasis following 3 Protocols:

Crasoc I: 13 vs 10cc of air into the TR Band and for 4 h of continuous compression. A total of 1937 patients were randomized prospectively in the time period of 2009-2010: 691 in the group of 13 cc-4 h and 1246 in the group of 10 cc-4 h.

Crasoc II: 10cc of air for 3 h vs 2 h of compression. A total of 941 patients were randomly selected in the year 2014 (total cardiac procedures: 1750, group 10 cc-3 h, 435, group 10cc-2 h, 506)

Crasoc III: 10cc of air for 2 h vs 1.5 h of compression. A total of 738 patients were randomly selected in the time period of mid-November 2015 to October 2016 (total cardiac procedures: 1451, group 10 cc-2 h-GS, 179, group 10 cc-1.5 h-GS, 559). The potency of the radial artery was investigated through plethysmography at 24 hours and Doppler was used to detect suspicious or negative plethysmography. When hemostasis was mild (10 cc of air) and short time (1.5 hours), the 24-hour RAO primary endpoint was significantly reduced, resulting in a 2.3% RAO rate, in compared to 9.4% for 13 cc-4 hours. Of the patients, 89% achieved hemostasis with only 10 cc of air and 97% of patients achieved hemostasis with less than the recommended 13 cc. Approximately, 8% of patients required more than 1.5 hours to stop bleeding. This study concludes that the short and soft hemostasis with the TR Band device minimize the Radial Artery Occlusion rate (RAO).

Pancholy, Coppola, Patel, and Roke-Thomas (2008) conducted a study with the objective of assessing efficacy and patency of hemostasis in the radial artery for preventing the incidence of RAO after the transradial catheterization. This study includes prospectively 436 patients who undergoing transradial catheterization divided into 2 groups randomly.

Group one consists of 219 patients who underwent the application of conventional pressure to the radial artery entry (That was achieved by managing the hemostasis of radial artery entry at the end of transradial catheterization with removing radial sheath followed with applying 4*4 gauze with the use of Hemoband™ plastic band around the wrist for 2 hours, then removing it slowly followed with placing light dressing above site entry) to achieve hemostasis in the radial artery and the participants in this cohort who had interruptions in the flow of radial artery during the hemostatic compression were documented and noted to have the "occlusive hold".

Group two consists of 217 patients whom their radial artery entry was managed at the end of procedure with the same pressure method that was used in group one except the intensity of applied pressure which was adjustable with Barbeau's test to ensure the patency of radial artery (by placing the pulse oximeter sensor over the index finger, in addition to tighten the Hemoband and removal of sheath, the occlusion in ipsilateral ulnar artery, then loosening the Hemoband™ continued until the return of

plethysmography signal that confirms the patency of radial artery and maintaining radial blood flow).

The patency of radial artery for both groups was studied at twenty-four hours and thirty days by using the Barbeau's test. The study found that 38 patients had the evidence of RAO at twenty-four hours, 20 patients had a persistent evidence of RAO at 30 days. There was a documented patency of the radial artery via hemostatic compression in group 2, and there was a lower incidence rate of RAO clinically and statistically (fifty-nine percent decrease at twenty-four hours and seventy-five percent at one month, with p value less than 0.05), as compared with group one. There was a significant high risk of developing RAO in the patients who had low body weight. This study didn't find any procedural variables to be associated with RAO. There were many variables that have an association with the occurrence of RAO and were differentiated in group one and these variables were age, gender, and the body weight.

First of all, it was found that the younger patients (65.3 6 12.6 years) didn't have any occlusion in the radial artery at one month than older participants (73.3 6 ±12.4 years).

The second variable was the gender which was very significant and documented with the occurrence of RAO in 15 female participants (12.9%) as compared with one male participant (1%) at one-month follow-up.

Finally, the last variable of the body weight that was significantly appeared between thin and heavy participant, the participants with low body weight

were found to have an occlusion in the radial artery at one month (68.58 6±15.70 kg) more than the heavier participants who didn't have any occlusion in the radial artery (88.61 6 20.33 kg).

‘‘occlusive hold’’ was defined as lack of forward radial artery flow while hemostatic compression) was positive for ninety-five (43.4%) of group one, Early recognition of ‘‘occlusive hold’’ in the group one (traditional hemostasis) was found to have significant relation with development of RAO at 30 days.

Reported radial artery patency in the hundred twenty-three (99.2%) of group one using traditional approaches were still patent at 30-day follow-up, and one (0.1%) patient with patency after 24 hours was developed RAO at 30 days. This summarized that radial patency in 99.1% of participants at the time of conventional hemostasis was able to maintain the patency at 30 days. Also, this study shows that hypertension, diabetes mellitus, duration of the procedure, or creatinine level had no significant effects on the RAO.

A randomized single-center comparison trial was conducted by (Cooper et al., 1999) on 200 patients whom referred for diagnostic cardiac catheterization to investigate the quality of life, patients preferences, and costs of cardiac catheterization between radial and femoral access site. All included participants should have palpable radial and femoral pulse and normal Allen test. The patients who were suspected to have precluding access, vascular disease, unstable coronary disease, needed additional investigations during the same hospitalization period, or were not able to

provide a new informed consent were excluded from the study. The standard physical examination was performed at the first day and at the first week after diagnostic cardiac catheterization. The Medical Outcomes Study Short Form was used to assess the quality of life. This tool contains 36 items (acute SF-36) and intervention-related questions. The visual analog scale (0-10) was used in the procedure-specific questions, for assessing the overall discomfort, ability of the patient to go to the bathroom, back pain, walking, and ability to self-care or self-feed. The questionnaires at the first day and week also assessed the presence of pain at the entry access site, and participant preferences for the approach of cardiac catheterization on the visual analog scale. The study tools were provided to the participants with standardized instructions for self-administration in accordance with the previous published guidelines. The hospital costs were measured prospectively.

There are 4 components of cost were measured: catheterization laboratory costs, cost of bed including nursing services, pharmacy cost, and all other additional costs. The physician costs were excluded because the fees were equal in the transradial and transfemoral access. At the first day after the transradial catheterization, assessment of body pain, mental health, social function, back pain, overall level of discomfort, ability to walk, and ability to go to the bathroom were improved in the transradial group (p value <0,01 for all comparisons). And there were changes in role limitations and mental health that were caused by emotional issues, and social dysfunctions were a little higher in the participants who were assigned randomly to the

cardiac catheterization via transradial access site. Over one week after doing the procedure, physical, mental, and social functions, also the overall discomfort, body pain, back pain, and ability to walk were improved in the transradial group. There were no significant differences in pain at the insertion site between the first day and week after the procedure. In other words, the catheterization laboratory costs were equal in transradial and transfemoral group. In the transradial group, the pharmacy and bed costs were significantly lower than the transferal group. The costs of the other services were lower in the transradial cardiac catheterization, but these differences were not statistically significant (P value= 0.12). Overall, there was a significant decrease in the median hospitalization costs with the transradial cardiac catheterization. There were many patients preferred the transradial access in cardiac catheterization (80% of the overall participants) as well (p value <0.0001).

Campos, Alves, Tsunemi, Peterlini, and Avelar (2018) compared two radial artery compression periods following coronary angiographies with compression bandages that were customized for the presence of vascular complications and hemostasis. The researchers conducted a randomized clinical trial that included patients who underwent transradial coronary angiographies in 2 groups: (G30), in which the compression bandage was worn for 30 minutes, and (G60), in which the compression bandage was worn for 60 minutes. Characteristics of the patients, procedures, incidence of hemostasis, and incidence of vascular complications were studied. Doppler vascular ultrasound was used to evaluate the patent artery of the

radial artery shortly after the compression bandage was removed and 30 days later. There were 152 G30 participants and 151 G60 participants in the study. Hemostasis was found in 76.3 percent of G30 participants and 84.2% of G60 participants (p = 0.063) during the initial assessment. The researchers discovered 18 late blockages, with 7 (5.5%) in G30 and 11 (8.2%) in G60. The results of this study showed that radial artery compression times following coronary angiographies had no effect on the incidence of vascular complications and hemostasis.

Santos et al. (2018) published a protocol for a single-center, parallel, open-label, randomized clinical trial. In this study, 600 people were expected to receive diagnostic/therapeutic cardiological interventions using the radial artery system. Adults who wanted to have their radial arteries aligned for diagnostic/therapeutic purposes will be chosen. During radial artery compression, the plethysmography waveform of the oximeter can be classified into 4 classes: 1) A: lack of curve attenuations after compression of the radial artery, 2) B: curve damping, 3) C: temporary loss of flow accompanied by recovery of pulse tracking within 2 min, and 4) D: loss of trace without restoration of the curve (Barbeau, Arsenault, Dugas, Simard, & Larivière, 2004). Exclusion criteria included left radial approach to the heart, D class upon Barbeau's examination, and failure to provide informed consent.

During planning for cardiac catheterizations or percutaneous coronary angioplasties, the patients underwent Barbeau's examination. Patients were given hemostasis with a TR Band TM device (intervention squad, IG) or an elastic adhesive bandage (1:1) at the end of the operation (control group, CG). Hemostasis with the TR Band TM unit was the intervention party. A nurse placed the TR Band TM patent hemostasis system on the patient. The unit was inflated with 13 ml of air on average or until no bleeding occurred. The unit was progressively emptied (2 ml every 10 min) after 2 h of compression and removed after 2 h and 30 min if no active bleeding was observed. The puncture site was sealed with a traditional dressing (gauze, bandage, and tape) after the system was fully removed, and Barbeau's test was done.

In the control group: hemostasis with elastic self-adhesive bandages. Nurses applied dressings with elastic self-adhesive bandages to the patients. The approach involved applying a compact gauze pad to the radial puncture site, followed by a strip of adhesive tape and two strips of self-adhesive elastic bandage placed in an "X" shape over the skin, dressing without surround the arm. After 2 h of compression, the unit was withdrawn if no active bleeding was detected. After complete removal of the device, the puncture site was covered with a conventional dressing (bandage, gauze, and bandages), and the Barbeau test was performed. Both groups of patients were given instructions on how to care for their punctured limbs after the operation, which included resting the punctured limb and not exercising the same day as the procedure. All patients were

asked to provide social, demographic, clinical, and procedural information. Clinical and socio-demographic details in preparation for the operation was documented by the nurse. The main outcome was the incidence of RAO, which is determined to be a "D" curve in the postoperative Barbeau test. The secondary outcome was the change in the Barbeau test curve, the extra time to stop bleeding (including the requirement for additional compressions); according to the definition of transradial coronary stenting (EASY), there is bleeding at the puncture site; the severity of pain Visual analog scale evaluation; development of clinically relevant arteriovenous fistulas; development of radial pseudoaneurysm; and possible complications in access sites requiring interventional vascular surgery (Bertrand et al., 2006; Pasero & McCaffery, 2010) and costs between the two units. The authors addressed how the findings of this research could include useful additional knowledge on the best method for hemostasis following transradial percutaneous cardiovascular intervention since it is a guideline for the study.

Chapter Three
Methodology

3.1 Introduction

Once the cardiac catheterization and the interventional procedures is completed, it is necessary to remove the radial sheath from radial artery because its presence in small diameter vessels is considered as a thrombogenic materials and may lead to complications.

We used two compression methods in controlling the radial artery entry after cardiac catheterization and interventions at NNUH, one of these methods is TR band XX*RF06 from Terumo, it's applied to achieve hemostasis at the puncture site by providing an adjustable amount of air injected into the compressive balloon of the TR band which provides a precise control over the compression intensity. The manufacturer of Terumo recommends to inject 13-18 cc of air to get the radial artery hemostasis with no instructions or recommendations on compression time. The second compression method is the gauze swab and elastic crepe bandage which had been described and done safely with qualified and trained catheterization lab technicians. The used gauze swab at NNUH is from Medi-Care Medical Supplies Company and it consists of 13 threads to achieve 10cm x 10cm-8ply.

3.2 Study design

A prospective, randomized, observational study to compare between the compressive dressing with gauze swab and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions in terms of benefits, vascular complications and cost effectiveness in term of Price.

3.3 Study site and setting

It was studied in Nablus, Palestine at Najah National University Hospital (NNUH) which is an academic teaching hospital with extensive experience in the transradial catheterization (TRC), and having three full time interventional cardiologist covering the elective and urgent cardiac catheterization over 24hrs.

3.4 Study population

The study participants are the Palestinian patients who were admitted at NNUH for cardiac catheterization and interventions, and whom voluntarily accepted to participate.

Research participants were recruited by inspecting the operating lists before the session starts. Research team prescreened the patients based on the inclusion/exclusion criteria. If potentially eligible, information about the study purpose and procedure was explained to the patients and the patient who agreed to participate in the study, the written consent form was signed by him/her were recruited to the study.

3.5 Inclusion criteria

a. Inclusion criteria

- In need for coronary angiography for diagnostic or interventional measures.
- Hemodynamically stable (systolic Blood pressure above 90mmhg).
- Presence of palpable pulse on at least one of the radial arteries.
- Not having an AV shunt for hemodialysis in both hands.
- Has never had a CABG using one of his/her radial artery.
- Not having a Reynaud phenomenon (a medical condition in which spasm of arteries cause episodes of reduced blood flow. Typically, the fingers) or lymphedema (swelling that generally occurs in one of arms or legs).
- Individuals aged 18 years or more.

b. Exclusion Criteria:

- Patients who are hemodynamically unstable (systolic blood pressure less 90mmhg).
- Patients who had undergone a previous procedure by ipsilateral radial puncture in case of impossibility to perform coronary angiography due to failure of puncture or non-progression of the catheter.

- Patients who presented vascular complications at the puncture site before the beginning of the hemostasis technique.
- Inability to insert 6Fr radial sheath in patients who have very small diameter radial artery or having a severe spasm.
- Patients who had infectious disease like COVID-19 virus infection.

3.6 Study sample and sampling

Sample size of the current study was calculated based on Rathore, et al (2010) study where seven hundred ninety patients were randomly assigned to receive either TR band or Radistop hemostatic compression devices after Transradial coronary procedure. There were significantly more patients reporting no discomfort in the TR band group compared to the Radistop group (77% vs. 61%; P = 0.0001).

This calculator uses the following formula for the sample size n:

$n = (Z\alpha/2+Z\beta)\ 2 * (p1(1-p1) +p2(1-p2)) / (p1-p2)\ 2.$

where $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), $Z\beta$ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p1 and p2 are the expected sample proportions of the two groups.

Sample size calculator provides with the recommended number of samples required to detect a difference between two proportions. In this study we required 128 patients in each group with a confidence level of 95% and a power of 80% with a sample proportion in group 1 of 77% and with a sample proportion in group 2 of 61%. Sample size for the current study is 256. We took200 patients in each group to cover drop out and increasing the power of the study. The final sample size was 400 patients.

Randomization: Computer-generated random numbers were used for randomization.

The participants were randomly allocated according to the randomization list generated by the GraphPad® software, developed by GraphPad Software Inc, San Diego, California, USA.

Assign subjects to groups 400 subjects into A and B equally.

Assign subjects to groups

Subject #	Group Assigned
1	A
2	B
3	A
4	B
5	B
6	B
7	A
8	B
9	B
10	B
11	B
12	B
13	A
14	A
15	B
16	B
17	A
18	B
19	B
20	B
21	A
22	A
23	B
24	A
25	B
26	B
27	A
28	A
29	A
30	B
31	B
32	B
33	A
34	A
35	B
36	A
37	A
38	A
39	B
40	B
41	A
42	B

Figure 1: Allocation of patients randomly to group A and B.

The sample size was 400 subjects. The study design was a prospective, randomized, observational study which was a direct comparison had been conducted between the two groups, one of which served as TR Band group, and the other was gauze swab and elastic crepe bandage group. And there wouldn't be crossover from one group to the other.

Measure's outcomes

Patient tolerance of the system was measured using a questionnaire, as well as local vascular complications and the time it took to achieve hemostasis.

Radial Artery Patency Evaluation

Prior to discharge, the patient's radial artery patency was tested. Radial artery occlusion was characterized as the absence of palpable radial artery pulsation and Doppler flow signal on hand was done as confirmatory test for all patients who had absent radial pulse and vascular complications in the puncture site like hematoma and bleeding.

Hemostasis at the Access Site and Local Complications:

After the compression system was removed, vascular problems were assessed and established as Oozing (blood leakage from puncture site requiring digital pressure), ecchymosis (bleeding into subcutaneous tissue planes causing bluish-purple discoloration 4 cm in diameter), The evaluation of hematoma is based on the classification of the EASY (Early Discharge after transradial Stenting of Coronary Arteries) study: type I ≤ 5 cm in diameter; type II ≤ 10 cm; type III >10 cm, without reaching the elbow; type IV - hematoma extending beyond the elbow; and type V - any hematoma with ischemic injury to the hand (Bertrand, Olivier F., et al 2009).

After the application of a compressive device, the patient's comfort is evaluated

Using a visual analogue scale, the patient's comfort level at the device's application site was measured during later wear of the device. The patients were specifically asked to explain the discomfort caused by the compression system at the application site and not to confuse it with any discomfort in the arm.

3.7 Procedure

After obtaining IRB and the approval of research committee of An-Najah National University hospital to conduct the study, Patients who agreed to participate in the study were randomly allocated to each group using Computer-generated random numbers. The individual, in charge of patient registration and randomization, had no involvement or knowledge of the patient's care. Prior to the operation, the investigator told the treating doctor of the treatment plan.

At the same time, all patients who underwent cardiac catheterization and interventional procedures were used TRA (Rt. and Lt.) approach as the default access with a standardized protocol. The radial arteries of the patients had been prescreened and at least one of both should be palpable before the procedure, the palm should be positioned supinated and hyperextended at the wrist and in a parallel way to the floor for facilitating TRA. 1-2cc of topical lidocaine 1% is administered at the puncture site to numb the skin to alleviate the pain resulted from needle puncture and

sheath insertion. Just after insertion of the radial sheath with Seldinger technique, each patient must receive 200 μg of intra-arterial nitroglycerine to get a vasodilatation effect and preventing radial spasm, with an addition dose of 200 μg intra-arterial nitroglycerine in case of radial spasm, also 5000 IU of intra-arterial heparin is administered for all participants who underwent cardiac catheterization with an additional dose of heparin (100 IU/kg) with maximum dose of 10 000 IU in case of cardiac intervention in order to maintain patent hemostasis.

The 6 Fr. glide sheath slender ® Hydrophilic Coated Introducer Sheath from Terumo and Merit were the commonly used introducer for all patients.

Regarding hemostasis after catheterization, some blood is withdrawn to make sure that there is no thrombus inside the sheath for both groups, then withdrawing the introducer sheath 2-3 cm out of radial artery then align the green marker of the TR Band which should be located 1cm proximal to the skin incision, and then fix the strap on the wrist with the adjustable fastener, positioning of the TR band is different from Rt. to Lt. radial approach, recording SpO2 in the finger thumb of the affected hand, after that 15cc of air injected in the band balloon with using special syringe while that withdrawing the sheath from the radial artery, then deflate the band slowly till the fresh blood is visualized in the puncture site then inject 2cc of air till the blood stopped following that pulse oximeter sensor was placed in the finger thumb of the affected hand to record the peripheral

oxygen saturation (SpO2) during compression, finally, evaluating the patient's comfort with using visual analogue scale.

The TR band will be relieved regularly every 15 minutes with withdrawing 2 to 3cc air. In case of re-bleeding, the 2 cc of air is injected again into the compressive balloon of the TR Band for another 30 minutes. After that, the TR Band should be checked and deflated every 15 minutes.

Within 4 hours after the procedure and before the patient discharge, the radial artery is checked for patency with palpating the radial pulse, capillary refill, hand color, temperature, inspecting the puncture site and the hand for any hematoma or bleeding. In case of access site hematoma or any ischemic sign, the patient will be sent to the radiology department for more evaluation by using radial artery Doppler.

In regard to hemostasis for the gauze swab and elastic crepe bandage group, first, some blood is withdrawn to make sure that there is no thrombus inside the sheath, the sheath is pulled out by 2-3 cm then one piece of small gauze (thin, translucent fabric with a loose open weave) is rolled into small square to get a height of 1cm gauze swab then apply it 1cm proximal to the skin incision to get localized pressure and wrap it with crepe bandage, SpO2 in the finger thumb of the affected hand should be obtained before wrapping the crepe bandage, the first wrap should be applied with enough pressure which should be relieved gradually in the next wraps. After that, pulse oximeter sensor was placed in the finger thumb of the affected hand to record the peripheral oxygen saturation

(SpO2), finally, evaluating the patient's comfort with using visual analogue scale.

The first evaluation of the occurrence of hemostasis after 15 min and then every15 min. In case of bleeding, further tension will be applied in the dressing and additional 30-minute intervals of compression will be performed, then re-evaluate the site every 15 minutes until complete hemostasis.

3.8 The period of the study

The study was enrolled from August, 2020 to January, 2021.

3.9 Data collection tool

Table 2: Data sheet

Patients Name			**Serial No.**			**Phone No.**		
Data Sheet : Comparison of compressive dressing with gauze swab and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions. A prospective, Randomized, Observational study								
Operator Name			**Amount of lidocaine 1%**		cc	**Access Site**	☐ Rt. Radial	☐ Lt. Radial
Previous angiographies		Num:	Sites	**Stage of Current Treatment**		☐ 1st	☐ 2nd	☐ 3rd
Previous PCIs	Stents:	Num:	Sites	**Previous Stage Access Site**				
Indication of Angiography (Patient Diagnosis)				**Puncture Duration** (from first attempt)			**# of Puncture Attempts (max is 6)**	
Cross Over to? (if none state no			Sheath size	4 Fr.	5 Fr.	6 Fr.	7 Fr.	**Procedural pain 1-10 Scale**
Procedure Duration (from the point of successful puncture)			**Heparin dose**			**Occurrence of arterial spasm** Yes / No		
			Vasodilator (Nitroglycerine)			**Intervention don**	PCI / PTCA / Non	
# of Diagnostic	Catheter:	Wire:	**# of Used Stents**		**Result of Cath**			
# of Guide	Catheter:	Wire:	**# of Used Balloons**		**Intra-Operative Complications**			
Blood Pressure			**Method of Compression**		☐ TR Band		☐ Crepe Bandage	
			Amount of Air Injected in the TR				---	
			Length of Crepe Bandage Applied		---			
Heart Rate			**SPO2 % During Band Setting**					
			Start Time					
NURSING								
Age	**Gender**	☐ M ☐ F	**Marital Satatus**		**Smoking**		**Consent Form**	
City	**Weight**		**Height**		**BMI**			
Past Medical History and Kidney Disease		☐ Arterial hypertension		☐ Smoking		**Current Clinical Presentation**	☐ Stable Angina	
		☐ Dyslipidemia		☐ Diabetes			☐ Acute Coronary Syndrome	
Use of Medications		☐ ASA	☐ ACE	☐ Beta Blocker		**Preoperative Evaluation**		
		☐ Clopidogrel		☐ Statins				
		☐ Anticoagulant	☐ Antiplatelet	☐ Thrombolytics		**Post Procedural pain 1-10 Scal**		
Ischemia to the Hand		☐ Pale	☐ Coldness	**Serious Complications**	☐ Stroke	☐ Death	**Removal of Band/ Crepe Bandage Time**	
		☐ Weakness	☐ Pulseless		☐ MI	☐ Arrhythmia		
Radial Bleeding		☐ Yes ☐ No	**Hematoma or Compartment** (EASY hematoma scale 1-5 if present)			**Send to Radiology for Doppler if Bleeding or Vascular Complications was**	☐ Yes ☐ No	
Hematoma is defined by EASY hematoma scale. This scale has 5 grades:								
Grade 1.	Local superficial hematoma					**Length of Hospital Stay**		
Grade 2.	Hematoma with moderate muscular infiltration							
Grade 3.	Forearm hematoma and muscular infiltration below the elbow					**Patients Satisfaction**		
Grade 4.	Hematoma and muscular infiltration above the elbow							
Grade 5.	Compartment syndrome							
RADIOLOGY								
Radiology Assessment of the of complications (Doppler U/S)		☐ Pseudo-aneurysm		☐ Radial artery perforation		**Occurrence of Spasm**	%	
		☐ Dissection	☐ AV fistula	☐ Immediate RAO				

3.10 Validity of the data sheet

For verifying the validity of the data sheet and knowing if the data sheet with its sections really measure what they are designed to measure. Data sheet was presented to two cardiologists, two catheterization lab technician, two PACU nurses, and one statistician. The items were adopted after being accepted by arbitrators, and there was unanimity on the data sheet of the study as well as acceptance of the modifications made by the researcher on the data sheet.

3.11 Statistical Analysis

SPSS Version 20 is used for data analysis. Descriptive statistics (frequencies, percentages, Means, Standard Deviations) are used. The following Tests and Methods were used to analyze the results assuming that the P-Value < 0.05 is considered significant:

- Chi-Square test: tests the differences between groups of patients for qualitative variables such as (Gender, Past Medical History and Kidney Disease, Use of Medications, Cross Over to Access, Previous Used Angiographic Sites, Stage of Current Treatment, Previous Stage Access Sites, Access Site, Occurrence of Arterial Spasm, Marital Status, Smoking, and Patients Satisfaction).

- Two Independent Samples T test(Adjusted for Unequal variances) : tests the differences between groups of patients for quantitative variables such as(Age, Amount Of Lidocaine 1%, Number Of Previous

Angiographies, Puncture Duration, No Of Puncture Attempts, Procedural Pain, Procedure Duration, Heparin Dose, Vasodilator, -No Of Diagnostic Catheter, No Of Diagnostic Wire, No Of Used Stents, No Of Guide Catheter, No Of Guide Wire, SBP, DBP, Heart Rate, SPO2% During Band Setting, Spo2 Without Compression, Weight, Height, BMI, Post Procedural Pain, Compression Time(Hours), Hematoma, Length Of Hospital Stay(Days), Fluoroscopy Time(Radiation In Minutes), Contrast Amount).

3.12 Ethical Considerations

The study was conducted in accordance with the World Medical Association (WMA) which has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving humans (2018). The ethical approval was taken to conduct the study from Institutional Review Board (IRB) at NNU. Information gathered in this research will be confidential.

Personal information will not be accessible to anyone besides researchers and those legally allowed. Additionally, in the event of publishing a report on this research or its results, only the conclusions will be displayed without revealing the identity of any of the participants.

All patients attending the catheterization lab at NNUH were approached by the researcher regarding the study purpose, methods, and any potential benefits or hazards of participation.

Both verbal and written consent procedures (Appendix I) were obtained in a private room and according to our institutional guidelines. The consent process was documented in the medical record per institutional guidelines.

All data were kept confidential and stored in a locked file cabinet inside locked offices. There will be no data access except for researchers. The principle investigator l has access to the original data forms. Research participants might decline participation without any negative repercussions whatsoever, and all patients will receive the full treatment plan. All patients who meet eligibility criteria regardless of gender are fully eligible to participate in the study.

Chapter Four

Results

417 patients were initially prescreened in the study. 17 were excluded, 5 because of the Cardiogenic shock and hemodynamic instability, 3 because of having COVID-19 virus infection, 4 because of having shunts in their both hands, 2 because of having no Palpable radial pulses in their both hands, 1 inability to insert 6Fr hydrophilic glide radial sheath, 2 have vascular complications in the radial artery (1 had radial dissection and the 2nd had catheter induce AV-Fistula in the radial artery) before applying the hemostatic device.

Out of the 400 patients included in the analysis 200 were randomized to the TR Band while 200 were randomized to the gauze swab and crepe bandage. No patients were excluded from result analysis in both groups.

Table 3: Baseline and Procedural Characteristics of the Study Patients.

	Method of Compression		**Total**	**P-value**
	TR Band (N=200)	**Crepe Bandage N(200)**		
Amount Of Lidocaine 1% (ml)	1.12 ± 0.37	1.17 ± 0.38	1.14 ± 0.37	0.257
Access Site				
Rt. Radial	181(90.5%)	181(90.5%)	362(90.5%)	1.000
Lt. Radial	19(9.5%)	19(9.5%)	38(9.5%)	
Number Of Previous Angiographies	1.37 ± 0.74	1.38 ± 0.87	1.38 ± 0.81	0.922
Previous Used Angiographic Sites				
1 Rt. Radial Artery	51(92.7%)	49(87.5%)	100(90.1%)	0.252
1 Lt. Radial Artery	1(1.8%)	2(3.6%)	3(2.7%)	
2 Rt. Radial Artery	0(0%)	3(5.4%)	3(2.7%)	
2 Lt. Radial Artery	0(0%)	1(1.8%)	1(0.9%)	
3 Rt. Radial Artery	3(5.5%)	1(1.8%)	4(3.6%)	
Stage Of Current Treatment				
1st	178(89%)	175(87.5%)	353(88.3%)	0.641
2nd	22(11%)	25(12.5%)	47(11.8%)	
Previous Used PCIS Sites				
1 Rt. Radial Artery	43(93.5%)	43(86%)	86(89.6%)	0.279
2 Rt. Radial Artery	2(4.3%)	6(12%)	8(8.3%)	
2 Lt. Radial Artery	1(2.2%)	0(0%)	1(1%)	

4 Rt. Radial Artery	0(0%)	1(2%)	1(1%)	
Previous Stage Access Sites				
1 Rt. Radial Artery	20(90.9%)	24(92.3%)	44(91.7%)	0.861
1 Lt. Radial Artery	2(9.1%)	2(7.7%)	4(8.3%)	
Indication of Angiography:				
Unstable Angina	134(67%)	137(68.5%)	271(67.8%)	0.748
NSTEMI	20(10%)	30(15%)	50(12.5%)	0.131
STEMI	5(2.5%)	7(3.5%)	12(3%)	0.558
Stable Angina	33(16.5%)	19(9.5%)	52(13%)	0.037
Puncture Duration (sec)	47.79 ± 23.59	47.24 ± 22.32	47.51 ± 22.93	0.811
No Of Puncture Attempts	1.26 ± 0.62	1.27 ± 0.51	1.26 ± 0.56	0.860
Cross Over To Access	3(1.5%)	3(1.5%)	6(1.5%)	1.000

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) only in the Indication of Angiography (Stable Angina), since its P-value is less than 0.05. The results show that the percentage in the Crepe Bandage group (9.5%) is significantly lower than that in the TR Band group (16.5%).

From the other hand, the results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in the rest of variables and indicators studied and appeared in the table, since their P-values are higher than 0.05.

Table 4: Procedural Characteristics of the Study Patients.

	Method of Compression		Total	P-value
	TR Band (N=200)	Crepe Bandage N(200)		
Procedural Pain	2.97 ± 1.74	2.86 ± 1.92	2.91 ± 1.83	0.567
Procedure Duration (Mins)	19.5 ± 11.64	21.97 ± 13.14	20.74 ± 12.46	0.048
Heparin Dose (IU)	6203.5 ± 1820.75	6359.5 ± 1843.78	6281.5 ± 1831.66	0.395
Occurrence Of Arterial Spasm	16(8%)	21(10.5%)	37(9.3%)	0.388
Vasodilator (µg)	215 ± 52.81	220.5 ± 60.4	217.75 ± 56.73	0.333
Intervention Done:				
PCI	56(28%)	63(31.5%)	119(29.8%)	0.392
PCI Primary	5(2.5%)	7(3.5%)	12(3%)	
PTCA	3(1.5%)	7(3.5%)	10(2.5%)	
None	136(68%)	123(61.5%)	259(64.8%)	
No Of Diagnostic Catheter	1.89 ± 0.59	1.9 ± 0.67	1.89 ± 0.63	0.812
No Of Diagnostic Wire	1.03 ± 0.2	1.05 ± 0.22	1.04 ± 0.21	0.338
No Of Used Stents	1.75 ± 0.97	1.76 ± 0.96	1.76 ± 0.96	0.951
Results of Cath:				
Normal	31(15.5%)	27(13.5%)	58(14.5%)	0.570
Ectasia	14(7%)	11(5.5%)	25(6.3%)	0.535
Arteriosclerosis	36(18%)	36(18%)	72(18%)	1.000
one vessel disease	28(14%)	25(12.5%)	53(13.3%)	0.658
2 vessels disease	46(23%)	59(29.5%)	105(26.3%)	0.140
3 vessels disease	39(19.5%)	37(18.5%)	76(19%)	0.799
patent old stents	36(18%)	21(10.5%)	57(14.3%)	0.032
Instent Restenosis (ISR)	6(3%)	3(1.5%)	9(2.3%)	0.312
Muscle Bridge	8(4%)	5(2.5%)	13(3.3%)	0.398
No Of Guide Catheter	1.13 ± 0.34	1.15 ± 0.61	1.14 ± 0.5	0.836
No Of Guide Wire	1.44 ± 0.87	1.67 ± 0.94	1.56 ± 0.91	0.114
Intra-operative complication	3(1.5%)	8(4%)	11(2.8%)	0.126
SBP	129.67 ± 17.49	128.99 ± 19.58	129.33 ± 18.54	0.716
DBP	71.8 ± 9.78	71.45 ± 8.92	71.62 ± 9.35	0.713
Amount Of Air Injected In the TR band	12.46 ± 1.1	-----	12.46 ± 1.1	-----
Heart Rate (BPM)	73.81 ± 11.13	73.34 ± 10.26	73.58 ± 10.69	0.664
SPO2% During Band Setting	93.77 ± 1.47	93.63 ± 1.3	93.7 ± 1.39	0.331
Spo2 Without Compression	97.94 ± 1.31	98.32 ± 0.86	98.13 ± 1.12	0.001

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) only in Procedure Duration and SPO2 Without Compression and Results of Cath (patent old stents), since the P-values corresponding to these three variables are less than 0.05.

Regarding Procedure Duration, the results show that the mean in the Crepe Bandage group (21.97) is significantly higher than that in the TR Band group (19.5).

Regarding SPO2 without Compression, the results also show that the mean in the Crepe Bandage group (98.32) is significantly higher than that in the TR Band group (97.94).

Regarding the Results of Cath (patent old stents), the results show that the percentage in the Crepe Bandage group (10.5%) is significantly lower than that in the TR Band group (18%).

From the other hand, the results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in the rest of variables and indicators studied and appeared in the table, since their P-values are higher than 0.05.

Regarding Intra-operative complication, the results were: 1 case has Balloon rupture, 1 case has Balloon rupture inside SVG to LAD, 1 case has Cardiogenic shock (sever hypotension), 1 case has coronary Air Embolism, 1 case has Coronary Artery Dissection (LAD), 1 case has no-reflow,

Bradycardia, Hypotension, 1 case has stent recoil and protrusion in the Aorta, and 4 cases have vagal attack.

Table 5: Demographic Characteristics of the Study Patients.

	Method of Compression		Total	P-value
	TR Band (N=200)	Crepe Bandage N(200)		
Age	58.27 ± 11.84	59 ± 11.19	58.63 ± 11.51	0.527
Gender				
Male	147(73.5%)	138(69%)	285(71.3%)	0.320
Female	53(26.5%)	62(31%)	115(28.8%)	
Marital Status				
Married	193(96.5%)	188(94%)	381(95.3%)	0.411
Single	4(2%)	5(2.5%)	9(2.3%)	
Widow	3(1.5%)	7(3.5%)	10(2.5%)	
Smoking	108(54%)	105(52.5%)	213(53.3%)	0.764
Weight	86.97 ± 19.34	84.87 ± 16.61	85.92 ± 18.04	0.244
Height	169.51 ± 12.59	169.01 ± 10.59	169.26 ± 11.62	0.668
BMI	30.21 ± 6.49	29.42 ± 5.8	29.81 ± 6.16	0.199

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in all variables and indicators studied and appeared in the table, since all P-values are higher than 0.05.

Table 6: Medical History of the Study Patients.

	Method of Compression		Total	P-value
	TR Band (N=200)	Crepe Bandage N(200)		
Arterial Hypertension	132(66%)	44(22%)	176(44%)	0.000
Hx. of Smoking	38(19%)	83(41.5%)	121(30.3%)	0.000
Dyslipidemia	23(11.5%)	33(16.5%)	56(14%)	0.150
Diabetes	89(44.5%)	56(28%)	145(36.3%)	0.001
Arrhythmia	17(8.5%)	11(5.5%)	28(7%)	0.240
Ischemic Heart Disease (I.H.D)	48(24%)	58(29%)	106(26.5%)	0.257
Valvular Heart Disease (V.H.D)	8(4%)	6(3%)	14(3.5%)	0.586
Heart Failure (H.F)	17(8.5%)	17(8.5%)	34(8.5%)	1.000
Cerebral Vascular Accident (C.V.A)	11(5.5%)	13(6.5%)	24(6%)	0.674
Kidney Disease	17(8.5%)	28(14%)	45(11.3%)	0.082
Thyroid Disease	6(3%)	3(1.5%)	9(2.3%)	0.312
Cancer	5(2.5%)	5(2.5%)	10(2.5%)	1.000
Benign Prostatic Hypertrophy (B.P.H)	5(2.5%)	4(2%)	9(2.3%)	0.736
Respiratory Disease	14(7%)	11(5.5%)	25(6.3%)	0.535
PVD	4(2%)	3(1.5%)	7(1.8%)	0.703
Gastrointestinal Disease	0(0%)	2(1%)	2(0.5%)	0.156
Blood Disorder	1(0.5%)	3(1.5%)	4(1%)	0.315
Liver Disease	0(0%)	2(1%)	2(0.5%)	0.156
Miscellaneous	10(5%)	8(4%)	18(4.5%)	0.630

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) only in Diabetes, Hx of Smoking, and Arterial Hypertension, since the P-values corresponding to these variables are less than 0.05.

Regarding Arterial Hypertension, the results show that the percentage in the Crepe Bandage group (22%) is significantly lower than that in the TR Band group (66%). Regarding Hx of Smoking, the results show that the percentage in the Crepe Bandage group (41.5%) is significantly higher than

that in the TR Band group (19%). Regarding Diabetes, the results show that the percentage in the Crepe Bandage group (28%) is significantly lower than that in the TR Band group (44.5%).

From the other hand, the results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in the rest of variables and indicators studied and appeared in the table, since their P-values are higher than 0.05.

Table 7: Outcomes of the Study Patients.

	Method of Compression		**Total**	**P-value**
	TR Band (N=200)	**Crepe Bandage N(200)**		
ASA	129(64.5%)	151(75.5%)	280(70%)	0.016
ACE	117(58.5%)	124(62%)	241(60.3%)	0.474
Beta Blocker	125(62.5%)	115(57.5%)	240(60%)	0.307
Clopidogrel	63(31.5%)	99(49.5%)	162(40.5%)	0.000
Statins	126(63%)	87(43.5%)	213(53.3%)	0.000
Anticoagulant	29(14.5%)	105(52.5%)	134(33.5%)	0.000
Antiplatelet	5(2.5%)	22(11%)	27(6.8%)	0.001
Thrombolytics	1(0.5%)	11(5.5%)	12(3%)	0.003
Post Procedural Pain	1.48 ± 1.28	0.9 ± 1.16	1.19 ± 1.25	0.000
Time to Hemostasis (Hours)	1.67 ± 0.97	1.11 ± 1.01	1.39 ± 1.03	0.000
Access site Bleeding	21(10.5%)	11(5.5%)	32(8%)	0.065
Access site Hematoma	0.18 ± 0.39	0.10 ± 0.30	0.14 ± 0.35	0.021
Send to Radiology for Doppler if Bleeding or Vascular Complications was Occurred	41(20.5%)	20(10%)	61(15.3%)	0.003
Length of Hospital Stay (Days)	1.47 ± 1.72	1.54 ± 2.11	1.50 ± 1.92	0.739
Patients Satisfaction (0-4)				
Very Satisfied	151(75.5%)	160(80%)	311(77.8%)	0.244
Satisfied	47(23.5%)	40(20%)	87(21.8%)	
Neither Satisfied Nor Dissatisfied	2(1%)	0(0%)	2(0.5%)	

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in all variables and indicators studied and appeared in the table except: ACE, Beta Blocker, Radial Bleeding, Length of Hospital Stay (Days), and Patients Satisfaction (0-4), since all the P-values in the table are less than 0.05 except corresponding to these five variables.

Regarding ASA, the results show that the percentage in the Crepe Bandage group (75.5%) is significantly higher than that in the TR Band group (64.5%).

Regarding Clopidogrel, the results show that the percentage in the Crepe Bandage group (49.5%) is significantly higher than that in the TR Band group (31.5%).

Regarding Statins, the results show that the percentage in the Crepe Bandage group (43.5%) is significantly lower than that in the TR Band group (63%).

Regarding Anticoagulant, the results show that the percentage in the Crepe Bandage group (52.5%) is significantly higher than that in the TR Band group (14.5%).

Regarding Antiplatelet, the results show that the percentage in the Crepe Bandage group (11%) is significantly higher than that in the TR Band group (2.5%).

Regarding Thrombolytics, the results show that the percentage in the Crepe Bandage group (5.5%) is significantly higher than that in the TR Band group (0.5%).

Regarding Post Procedural Pain, the results show that the mean in the Crepe Bandage group (0.9) is significantly lower than that in the TR Band group (1.48).

Regarding Compression Time (Hours), the results show that the mean in the Crepe Bandage group (1.11) is significantly lower than that in the TR Band group (1.67).

Regarding Hematoma, the results show that the mean in the Crepe Bandage group (0.10) is significantly lower than that in the TR Band group (0.18).

Regarding Cases sent to radiology for Doppler if bleeding or vascular complications was occurred, the results show that the percentage in the Crepe Bandage group (10%) is significantly lower than that in the TR Band group (20.5%).

Table 8: Radial Outcomes of the Study Patients.

	Method of Compression		Total	P-value
	TR Band (N=200)	Crepe Bandage N(200)		
Fluoroscopy Time(Radiation In Minutes)	5.36 ± 6.05	6.58 ± 6.23	5.97 ± 6.17	0.048
Contrast Amount	75.03 ± 49.48	82.02 ± 53.01	78.52 ± 51.33	0.173

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in Fluoroscopy Time (Radiation in Minutes), since the P-value corresponding to this variable is less than 0.05. The results show that the mean in the Crepe Bandage group (6.58 min.) is significantly higher than that in the TR Band group (5.36 min.).

From the other hand, the results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in Contrast Amount, since its P-value is higher than 0.05.

Table 9: Outcomes of the Hematoma Grades and Radial Artery Occlusion.

	Method of Compression		Total	P-value
	TR Band (N=200)	Crepe Bandage N(200)		
Hematoma Grades				
Grade 1	32(16%)	17(8.5%)	49(12.3%)	0.022
Grade 2	2(1%)	2(1%)	4(1%)	1.000
Grade 3	2(1%)	1(0.5%)	3(0.8%)	0.562
Grade 4	0(0%)	0(0%)	0(0%)	----
Grade 5	0(0%)	0(0%)	0(0%)	----
Acute Radial Artery occlusion	5(2.5%)	1(0.5%)	6(1.5%)	0.100
Radial artery occlusion from previous cardiac catheterization and intervention	3(1.5%)	1(0.5%)	4(1%)	0.315

* The Numbers in the table represent: Mean ± Standard Deviation for Quantitative variables and frequencies with percentages N (%) for Qualitative variables.

** The P-values are related to the Two independent samples T-test for Quantitative variables and the Chi-square test for Qualitative variables.

The results in the table above show that there are significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) only on Hematoma Grade 1, since its P-value is less than 0.05.

The results show that the percentage of Hematoma Grade 1 in the Crepe Bandage group (8.5%) is significantly lower than that in the TR Band group (16%).

From the other hand, the results in the table above show that there are no significant differences at 0.05 level between the two compression methods (TR Band, Crepe Bandage) in all the rest of variables studied and shown in the table, since their P-values are higher than 0.05.

Table 10: The cost of TR Band, crepe bandage and a gauze swab.

A crepe bandage + A gauze swab (N=200)	TR Band (N=200)
The cost of one piece of the sterile gauze is 0.25NIS.	cost: 65NIS /unit
The cost of 10cm crepe bandage is 3.10NIS.	
Total: 3.35 NIS/ patient 3.35*200= 670 NIS	Total cost: 65*200= 13,000 NIS

The total cost of sterile gauze and 10 cm crepe bandage for 200 patients was 670 NIS, according to the table above, while TR Band cost 13,000 NIS. It is obvious that using sterile gauze bandages and 10 cm crepe bandages saves money and is therefore more cost effective (Table 11).

Chapter Five
Discussion

5.1. Discussion

This observational, prospective, randomized study directly compared two compression devices (TR Band and elastic crepe bandage gauze swabs) to understand their hemostatic ability and their impact on ARO. The main results were as follows: 1) Grade 1 hematomas and access site bleeding which were more prevalent and higher in the TR Band, 2)TR Band had a higher rate of acute RAO before discharge (2.50% vs. 0.5%; $p = 0.100$), but it was not significant 3) Time to hemostasis is significantly lower in the gauze swab and crepe bandage group (1.67 vs. 1.11 ($p = 0.000$), 4) Gauze swab and crepe bandage was more tolerated by the participants as seen through the numerical visual analogue pain scale assessment (1.48 vs. 0.9 ($p = 0.000$).

Regarding Grade 1 hematomas and access site bleeding which were more prevalent and higher in the TR Band, there were 32/200 (16%) patients in TR Band group with Grade 1 hematomas compared to 17/200 (8.5%) in gauze swab with elastic crepe bandage group. This result is in alignment with the study result conducted by de Carvalho Campos, et al (2018) showed that incidence of hematomas at the puncture sites was the most prevalent immediate complication in the two groups, classified as type I, with a high incidence, but all of which resolved spontaneously without intervention in the patients who underwent elective transradial coronary

angiographies who were divided into 2 study groups: (G30), whose compressive dressing was worn for 30 min, and (G60), whose compressive dressing was worn for 60 min. Also, the result of the current study is consistent with the prospective cohort study with compression bandages with gauze bandages and elastic bandages placed for 4 h after the diagnostic coronary angiographies conducted by Almeida, et al (2012), showed type I hematomas in 7.5% and type II hematomas in 2.4% of the 120 patients assessed by vascular ultrasound following removal of the bandages.

In the current study it was shown that TR Band had a higher rate of acute RAO before discharge (2.50% vs. 0.5%; $p = 0.100$). This result is not in alignment with the study result conducted by Con, et al (2018) when used 3 approaches for radial artery hemostasis after PCI using a custom compression bandage, pneumatic bracelet (PW), or rotary bracelet (RW) that were compared. The study found that patients with compression bandages had an elevated incidence of RAO 24 h following the intervention and a reduced level of satisfaction ($p < 0.05$).

Regarding the time to hemostasis which is significantly lower in the gauze swab and crepe bandage group when compared to TR Band group, in terms of hemostasis, the current study found that compression by gauze swab with elastic crepe bandage for 1.11± 1.01 h at the site of the puncture following elective transradial coronary angiographies was significantly lower than TR Band 1.67 ±0.97 ($p = 0.000$). The findings of this study are

consistent with the findings of de Carvalho Campos et al (2018), who demonstrated that compression dressings for a short duration of time at the puncture site for 30 min following any transradial coronary angiographies were as safe and effective in terms of hemostasis as compression dressings for 60 min, as well as the presence of both immediate and late complications.

The elevated rate of acute RAO (2.50 vs. 0.5%; $p = 0.100$) before discharge in the TR Band may be explained with higher rate of grade 1 radial hematomas, which were probably associated with the design of the TR Band. In case the hematomas were visualized, notably, in the current study, compression was applied more aggressively and for a longer duration to hinder these hematomas from expanding further, which can definitely increase the risk of radial artery occlusion as seen in the compression of radial arteries without occlusion (CRASOC) studies (Dangoisse, et l 2012; de Carvalho Campos, et al 2018). Additionally, receiving anti-coagulant, anti-platelets and thrombolytic medications was higher in the gauze swab and crepe bandage group which was shown to protect against the occurrence of RAO, as demonstrated in the PROPHET 2 study (Pancholy, et al 2016).

Because of only one patient had RAO in gauze swab with elastic crepe bandage group, it is possible that the compression time of about 1.11 hours in the gauze swab with elastic crepe bandage group was a significant factor in lowering the incidence of RAO. This finding is consistent with the

findings of Pancholy et al. (2012), who investigated the effects of the duration of the hemostatic compression on the occurrence of RAO following transradial coronary interventions and discovered that patients who wore a pneumatic bracelet to compress the radial artery for 6 h had a higher frequency of immediate ($p = 0.025$) and then late ($p = 0.035$) RAO than those who wore the bracelet for 2 h. These findings were also consistent with a randomized study that found compression time to be a good predictor of RAO, lending credence to the hypothesis that compression time be reduced in order to minimize radial damage (Dharma, et al 2015). According to some authors in another study assessed the effect of 3 volumes insufflation of the bracelet corresponding to the intensity of compression and residence time on the incidence of RAO and showed that the shorter the compression time and the lower the intensity, the lower the rates of RAO (Dangoisse, et al 2017).

In terms of the level of discomfort that these devices might cause, the hemostatic compressive devices were well-tolerated and efficient. However, discomfort was more associated with TR Band. This finding is consistent with the findings of Rathore et al. (2010), who discovered that both hemostatic compressive devices, the TR Band and the Radistop device were well-tolerated and efficient. However, discomfort was more associated with the Radistop device.

Higher rate of discomfort was reported in the TR Band group on the visual pain assessment tool (1.48 vs. 0.5; p=0.000) may be related to the larger pneumatic bladder of the TR band and its construction from plastic as seen in the Sanghvi, Kintur A., Mathew Montgomery, and Vincent Varghese. (2018) when they are comparing between the TR band and Safeguard pneumatic compression devices, in the current study the used gauze swab and crepe bandage was perceived more comfortable by participants may be related to stretchable effect of the crepe bandage that made from cotton, polyester and latex free elastic yarns, also the construction of the gauze swab which is made from accomplished cotton yarn to achieve higher tending capacity and absorption rate.

Previous research has found radial artery occlusion rates ranging from 3 to 10% (Rathore, et al 2010, Pancholy, et al 2008). In the current study radial arterial occlusion was observed before discharge in 2.5 percent of our TR band patients and 0.5 percent of our crepe bandage patients following a transradial coronary artery procedure. Several predicting factors, including diabetes, Arterial hypertension, dyslipidemia, statin and smoking which were significantly higher in TR Band group compared to crepe bandage group have been linked to radial artery occlusion in TR Band group. These results were in agreement with the study results conducted by Saito, et al (1999) which have found diabetes mellitus to be associated with radial artery occlusion.

Other factors that have been linked to radial artery occlusion include 63 (31.5 percent), fewer patients in TR Band group taking Clopidogrel compared to 99 (49.5%) in the crepe bandage group (p = 0.000). Patients taking ASA 151(75.5%), anticoagulants (105 (52.5%), antiplatelets (22 (11%), and thrombolytics (11 (5.5%) in crepe bandage group were significantly more than patient in the TR band group. These factors could be protective factors for RAO in the crepe bandage patients. Some of the studies looked at the impact of various pharmacological interventions on RAO, primarily postoperatively. In one study, administering a vasodilator cocktail before and after the procedure, in addition to IV heparin, appears to have reduced the incidence of RAO (Abboud, et al 2013). Ahmed et al. (2012) compared warfarin to LMWH for RAO reduction and concluded that warfarin was worse than LMWH. In a separate prospective study conducted by Zankl et al (2010), investigated the effect of LMWH on the treatment of the RAO postal procedure and discovered that LMWH significantly improved the radial artery recanalization rate. According to these studies, using additional anticoagulation procedures may improve RAO outcomes

Regarding the lack of radial pulse that is frequently explained as RAO, however, this has the potential to lead to an underestimation of the true occurrence of RAO. In the current study, there were significantly more patients 41(20.5%) in TR Band group sent to Radiology for Doppler if bleeding or vascular complications compared to 20(10%) in crêpe bandage group, (p=0.003). In a 2007 study, it was found that the incidence of RAO

as defined by the lack of radial pulse was 4.4%, and the incidence of RAO without radial artery blood flow was 10.5% (Sanmartin, et al 2007). Therefore, it has been recommended that a more objective approach to assess the incidence of RAO through radial flow like ultrasound was needed (Rao, et al 2014).

Using a smaller size access device (Aminian, et al 2014),vasodilator (Abboud, et al 2015) , anticoagulation (Bernat, et al 2011), using the shortest duration of time to achieve hemostasis (Aminian, et al 2014) was adopted as best practice to utilize the radial artery access for cardiac catheterization and interventions, and preventing the vascular complications. In addition, the confounders were eliminated with the homogeneous distribution of the arterial spasm (Coppola, et al 2006), female gender (Aykan, 2014), smaller BMI (Pancholy, 2008), and operator experience (Tavakol, et al 2012) which was considered as risk factor for RAO in both groups that's interpret the direct effect of compression devices with our outcomes.

The TR band balloon had a wider surface area when compared to the enrolled small gauze swab. Gauze swab and crepe bandage can exert more precise and localize compression pressure on the radial entry and thus lower pressure is required to achieve the hemostasis, moreover enrolling the gauze swab to a small piece with a height of 1cm above the radial puncture site before wrapping the crepe bandage helps to avoid concurrent compression pressure on the ulnar artery that lessened the blood

engorgement and thrombosis in the distal hand with increasing the blood inflow and outflow to the used hand (Rathore et al 2010)

Therefore, accurate placement of both compression methods is very important, maximum point of the compression (Green marker above the TR Band balloon and the central point of the enrolled gauze swab) should be applied at the level of arteriotomy which is estimated to 1cm proximal to the skin puncture (Figs. 1.2, 2.2), and not at the level of skin puncture (Fig. 2.1).

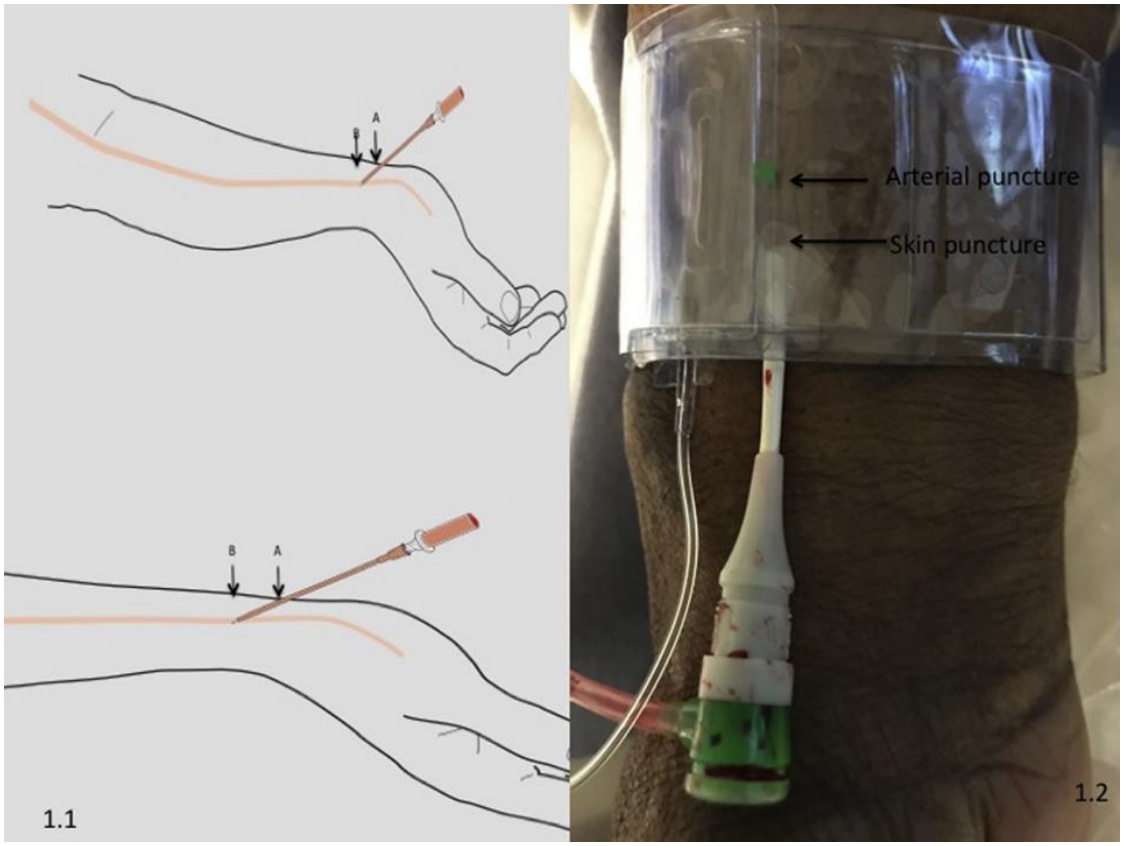

Figure 2: The placement of TR band with the center of pneumatic bladder at the arterial puncture level.

The distance between the skin puncture (A) and the arterial puncture (B) will vary depending on the angle of insertion of the needle and the depth of the radial artery. 1.2: The TR band is placed in the center of the inflatable balloon at the level of the arterial puncture.

If the generated pressure of both compression methods is applied directly to site of the skin puncture but doesn't cover the arteriotomy, the blood will continue to ooze out underneath the skin till getting hematoma in the forearm proximal o compression placement without visualized bleeding from skin puncture site, moreover the TR band strap is 4cm in diameter, thus it couldn't cover the extended hematoma alone and it couldn't apply compression for multiple widespread punctures in the proximal and distal radial artery (Rathore et al 2010).

5.2 Limitations

This was a single center trial, we couldn't measure the generated pressure from the gauze and crepe bandage compression method, Doppler ultrasound for the radial artery after cardiac catheterization was done just for those participants had no palpable radial pulse and getting vascular complications (hematoma, bleeding) in the radial artery entry before discharge from hospital, we didn't record the dose of anxiolytic sedative agents which were given to patients treated with these medications depending on their clinical profile during the procedure which could have possible effect on the study result.

5.3 Conclusion

Enough pressure with shortest time to hemostasis was linked to reduced incidence of acute RAO. The development of access site hematomas was linked to higher incidence of RAO. While the overall safety, time to hemostasis and vascular complications (hematoma and RAO) Gauze swab are less in the gauze swab and crepe bandage group. In clinical practice, hemostasis with gauze swab and crepe bandage is recommended as a low-cost strategy, lending support to the hypothesis that compression time should be reduced to reduce radial injury.

5.4 Recommendations

crepe bandage compression method after transradial cardiac catheterization and interventions was superior to TR band compression method in terms of hemostasis and vascular complications (Grade 1 hematoma, acute RAO), for that it promising to save radial artery patency for further future needs for radial artery uses.

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Annexes

Annex1

Consent Form

نموذج موافقة خطية للمشاركة في دراسة بحثية

الباحث الرئيسي: فاتح رائد عواد.

الباحث الرئيسي المساعد: د. عائدة القيسي.

الباحث المساعد: د. يونس دار عموري.

عنوان الدراسة: "مقارنة نتائج إغلاق الشريان الكعبري بعد القسطرة القلبية والعلاجية باستخدام ضمادة (رباط طبي) او باستخدام اسوارة بلاستيكية تحتوي على بالون ضاغط باستخدام الهواء"

الدراسة البحثية: لقد طلب إليّ المشاركة في دراسة بحثية تحت إشراف د.يونس دار عموري في مختبر القسطرة القلبية، في مستشفى النجاح الوطني الجامعي– نابلس–فلسطين ، وتحت إطار قوانين مستشفى النجاح الوطني الجامعي وقوانين إجراء القسطرة القلبية.

الهدف: تهدف المقارنة بين طرق إغلاق الشريان الكعبري بعد القسطرة القلبية والعلاجية ، للكشف عن ايجابيات وسلبيات كلتا الطريقتين.

آلية المشاركة: نعم لا

سيطلب مني الإجابة عن أسئلة حول الحالة الصحية قبل التدخل الطبي،والسماح للطبيب بالدخول بالشريان من المكان المقرر في الدراسة وأسئلة بعد الانتهاء من التدخل الطبي.

المشاركين: بمشاركتي سأكون واحد من ألف مشترك من المشتركين الذين سيتم إجراء الدراسة البحثية عليهم.

المدة اللازمة: مشاركتي في هذه الدراسة ستستغرق من 20–60 دقيقة؛ وهو الوقت اللازم لإجراء القسطرة القلبية بناء على حالة المريض ونتائج التشخيص والحاجة لتدخل علاجي, إضافة إلى ساعة أو ساعتين بعد القسطرة لإزالة الضمادة عن مكان الدخول.

التطوع للمشاركة: اختار أن أتطوع للمشاركة ولا أطالب بدفع أي مبلغ مقابل مشاركتي.

المخاوف/المخاطر: هي ذاتها المخاطر المحتملة في حالة القسطرة القلبية، وتشمل :الم في مكان الدخول، نزيف،انتفاخ، حساسية (نتيجة المادة المشعة)، انسلاخ او إيذاء بالشرايين القلبية ،وكذلك مخاطر التخدير او احتمال الحاجة لنقل الدم او احد مشتقاته وغيرها من مخاطر القسطرة القلبية.

الفوائد: ستفيد نتائج الدراسة البحثية بالكشف عن ايجابيات وسلبيات طرق إغلاق الشريان الكعبري بعد القسطرة التشخيصية والعلاجية، مما سيساعد مستقبلا في اعتماد إحدى هاتين الطريقتين مما سيخفف آلام المرضى ويقلل المضاعفات.

الاستثناءات: سيقوم الباحثون باستثناء المرضى الذين سيخضعون للقسطرة القلبية في حالة مستعجلة نتيجة احتشاء طارئ في عضلة القلب.

الخصوصية: سيتم بذل كل الجهود لحفظ خصوصية المعلومات التي تم تسجيلها، ولا يستطيع أحد الاطلاع على هويتي الشخصية سوى الباحثين المسؤولين الذين يسمح لهم القانون بذلك، وإذا تم نشر تقرير لهذه الدراسة، أو تم عرض نتائجها في مؤتمر علمي مهني، فإنه سيتم عرض مجموعة النتائج التي تم التوصل إليها (فقط) دون التعريف باسمي وهويتي أو باسم أحد المشاركين.

الحق في الرفض او الانسحاب: إنّ مشاركتي بإرادتي وإنه بإمكاني أن أرفض المشاركة أو أن أتوقف عن المتابعة وأنسحب في الوقت الذي أريد دون التعرض لأي لوم أوّ عقوبات، أو فقد الفوائد التي أستحقها.ّ وإني كذلك أتفهم أن الباحث له الحق بإخراجي من الدراسة في أي وقت شاء.

الحقوق أثناء المشاركة: إن لي الحق بتوجيه الأسئلة حول أي جزء من الدراسة، وفي أي وقت، ولي الحق أيضا في عدم الموافقة والإمضاء حتى اسأل عما أريد واحصل على الإجابات لأسئلتي.

للتواصل: إن كان لدي أي سؤال عن علاجي أو الأساليب والوسائل البحثية، فإنه بإمكاني التواصل مع قسم القسطرة القلبية في مستشفى النجاح الوطني الجامعي–نابلس، ممثلا برئيسه د.يونس دار عموري .

مستشفى النجاح الوطني الجامعي– قسم القسطرة القلبية (0097292331471)

الدكتور يونس دار عموري (0598434614)

إن كان لدي أي سؤال يخص حقوقي كمشارك في البحث، فإنه بإمكاني التواصل مع:

لجنة أخلاقيات البحث العلمي في جامعة النجاح الوطنية – نابلس

كلية الطب – جامعة النجاح الوطنية

توقيع المشترك:

أنا الموقع أدناه المريض ولي الأمر القريب (صلة القرابة:_____)

أوافق على إخضاع نفسي المريض التابع لي قريبي

لأكون جزء من هذه الدراسة ،ولقد قرأت وفهمت كل أجزاء هذا النموذج، ولقد أجاب الطبيب عن جميع أسئلتي حول هذا البحث وحول المشاركة ، **أوافق على المشاركة في هذه الدراسة.**

اسم المريض الكامل: _____

الاسم الكامل التوقيع

التاريخ

توقيع الباحث:

لقد أوضحت وشرحت بأفضل ما استطيع مكونات الدراسة بما فيها من جميع المعلومات التي يحويها هذا النموذج، ولقد أجبت بدقة عن جميع أسئلة المشترك في البحث

الاسم الكامل توقيع الطبيب

التاريخ

Annex2

IRB

An-Najah
National University
Health Faculty of medicine&
Sciences
IRB

جامعة النجاح
الوطنية
كلية الطب وعلوم الصحة
لجنة اخلاقيات البحث العلمي

Ref : Mas June /20/10

IRB Approval Letter

Study Title:

"Comparison of compressive dressing with gauze and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions. A prospective, randomized, observational study"

Submitted by:
Fateh Raed Awwad

Supervisor:
Dr. Aidah Abu Alsoud Alkaissi , Dr.Yunis Dar Ammouri

Date Approved:
30th June 2020

Your Study Title **"Comparison of compressive dressing with gauze and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions. A prospective, randomized, observational study"** was reviewed by An-Najah National University IRB committee and was approved on **30th June 2020.**

Hasan Fitian, MD

IRB Committee Chairman
An-Najah National University

IRB

Annex3

Facilitation request for NNUH

An-Najah
National University
Faculty of medicine
&Health Sciences
Department of Graduate
Studies

جامعة النجاح
الوطنية
كلية الطب وعلوم الصحة
قسم الدراسات العليا

التاريخ: 2020/7/22

حضرة الدكتور كمال حجازي المحترم / المدير التنفيذي مستشفى النجاح التعليمي ، ،

تحية طيبة وبعد،

الموضوع: تسهيل مهمة طالب الماجستير فاتح رائد صالح عواد / ماجستير تمريض عناية مكثفه

يهديكم قسم الدراسات العليا في كلية الطب وعلوم الصحه / جامعة النجاح الوطنية أطيب التحيات ونشكر لحضرتكم حسن تعاونكم معنا ونرجو التكرم بالموافقه على تسهيل مهمة الطالب المذكورة أعلاه ، حيث أنه سيقوم بعمل دراسة بغرض البحث العلمي لأطروحة التخرج تحت عنوان:

Comparison of compressive dressing with gauze and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions. A prospective, randomized, controlled clinical

في مستشفى النجاح الوطني الجامعي في قسم القسطرة ، لذا نرجو التكرم بالموافقة و تسهيل مهمة الطالب.

تحت اشراف: -د. عائدة القيسي ، د.يونس دار عموري

- مرفق ملخص الدراسه و IRB
- Data Sheet

وتفضلوا بقبول الطلب ولكم فائق الاحترام ، ،

د.حسن فتيان

رئيس قسم العلوم الصحية في كلية الدراسة العليا

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Annex4

Facilitation Request for Ministry of Health

Please provide the following information to apply for research data collection permission at the Palestinian Ministry of Health institutions:

Research Title **اسم البحث**	**Comparison of compressive dressing with gauze swab and elastic crepe bandage versus TR band in the management of the radial approach for cardiac catheterization and interventions. A prospective, Randomized, Observational study"**
University Name اسم الجامعة	**Najah National University**
Principal Investigator/ Supervisor's name اسم الباحث/ المشرف	**Principle Investigator: Fateh Raed Awwad Clinical and faculty Supervisor's: Dr. Yunis Darammori Dr. Aidah Abu Alsoud Alqaisi.**
Students participating in the research أسماء الطلاب المشاركين في البحث	----------
Specialty التخصص	**Master Degree Of Critical Care Nursing .**
Abstract ملخص الدراسة	**Comparing between two methods of compression therapy for managing radial approach after Cardiac catheterization and intervention in terms of benefit, complications and cost effectiveness .**
Methodology منهجية البحث	**A prospective, Randomized, Observational study, single center at An Najah National University Hospital**
Data collection methods and tools طرق جمع البيانات والأدوات	**Simple Randomization Technique with using GraphPad software for eligible Patients who accept to participate in the study, then Fullfill the Subjective and objective Data sheet.**
Dates and time of data collection تواريخ ووقت جمع البيانات	**The study was enrolled from August, 2020 to January, 2021**
Sample size حجم العينة	**400 Patients**
Who will collect data or samples من سيجمع البيانات أو العينات	**Cardiology Consultant , cath Lab technicians, the Cardiology nursing and the principle investigator**
Questionnaire or questions of the interview (copy) استبيان أو أسئلة المقابلة (نسخة)	**Will be attached**
Ethical considerations الاعتبارات الاخلاقية	**Declaration of Helsinki and ethical approval from Institutional Review Board (IRB) at An Najah National University (the IRB Approval will be attached)**
Support the Ministry of Health with a copy of the final research تزويد الوزارة بنسخة من نتائج البحث (في حال البحث للبكالوريوس يكتفى بنسخة الكترونية)	
Contacts: Dr. Amal Abu Awad – Director General of Education in Health: **ibnsina99@yahoo.com** Mobile: 0562402187 Telefax: 09-2333901 Basima Joudeh : basimamoh@gmail.com mobile: 0562401397	

جامعة النجاح الوطنية

كلية الدراسات العليا

مقارنة نتائج إغلاق الشريان الكعبري بعد القسطرة القلبية والعلاجية باستخدام ضمادة (رباط طبي) وقطعة شاش او باستخدام اسوارة بلاستيكية تحتوي على بالون ضاغط باستخدام الهواء

إعداد

فاتح رائد عواد

إشراف

د. عايدة القيسي

د. يونس عموري

قدمت هذه الاطروحة استكمالاً لمتطلبات الحصول على درجة الماجستير في برنامج تمريض العناية المكثفة، من كلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس- فلسطين.

2021

مقارنة نتائج إغلاق الشريان الكعبري بعد القسطرة القلبية والعلاجية باستخدام ضمادة (رباط طبي) وقطعة شاش او باستخدام اسوارة بلاستيكية تحتوي على بالون ضاغط باستخدام الهواء

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الملخص

المقدمة: الضمادة البلاستيكية هي أداة طبية على شكل اسوارة تحتوي على بالون ضاغط في منتصف الاسوارة له مدخل خاص يتم حقن الهواء من خلاله ليتم توليد قوة او ضغط على مدخل الشريان الكعبري لتمنع رشوح الدم أو النزيف.

الرباط الطبي وقطعة الشاش يتم صنعها وغزلها من القطن ولها استخدامات طبية عديدة، وفي بحثنا يتم تشكيل قطعة مصغرة من قطعة شاش واحدة معقمة على مدخل الشريان الكعبري ومن ثم لفها بالرباط الطبي لتشكل قوة ضاغطة على مدخل الشريان الكعبري ومنع النزيف.

الهدف: تهدف المقارنة بين طرق إغلاق الشريان الكعبري بعد القسطرة القلبية والعلاجية، للكشف عن ايجابيات وسلبيات كلتا الطريقتين من ناحية نزيف الدم ومضاعفات الشريان الكعبري ومقارنة التكلفة المالية لكلتا الطريقتين فقط من ناحية سعر الشراء.

طريقة ومكان البحث: تم إجراء البحث في مستشفى النجاح الوطني التعليمي في نابلس– فلسطين والذي امتد من شهر شعبان لعام 2020 إلى شهر يناير لعام 2021، بحيث تم إشراك أربعمائة مريض في الدراسة بحيث شملت المجموعة الأولى على 200 مريض خضعوا لإغلاق الشريان الكعبري باستخدام ضمادة وقطعة شاش والمجموعة الثانية على 200 مريض خضعوا لإغلاق الشريان الكعبري باستخدام اسوارة بلاستيكية تحتوي على بالون ضاغط باستخدام الهواء، حيث أن جميع المشاركين قد قدموا لإجراء قسطرة قلبية أو علاجية، وقد تم إجراء مسح شامل لجميع

المرضى للتأكد من مطابقتهم لمعايير المشاركة في الدراسة ومن ثم تم الحصول على الموافقة الخطية لمشاركتهم في الدراسة.

النتيجة: المرضى الذين تم التحكم في شريانهم الكعبري بعد القسطرة القلبية أو العلاجية عن طريق الضمادة الطبية وقطعة الشاش كانوا أقل عرضة للنزيف وأقل عرضة للإغلاق الكامل للشريان الكعبري وأن المدة الزمنية اللازمة لوقف النزيف كانت أقل بالإضافة إلى الشعور بالألم وعدم الراحة كانت أقل، أما المرضى الذي تم إغلاق شريانهم الكعبري بعد القسطرة القلبية أو العلاجية عن طريق الأسوارة البلاستيكية كانوا أكثر عرضة للنزيف والإغلاق الفوري للشريان الكعبري، وقد احتاجوا إلى مدة زمنية أطول من الضغط بالإضافة إلى أن الشعور بالألم وعدم الراحة كان أكثر.