An-Najah National University

Faculty of Graduate Studies

COMPARISON OF VASCULAR CLOSURE DEVICES VERSUS MANUAL COMPRESSION IN TERMS OF POSTOPERATIVE COMPLICATIONS AMONG PATIENTS UNDERGOING CEREBRAL ANGIOGRAPHY: A HOSPITAL-BASED OBSERVATIONAL STUDY

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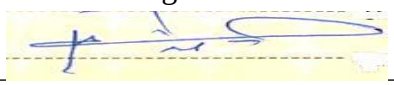
Wael Sadaqa	
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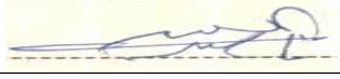
Dr. Naser Hanbali	
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Dedication

To everyone who gave me the moral support for the completion of this task.

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First, I give all the glory to God, the source of my strength, for granting me both the mental and physical endurance to complete this monumental task.

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To everyone who gave me the moral support for the completion of this task, Thank you.

Author

Duaa Faraj

2022

Declaration

I, the undersigned, declare that I submitted the thesis entitled:

COMPARISON OF VASCULAR CLOSURE DEVICES VERSUS MANUAL COMPRESSION IN TERMS OF POSTOPERATIVE COMPLICATIONS AMONG PATIENTS UNDERGOING CEREBRAL ANGIOGRAPHY: A HOSPITAL-BASED OBSERVATIONAL STUDY

I declare that 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.

Student's Name: _____

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Date: _____

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ABSTRACT

Background: Transfemoral cerebrospinal angiographies are commonly performed in different healthcare settings around the world. Vascular closure devices (VCDs) and mechanical compression (MC) approaches are used to achieve hemostasis.

Objectives: This study was conducted to assess and compare postinterventional complications occurring among patients who underwent transfemoral cerebral angiography when MC or a VCD (Angio-Seal VIP) were used.

Methodology: This was a retrospective cohort study in which patients who underwent cerebral angiography At An-Najah National University and for whom MC or a VCD (Angio-Seal VIP) were used. The clinical files and records of the patients were reviewed for data collection.

Results: A total of 166 patients were included. Of those, 89 had MC and 77 had Angio-Seal VIP. Patients in the MC group had significantly higher prothrombin time (p-value = 0.009), partial thromboplastin time (p-value < 0.001), and international normalized ratio (p-value < 0.001). Angio-Seal VIP was associated with significantly shorter time to hemostasis (p-value < 0.001), lidocaine use (p-value = 0.012), use of acetylsalicylic acid (p-value = 0.001), and use of tirofiban (p-value < 0.001). More patients in the MC group reported discomfort at discharge compared to patients in the Angio-Seal VIP group (p-value = 0.001), stayed significantly longer duration in the intensive care unit (ICU) (p-value < 0.001), in the hospital (p-value < 0.001), needed longer mechanical ventilation hours (p-value = 0.030), reported higher

postinterventional pain (p-value = 0.011), and needed prolonged bed rest hours (p-value = 0.007).

Conclusions: Findings of this study indicated that Angio-Seal VIP was associated with less postinterventional complications compared to MC for patients undergoing transfemoral cerebral angiographies. Although both methods could be safe and effective in helping achieve hemostasis, Angio-Seal VIP could reduce postinterventional complications that can lead to longer mechanical ventilation hours, higher postinterventional pain, longer stays in the ICU, in hospital, longer bed rest, and higher patient discomfort at discharge.

Keywords: Catheterization, cerebral angiography, femoral artery, hemostasis, mechanical compression, vascular closure device.

Chapter One

Introduction and Theoretical Background

Vascular interventions have witnessed dramatic evolutions and advancements in the last few decades. These evolutions and advancements allowed a shift from obsolete open surgical interventions to an increasingly used forms of percutaneous endovascular interventions (1). In 1953, the Swedish interventional radiologist Sven Ivar Seldinger introduced his technique, known as Seldinger technique, that allowed obtaining safe access to blood vessels and hollow organs (2). Since then, percutaneous access through the femoral artery became the most commonly used method of access in diagnostic and therapeutic vascular interventions (3). According to recent estimates, more than seven million percutaneous interventions are done on yearly basis around the world (1). Despite the fact that access through the radial artery is gaining more popularity, access through the femoral artery is still being used in the majority of the majority of the percutaneous interventions performed in different settings worldwide (4, 5).

1.1 Cerebral angiography

In clinical practice, cerebral angiography remains the gold standard method used to visualize blood vessels and detect presence of aneurysms or other extracranial cerebrovascular disease (6). Cerebral angiography can be done *via* either the transradial or the transfemoral routes. Recent evidence has suggested that both transradial and transfemoral approaches are safe and effective (5). Although the transradial access was shown to be associated with fewer local vascular complications compared to the transfemoral access, in today's practice, cerebral angiography is primarily performed using transfemoral access rather than transradial access in the majority of settings (5, 7). Studies have shown that the transfemoral access was associated with more access site complications (8). Therefore, recent guidelines recommend against using the transfemoral access for patients with occlusive lesions in the abdominal aorta or iliac artery and those with severe atherosclerosis (8, 9).

Compared to the transradial access, transfemoral access requires prolonged limb immobilization and prolonged compression of the femoral artery to prevent/reduce incidence of bleeding and other potential access site complications (5, 10). Therefore,

patients who undergo cerebral angiography using the transfemoral approach are subjected to longer periods of bed rest compared to those who undergo cerebral angiography using the transradial approach. These prolonged periods of bed rest were shown to be associated with incidence of back pain, deep venous thrombosis, and urinary retention, among other complications (11). The transradial route is shown in Figure 1.1 and the transfemoral route is shown in Figure 1.2.

Figure 1.1

Cerebral angiography via the transradial route (Courtesy: (12), Created under a Creative Commons license)

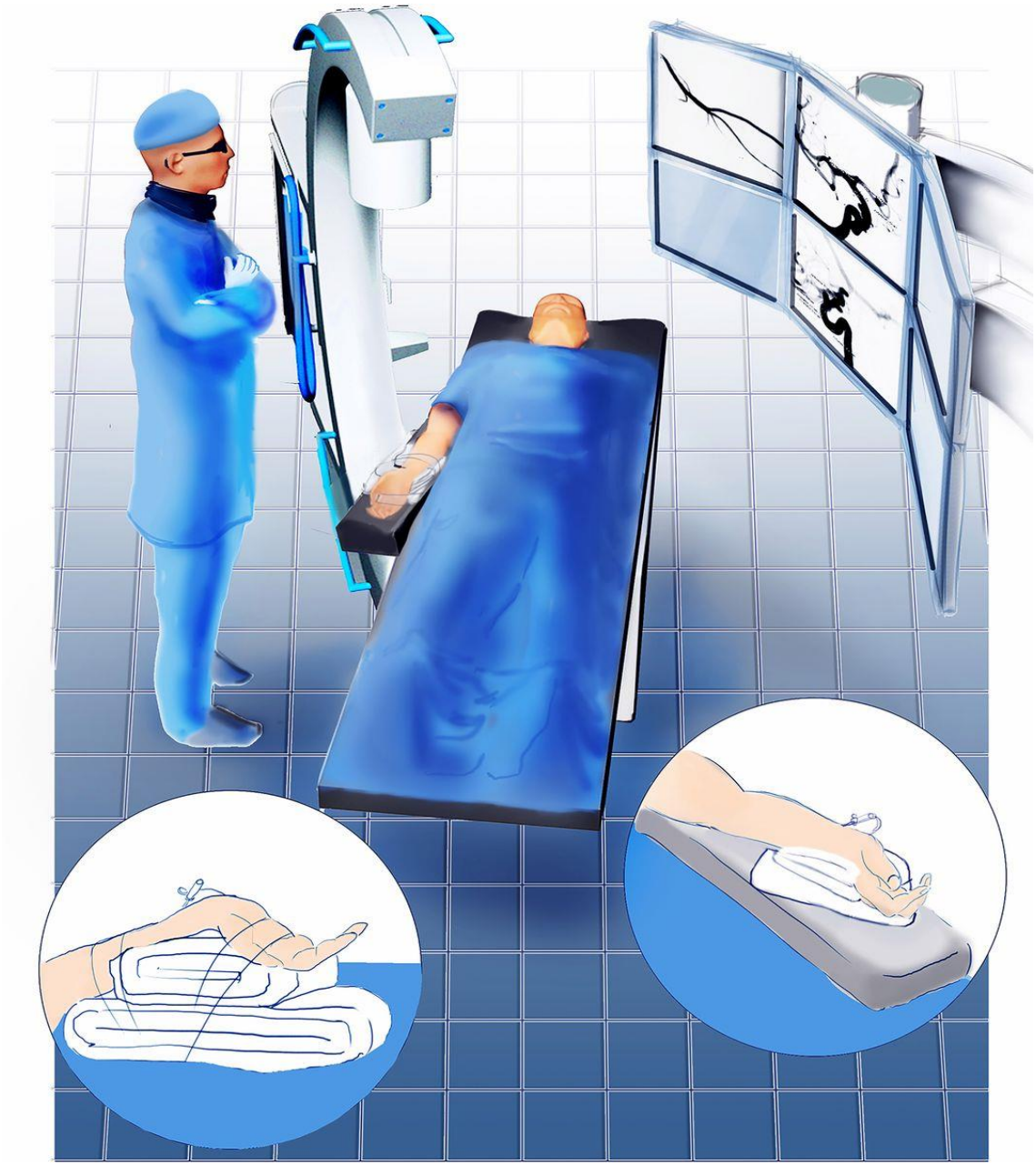
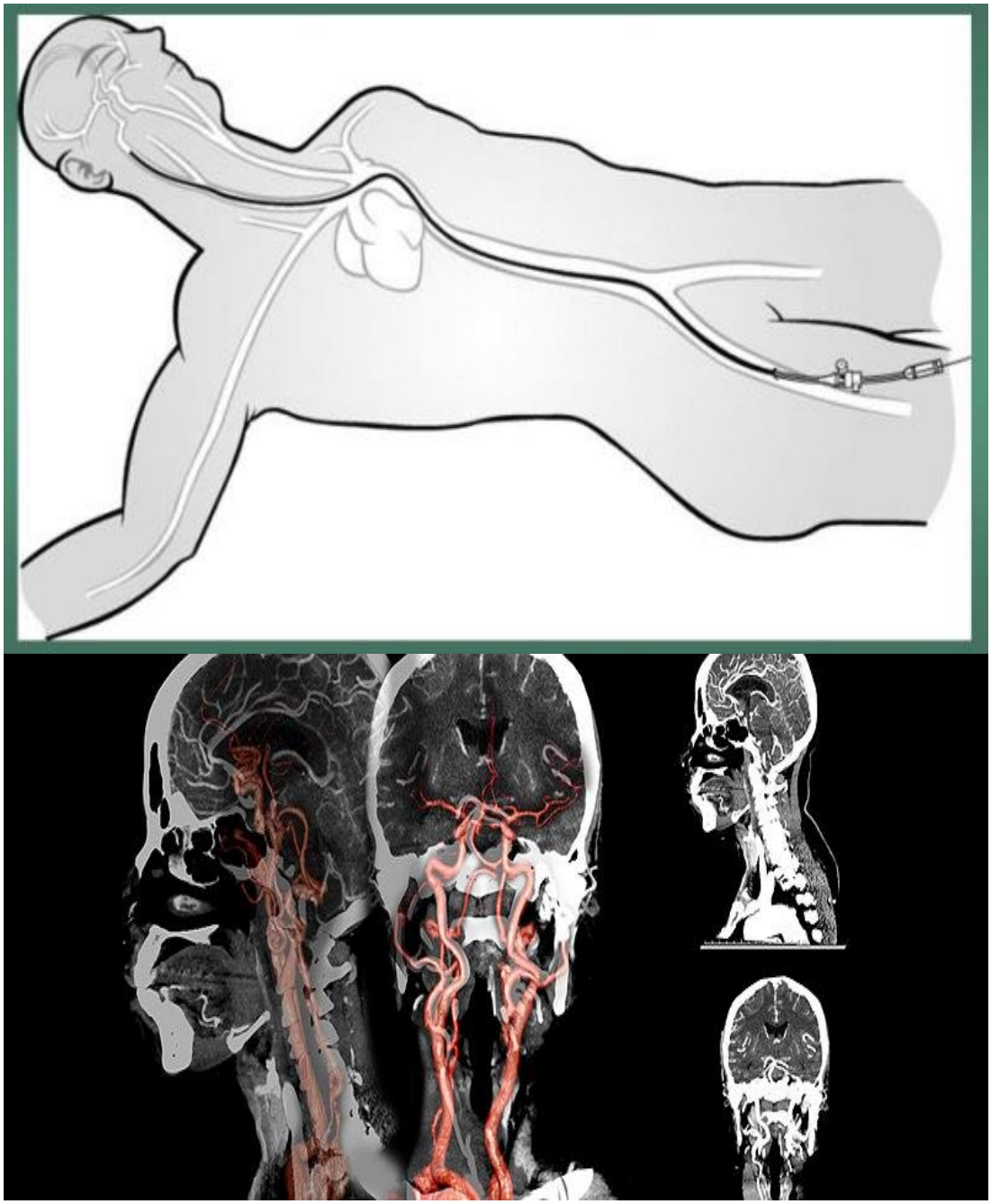


Figure 1.2

Cerebral angiography via the transfemoral route



1.1.1 Transfemoral access

Since its first use, the transfemoral arterial approach has evolved as one of the most commonly used techniques in cerebral angiography (13). This pathway was long considered conventional and the most valuable in performing cerebral angiographies. It is well-established that the blood circulation to the brain passes through 2 main arterial divisions: anterior and posterior distribution circulation. The brain is mainly supplied

with blood (about 80%) through the anterior circulation (14). Previous studies have shown that most of the acute ischemic strokes occur due to occlusion of large vessels like the carotid artery (15). In diagnostic or interventional cerebral angiographies, a catheter is often inserted via the femoral artery. The service providers then navigate within the neurovasculature to the site of the clot as shown in Figure 1 (16). Despite the existence of other points of access like radial, brachial, carotid, and transcervical, the femoral access is the most commonly used because of the larger size of the artery, size and length of the interventional or diagnostic equipment, and long history of use.

1.2 Hemostasis

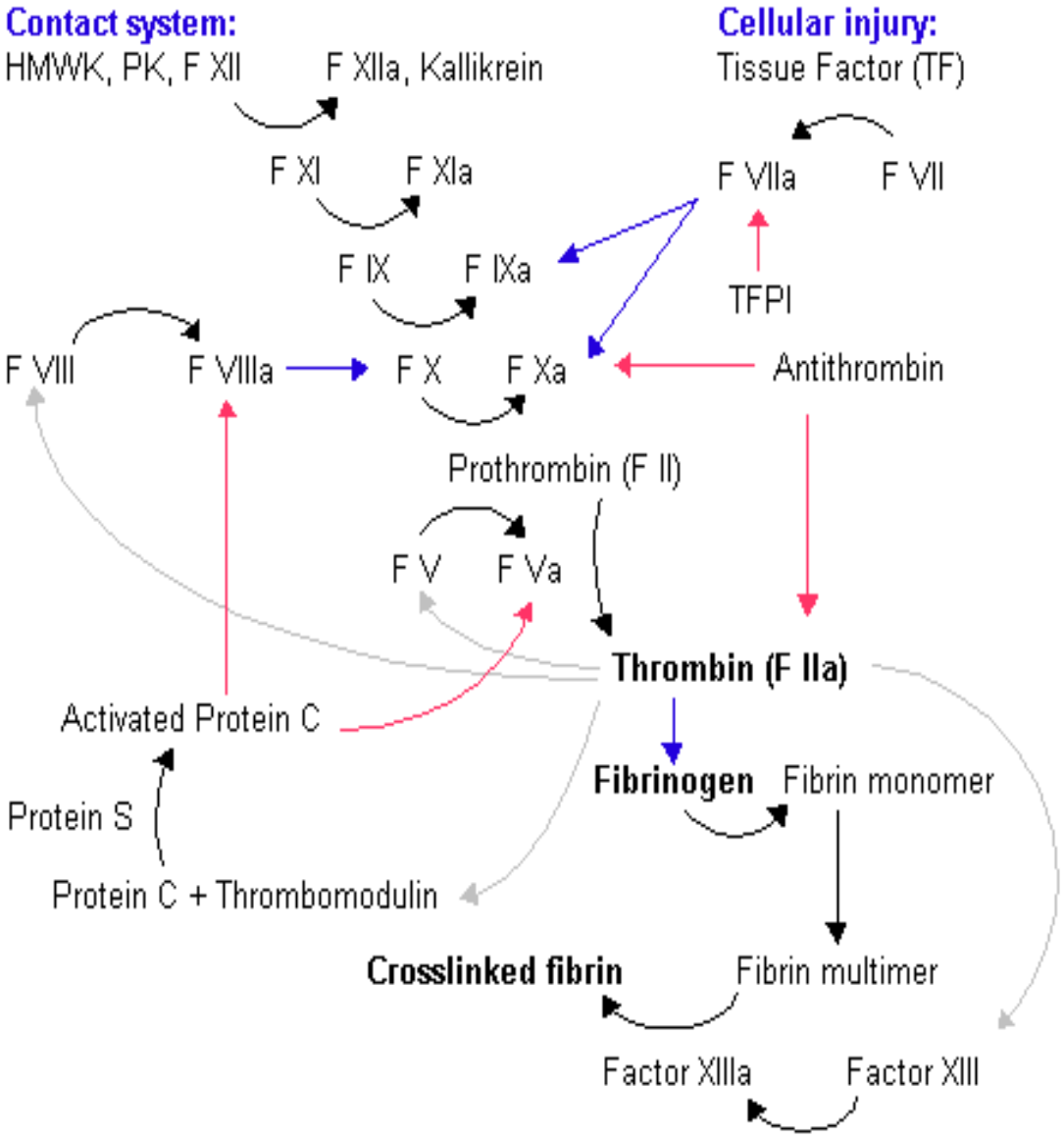
Hemostasis is a process that encompasses tight regulation of the process of blood coagulation/clotting, activation of platelets, and repairing the vasculature (17). Following an injury to a blood vessel, the hemostatic system activates many receptors that play in concert with different components of the blood to seal off the damages inflicted to the injuries blood vessels and the tissues that surround those injured vessels.

1.2.1 Coagulation system

The coagulation system is one of the most important contributors to the hemostatic system in the human body (17). Together with platelet activation, the coagulation system forms a plug that seals the injured blood vessel. When a blood vessel is injured or the endothelial tissue is damaged, the tissue factor (TF) becomes exposed to the components present in the bloodstream. The exposed TF binds to factor VII, which in turn, activates it into VIIa. This active complex (TF-VIIa) activates factor X and prothrombin. On the platelet surfaces, thrombin activates the factor XI-IX feedback loop. The activated factor IXa would activate more of the factor X. Thrombin would also activate factors VII and factor V. This would increase the catalytic activities of factors IX and X. Activation of thrombin would lead to deposition of fibrin threads. After that platelet activation and blood coagulation system are switched off by proteolytic feedback and other inhibitors. The coagulation cascade is shown in Figure 1.3.

Figure 1.3

Coagulation cascade (Source: Wikimedia Commons, Created under a Creative Commons license)



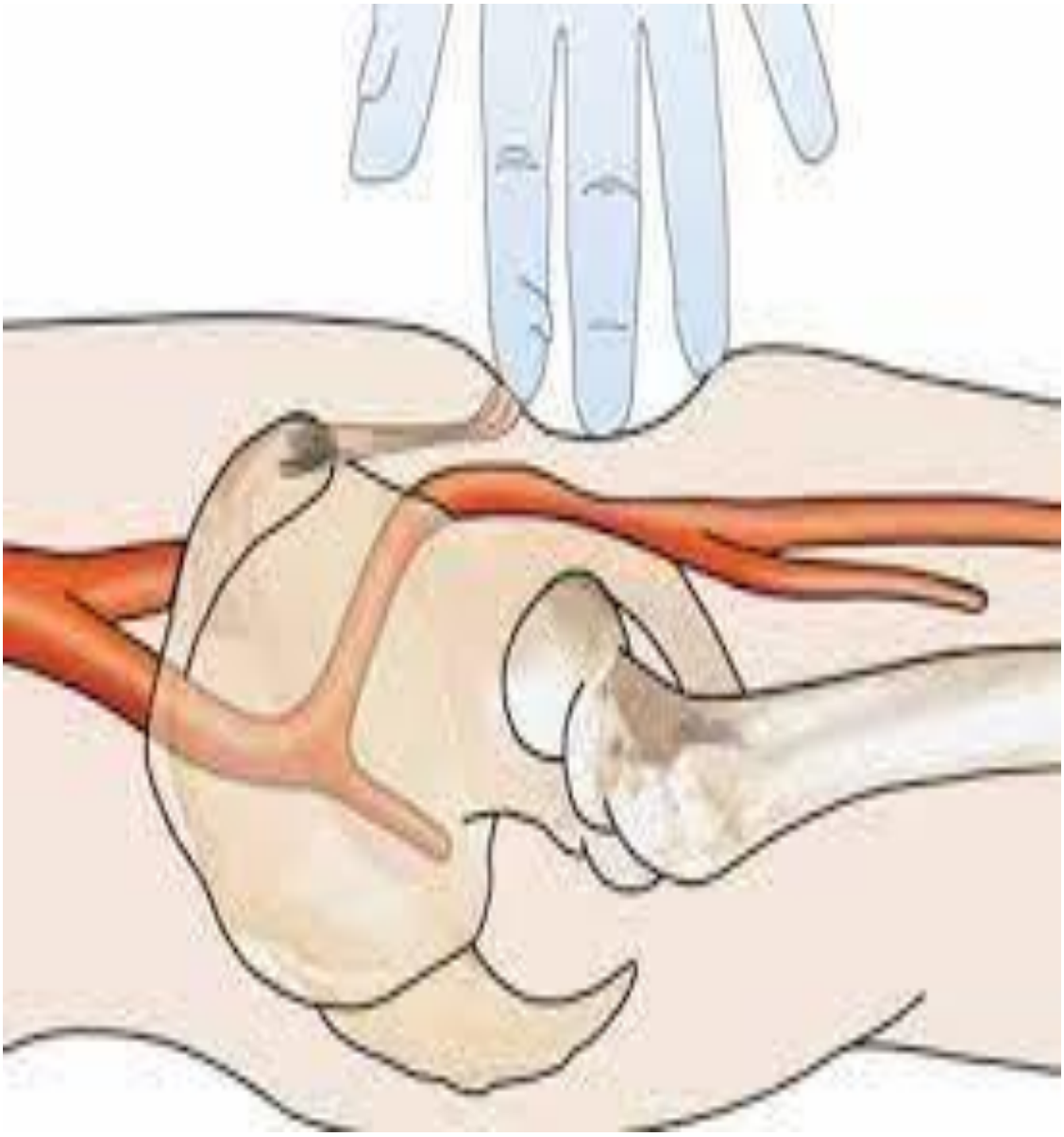
1.2.2 Methods of achieving hemostasis

To achieve hemostasis, manual compression (MC) remains the gold standard (18, 19). In practice, MC is a time-consuming process as it required about 20-30 min to achieve hemostasis. Additionally, MC can be personnel and resource intensive procedure (20). Patients would also need an extended period of bed rest upon completion that can extend to 4-8 hours. MC can also cause discomfort to both the patients and to the

providers. The manual compression method to achieve hemostasis is shown in Figure 1.4.

Figure 1.4

Manual compression method to achieve hemostasis



Due to changes in lifestyle and levels of physical activity, obesity has been on the rise since the last few decades (21). As a result, a considerable number of patients are on antiplatelets and anticoagulants (22, 23). Additionally, the sizes of percutaneous devices used in thoracic endovascular aortic repair and those used in repairing endovascular aneurysms (1). This has limited the utility of MC which in many times could be inutile in achieving adequate hemostasis.

1.3 Vascular closure devices

Since early 1990s, vascular closure devices (VCDs) were introduced and has gained a considerable popularity in percutaneous vascular interventions (24, 25). These VCDs were designed to help achieve hemostasis by closing the arteriotomy caused by the percutaneous vascular interventions. VCDs aim to decrease bleeding from the arterial puncture site, enable early ambulation, and enhance patient comfort. In today's percutaneous vascular interventions, VCDs are increasingly popular with a market of more than 1 billion US dollars (1). The VCD that was used in this study is shown in Figure 1.5. Insertion of the VCD is shown in Figure 1.6.

Figure 1.5

The vascular closure device (Angio-Seal VIP) that was used in the study

Figure 1.6

Insertion of the VCD

1.4 Access site complications

Percutaneous vascular interventions have increased by more than 10-fold since the year 1995. A significant morbidity has been attributed to local vascular access site complications which were estimated to occur in 1% to 11% of the cases (1, 26). Recently, the rate of access site complications decreased as a result of advancements in angiography techniques (27, 28). Ortiz et al reported that the majority (about 74%) of the access site complications were minor, about 15% were moderate and required blood

transfusions or injections of thrombin, and about 11% were serious and required surgery (26). However, access site complications can cause prolonged stay in the hospital, increased discharge rates to nursing/rehabilitation centers, and could be associated with higher healthcare costs. Additionally, the 30-day mortality was higher among patients who experienced access site complications compared to those who did not experience access site complications (1).

Although MC and VCDs are safe and effective methods that can be used to help achieve hemostasis in percutaneous vascular procedures, recent systematic reviews and meta-analyses of use of different VCDs showed improvements in patients' satisfaction and comfort after percutaneous vascular procedures compared to MC (1, 29). On the other hand, small differences postinterventional complications were detected when MC and VCDs were used. In general, VCDs were associated with lower incidence of major complications compared to MC. This was said to improve success rates of percutaneous vascular procedures and increase turnover of patients. However, the use of VCDs was associated with slightly higher risk for thrombotic complications and infections compared to MC (1, 29, 30).

1.5 Outcomes of MC and VCDs

Gewalt et al., (2018) conducted a randomized clinical trial (RCT) to compare the outcomes of VCDs versus MC were after transfemoral catheterization in women (31). The trial included 1395 women who underwent transfemoral catheterization for diagnostic coronary angiography. In this study, the outcomes of MC, extravascular VCDs, and arteriotomy closure with an intravascular VCDs were compared. The study had an aim to investigate safety and efficacy of the different VCDs and to compare their outcomes in terms of access-site problems 30 days after the intervention with those of MC. The trial showed that the women included had elevated risk for vascular access-site problems when compared to their men peers. The vascular access-site problems were comparable among the women who were assigned to either VCDs or MC. When the interaction between gender and treatment effect was studied, there was no significant interaction. The time to achieve hemostasis was significantly lesser when VCDs were used compared to MC. The study also showed that significantly more women who used VCDs needed repeated MC. Vascular access-site complications significantly reduced when the intravascular VCDs were used compared to extravascular VCDs (31). The

study concluded that VCDs and MC are comparably safe while the time to achieve hemostasis was significantly shorter when VCDs were used compared to MC.

In another large scale, multicenter, randomized, open label clinical trial, Schulz-Schüpke et al., (2014) compared the outcomes of standard MC were compared with the outcomes of 2 VCDs (an intravascular and an extravascular) (32). The study aimed to compare the effectiveness of the 2 devices in comparison to the standard MC method. Another objective was to compare the efficacy of the 2 types of VCDs. The study included 4524 patients who underwent coronary angiography. In this trial, vascular access-site problems were compared at 30 days. The investigation demonstrated that the time to achieve hemostasis was significantly lesser when VCDs were used compared to MC. When the two types of devices were compared, the time to hemostasis was significantly lesser among the patients who used intravascular VCDs compared to extravascular VCDs. Similarly, the closure device failures were significantly lower among the intravascular VCDs compared to the extravascular VCDs. The study demonstrated that VCDs were non-inferior compared to MC in terms of vascular access-site problems and the time to achieve hemostasis.

Xhepa et al., (2014) compared the effectiveness of different VCDs and MC in a large RCT (33). The purpose of this prospective, RCT was to examine the outcomes linked with the use of VCDs or MC to achieve femoral hemostasis. The null hypothesis was that vascular access site-related complications were similar between VCDs and MC for achieving femoral hemostasis following coronary angiography. Random assignment of FemoSeal VCD, EXOSEAL VCD, or MC was performed on patients having coronary angiography *via* the common femoral artery. At 30 days post-randomization, the primary endpoint was the occurrence of the composite of arterial access related problems (pseudoaneurysm, hematoma >5 cm, access-site-related bleeding, arteriovenous fistula, acute ipsilateral leg ischemia, documented local infection, or the need for vascular surgical/interventional treatment). The study showed that VCDs were non-inferior compared to MC.

In 2018, Mankerious et al., conducted another study for the evaluation of the efficacy and safety of arteriotomy closure with the intravascular FemoSeal VCD in comparison to MC in patients who are scheduled to receive diagnostic cardiac catheterization through the common femoral artery (34). The aims of this study were to evaluate the

effectiveness and safety of arteriotomy closure with the intravascular FemoSeal VCD. The study included a sub-analysis of 3018 patients who received diagnostic coronary angiography via the femoral artery and were randomly assigned to arteriotomy closure with intravascular FemoSeal VCD or MC as part of the ISAR-CLOSURE trial. The ISAR-CLOSURE trial was conducted in order to evaluate the effectiveness of arteriotomy closure with intravascular FemoSeal VCD. The primary outcome was a composite measure of vascular issues at 30 days that were related to the access location. The amount of time needed to achieve hemostasis and the number of times MC was performed were secondary outcomes. Vascular access-site problems were lower in patients assigned to the FemoSeal VCD compared to MC (6.0% vs 7.9%; p-value = 0.04). This was primarily due to a decreased incidence of hematomas in the FemoSeal group (4.3% vs 6.9%; p-value = 0.01). Vascular access-site issues were reduced among patients who received FemoSeal VCD compared to MC. The incidence of pseudoneurysm was the same in both groups, at 1.5% (p-value = 0.88), with no significant difference between the 2 methods. When compared to MC, the FemoSeal VCD significantly shortened the amount of time needed to achieve hemostasis (0.5 min [IQR, 0.2-1.0 min] vs. 10 min [IQR, 10-15 min]; p-value = 0.001). When using the FemoSeal VCD, there was a significantly higher incidence of repeated MC (1.5% versus 0.7%; p-value = 0.03). When compared to MC, the use of the FemoSeal VCD in patients who received transfemoral diagnostic coronary angiography was associated with a shorter hemostasis time and a reduced vascular access-site issues as a result of fewer hematomas. In addition, the time to achieve hemostasis was shorter.

Cox et al., (2015) conducted a systematic review of RCTs to investigate the effects VCDs on the amount of time it takes for bleeding to stop, the amount of time it takes for patients to be able to walk and leave the hospital, and the amount of time it takes for patients to develop immediate and long-term complications (35). In the past, there has not been carried out an analysis that is both methodical and exhaustive of these evaluations and results. Comparisons were made between the use of VCDs and MC. The following medical devices were included in the study: ProStar® (Abbot Vascular, Menlo Park, CA), AngioSealTM (Sherwood-Davis & Geck, St. Louis, MO/St Jude Medical, St. Paul, MN), FISH Device, Bloomington, IN), ProGlide® (Abbott Vascular, Abbott Park, IL), StarClose SE® (Abbott Vascular), VasoSeal® (Datascope Corporation, Montvale, NJ) femoral introducer sheath and hemostasis. VCDs were

compared to MC and to the other devices that were used for the outcomes: time to ambulation, time to hemostasis, time to discharge, and outcomes such as limb ischemia, hematoma, pseudoaneurysm, bleeding, and overall minor and major complications, as well as cost analysis, trends over time, and effects on the quality of life. The methods encompassed both diagnostic work and therapeutic adjustments. The outcomes of the searches conducted in PUBMED and MEDLINE revealed a total of 1,363 papers pertaining to VCDs. There were 176 different manuscripts that were manually compressed for the research project. Out of these, there were a total of 34 RCTs that were analyzed. Studies that were published between 1992 and 2015 and met the inclusion criteria described a total of 14,401 patients, with 5,659 patients undergoing MC and 8742 patients undergoing VCD use. Studies that met the inclusion criteria were included. For VCD patients as a whole, the rate of successful procedure completion was 95.7% overall. The ExoSealTM subset had an average failure rate of 37.9%, which was the highest rate of unsuccessful device use recorded in all of the sets. When compared to VCDs, which took 5.95 min to stop the bleeding, the median time it took for MC to stop the bleeding was 22.9 min. FemoSealTM had the smallest median time to stop the bleeding at 0.75 min. When comparing the type of procedure and its median hemostasis time, MC versus VCD was 17 min versus 3.7 min for diagnostic procedures and 29.1 min versus 7.6 min for interventional procedures with similar sheath sizes at 6F and 7F, respectively. In both cases, the sheath size was kept the same. Similarly, the median time to ambulation for patients who received MC was 8 h, whereas patients who received a VCD only needed 3.5 h. The median amount of time until discharge was also the same, at 1.6 days. Comparing MC to VCD during the past ten years, the median number of days before discharge has decreased from 3.1 to 2.2, with current trends standing at 0.8 and 0.5 days, respectively. This indicated that the time it takes to be discharged from MC has decreased. The overall rates of issues were comparable between MC at 13.1% and VCDs at 12.2%; however, the rates of problems greatly differed depending on which VCD was used. Patients who were randomly assigned to receive the vascular closure device and who had previously been treated with angioplasty expressed a preference for the usage of the VCD in the event that they required additional angioplasty treatment in the future. Because patients were able to go home sooner and spend less time in the care of physicians and nurses, the VCD was able to demonstrate a 13% reduction in overall healthcare expenses. The findings of the

meta-analysis of 34 RCTs showed that the utility of VCDs has resulted in a shorter hemostasis time, discharge, and ambulation compared to patients who received MC. Because of the emphasis placed on and the implementation of same-day procedures, the use of VCDs has resulted in a significant reduction in cost as well as a reduction in the amount of time required to be discharged from the hospital to half a day. The risk of complications is roughly the same across all available devices, but this number can range significantly between products. It has also been noted that using VCDs results in a higher quality of life in the short run compared to using MC. As further technology breakthroughs of VCDs become accessible, there is a possibility that further therapeutic and financial improvements will be found.

Noori and Eldrup-Jorgensen, (2018) conducted another systematic review to provide an UpToDate summary of various VCDs and to examine current evidence comparing particular devices with both MC and each another (36). Indications for use, benefits and drawbacks, risks and benefits, efficacy and safety, and results were covered in this review. The search was conducted using MEDLINE and PubMed. Only clinical trials that evaluated the efficacy of various VCDs and had access obtained through the common femoral artery or vein were considered for inclusion. These trials had to have been published within the past 10 years. This study only considered research that was conducted with human participants and was published in English language journals. There were 34 articles that were relevant to the search strategy. In the course of these research, several procedures, ranging from diagnostic catheterizations to endovascular percutaneous aneurysm repairs, were carried out. There is a significant amount of inconsistency amongst the research, particularly with regard to the terminology used and the methods used to measure the results. The research showed that the use of VCDs led to improvements in patients' levels of comfort and happiness, as well as in the amount of time it took to achieve hemostasis and begin ambulating. Even after meta-analysis or Cochrane review, complication rates as well as safety and efficacy between devices and MC remained identical. This is despite the fact that the majority of studies have insufficient power to demonstrate differences. After percutaneous vascular treatments, VCDs have been proven to significantly increase patients' levels of comfort and happiness, as well as the amount of time it takes to achieve hemostasis and resume normal activity. Rate of complication, efficacy and safety, and outcomes remain identical between MC and VCDs, according to various small RCTs, a Cochrane review,

and meta-analyses (12% for VCDs vs. 13% for MC). VCDs had lower incidence of significant problems and high success rates, which provides convenience for the practitioner and simplifies patient turnover. VCDs can also be used to treat a wide range of conditions. In comparison to MC, the risk of developing infectious complications with VCDs is lower (0.6 percent with VCDs as opposed to 0.2 percent with MC) and the chance of developing thrombotic complications with VCDs is nonexistent (0.3 percent with VCDs as opposed to zero percent with MC). It is essential to strike a balance between the aims of maximizing the patient's level of comfort, maximizing the resources available to the staff, and maximizing the amount of time spent walking before the procedure (ie, individualize use of VCDs to specific clinical scenarios). After femoral artery puncture, the user needs to be familiar with the device as well as its limits in order to accomplish hemostasis in a safe and effective manner.

A recent randomized clinical trial was conducted by Jakobsen et al., (2022) to evaluate the MynxGrip VCD in comparison to MC following femoral access coronary angiography to determine whether method was more effective and safer (37). The study was carried out in a single-center, randomized, two-arm, non-blinded, noninferiority study. The limited number of participants ultimately led to an early termination of the study. A total of 869 patients were assigned to have their closure performed using the MynxGrip VCD or MC, and 865 of those patients participated in the analysis. After 30 days, the incidence of the primary endpoint of major adverse vascular events was 1.2% in the group that received MynxGrip, whereas it was 0% in the group that received MC ($p = 0.06$). The MynxGrip group saw a median hemostasis time of 4 [3:5] min, while the MC group experienced a time of 10 [7:11] min (p 0.0001) The median timeframes to mobilization were 73 [65:87] min for the first group and 76 [70:88] min for the second group ($p = 0.01$). After the femoral arterial access was blocked by the MynxGrip VCD and MC, the incidence of MAVE decreased significantly. The study demonstrated a numerical advantage for MC, but this advantage did not approach the level of statistical significance required to be considered significant. When compared to the MC group, the MynxGrip group's time to achieve hemostasis was significantly faster.

In 2015, Barbash et al., (2015) conducted another study to evaluate and contrast the effectiveness of a VCD based on either Perclose ProGlide or Prostar XL (38). The multi-center CONTROL study included 3,138 consecutive percutaneous transfemoral

transcatheter aortic valve implantation patients. These patients were categorized according to their vascular closure strategy, which was either the Prostar XL- (Prostar group) or the Perclose ProGlide-based vascular closure strategy (ProGlide group). In order to compile a group of patients with comparable baseline characteristics, a matching method based on propensity scores was utilized. The propensity matching method revealed 944 patients who were good matches (472 patient pairs). The primary composite endpoint of in-hospital mortality or major vascular issues occurred more frequently in the Prostar group when compared with the ProGlide group (9.5 vs. 5.1%, p-value = 0.016). This difference was driven by elevated rates of major vascular complication in the Prostar group (7.4 vs. 1.9%, p-value = 0.001) in the Prostar group. However, death rates during hospitalization were similar in the two groups (4.9 vs. 3.5 %, p-value = 0.2). However, overall, Prostar use was related to higher rates of acute kidney injury (17.6 vs. 4.4%, p-value = 0.001), major bleeding (16.7 vs. 3.2%, p-value = 0.001), and longer hospital stays (median 6 vs. 5 days, p-value = 0.007). Femoral artery stenosis occurred less frequently in the Prostar group (3.4 vs. 0.5%, p-value = 0.004). Prostar XL-based vascular closure in transfemoral transcatheter aortic valve implantation procedures were associated with higher rates of major vascular complications when compared to ProGlide; however, in-hospital mortality is similar with both devices.

Cheng et al., (2022) conducted a multicenter study to evaluate and contrast the perioperative success rates of MC and four VCDs following peripheral vascular interventions (39). A search was conducted on the Vascular Quality Initiative database for all lower extremity peripheral vascular interventions performed between 2010 and 2020 that required access to the common femoral artery. StarClose SE (Abbott Vascular, Redwood City, California), MynxGrip (Cordis, Santa Clara, California), Perclose ProGlide, and Angio-Seal (Terumo, Somerset, New Jersey) were the VCDs that were utilized in this study. These four VCDs, which were called A, B, C, and D, were compared to the MC in terms of their baseline features, procedural details, and results (access site hematoma and stenosis/occlusion). This comparison was carried out in a blinded method. Those who had a sheath size of more than 8F were not considered. It was decided to execute a 1:1 matching of the propensity scores. Both unpaired and matched data were analyzed using univariable and multivariable approaches, respectively. The investigation revealed a total of 84,172 peripheral vascular

interventions located in the lower extremities. There were 32,013 users who had previously used MC, and 52,159 users who had previously used VCDs (A, 12,675; B, 6224; C, 19,872; D, 13,388). The patients had a mean age of 68.7 years, and men made up 60.4% of the total population. Claudication, which accounted for 43.8% of all cases, and tissue loss, which accounted for 40.1% of all cases, were the most common reasons for intervention. When compared to MC, VCDs were prescribed to patients with obesity, diabetes, and end-stage renal illness at significantly higher rates (P .001 for each of these comparisons). Patients who had coronary artery disease, chronic obstructive pulmonary disease, hypertension, prior percutaneous coronary and extremities procedures, and significant amputations were less likely to have VCDs implanted in them (p-value = 0.001 for all of these conditions). During femoropopliteal (73% vs 63.8%) and tibial (33.8% vs 22.3%) interventions, the use of VCD was more prevalent than the use of MC; however, the use of VCD was less common during iliac interventions (20.6% vs 34.7%; p-value = 0.001 for all). Protamine was utilized significantly less frequently when combined with VCDs (19.1% versus 25.6%; p-value = 0.001). There were a total of 2003 hematomas that had developed (2.4%), and 278 (13.9%) of those hematomas required either thrombin or surgical intervention. The use of any VCD had resulted in fewer hematomas that required intervention (0.2% vs 0.5%; p-value = 0.001) and fewer hematomas (1.7% vs 3.6%; p-value = 0.001). This was in comparison to the use of MC. The rate of the development of any hematoma was as follows when the results were broken down by hemostatic technique: MC had a 3.6% rate, VCD A had a 1.4% rate, VCD B had a 1.2% rate, VCD C had a 2.3% rate, and VCD D had a 1.1% rate (p-value = 0.001). The following is a breakdown of the rate of hematomas that required medical attention: MC had a value of 0.5%; VCD A had 0.2%; VCD B had 0.2%; VCD C had 0.3%; and VCD D had 0.1% (p-value = 0.001). There was no significant difference in the rate of access site stenosis or occlusion between the MC group and any other VCD group (0.2% versus 0.2%) (p-value = 0.12). According to the findings of a multivariable analysis, the use of any VCD as well as the usage of the individual VCDs in comparison with MC was independently linked with the development of less hematomas. There was no discernible difference in the frequency of access site stenosis or occlusion between the use of either VCD and MC. The findings from the matched analysis were very comparable. Despite the fact that the overall rates of hematomas that required intervention were few regardless of the

hemostatic technique, VCD use, regardless of type, compared favorably with MC, with significantly fewer access site issues after peripheral vascular interventions. This was the case even though the overall rates of hematomas that required intervention were low.

Lee et al., (2022) conducted a study to evaluate the factors that affected access-site issues in patients with peripheral arterial disease in lower extremity or hepatocellular carcinoma who underwent vascular intervention through the common femoral artery (40). Patients were included in the study if they had undergone vascular intervention through the common femoral artery. The study was conducted between December 2015 and November 2018 with a total of 287 patients who had either peripheral vascular intervention with ultrasonography guided catheter-directed chemotherapy access or transarterial chemoembolization. In 127 of the patients, a standard 18-gauge (G) access was used, and in 160 of the patients, Micropuncture® 21-G needles were employed. The vast majority of access sites were controlled using VCDs, whereas certain access sites were treated using MC. All of the patients had ultrasound examination of the puncture site within the first twenty-four hours after the surgery. The findings showed that 55 out of 287 patients experienced problems at the access site, including 20 pseudoaneurysms (7.0%), 34 hematomas (11.9%), and 1 dissection (0.4%). The use of 18-G needles (odds ratio, 2.18; 95% confidence interval [CI], 1.17-4.07; p-value = 0.014), smoking (odds ratio, 2.23; 95% confidence interval [CI], 1.16-4.27; p-value = 0.016), and approach route (odds ratio, 3.23; 95% confidence interval [CI], 1.33-7.82; p-value = 0.009) were the risk factors related to access-site issues in the crude model. The corrected model revealed that needle size was the sole predictor related with access-site problems. The odds ratio for needle size was 2.13, with a 95% confidence interval ranging from 1.10-4.12. In this particular research, the needle profile was the only component that was found to be linked with access-site problems. Because of this, using a needle with a lower profile than an 18-G needle will result in a lower risk of experiencing difficulties at the access site.

Diamantopoulos et al., (2021) conducted a prospective study to investigate the efficacy and safety of the Mynx Control extravascular closure device (Cordis Corporation, Florida, United States) which was used to close the femoral artery in patients who were undergoing peripheral arterial procedures (41). One hundred Mynx Control devices

were implanted in 91 patients who were undergoing peripheral artery procedures between the months of January 2020 and February 2021. The patients' ages ranged from 67.5 to 16.9 years on average. During the deployment of Mynx Control, ultrasound and/or fluoroscopy were used, and after the procedure, ultrasound was used to identify any issues. The femoral artery was punctured a total of 98 times, with 62 (62%) being antegrade and 38 (38%) being retrograde. The average amount of time needed for active clotting prior to device deployment was 221 seconds. The key outcomes were technical success, device failure, and the percentage of patients who experienced complications up to 30 days after the procedure. The findings showed that a vascular sheath with a size 5F was utilized in 43 out of 43 instances (43%), compared to 36 out of 36 cases (36%), which utilized a size 6F sheath, and 21 out of 21 cases (31%), which utilized a significant number of our patients (62%) had antegrade access. In both antegrade and retrograde instances, the overall rate of successful technical completion was 97%. There was a total of 4 instances of mild complications, including 3 cases (or 3%) of pseudoaneurysm and 1 instance (or 1%) of hematoma. There were no serious problems that were reported either immediately after the surgery or 30 days after the index procedure. When it comes to attaining hemostasis in patients who are undergoing antegrade and retrograde peripheral angioplasty treatments, the vascular closure device known as Mynx Control is proven to be both safe and successful.

Gouëffic et al., (2022) conducted a study to evaluate the safety and effectiveness of a discharge on the same day following manual compression in patients who had been treated for LEAD endovascular revascularization with a 5F sheath (42). FREEDOM OP was a multicenter, single-arm, prospective trial that was conducted across the country. Patients who met the criteria for same-day discharge from the hospital and had symptoms of LEAD (Rutherford 2-5) were included in the study. The total in-hospital admission rate, which also takes into account the rate of overnight surveillance and the incidence of rehospitalization after one month, was the primary outcome. The findings showed that there were 114 patients enrolled between September 2017 and August 2019. The patients had an average age of 66 years, give or take 10, and the vast majority of them were claudicants (103, or 94%). The majority of femoropopliteal lesions (178, or 70%) were treated, and the overall success rate for the procedure was 97%. Deliveries included one hundred forty-two 5F stents and fifty-one 5F medication coated balloons. 13 min and four seconds was the mean amount of time required for MC. The

rate of significant access-related problems was 4.5%. The overall rate of hospitalization admission was 11%. Seven patients were observed throughout the night, and five of them were readmitted (2 for the target lesion). Within the first twenty-four hours after being discharged, the patient did not require readmission to the hospital. There was not a single serious cardiovascular event that was observed, including death. In comparison to when they were first evaluated, the patients' clinical status (p-value = 0.0001) and hemodynamics (p-value = 0.0001) showed statistically significant signs of advancement. MC was shown to be feasible and safe for same-day discharge following lower extremity arterial disease revascularization using a 5F sheath femoral technique, as was demonstrated by the FREEDOM OP study.

Another study by the same group that aimed to compare the safety and efficacy of the suture-based ProGlide® VCD and the polymer-based FemoSeal® VCD in achieving hemostasis at the femoral access site following lower-limb arterial endovascular revascularization (43). This comparison was made to determine which device was more effective in achieving hemostasis. The STEP study was a multicenter RCT that included patients receiving lower-limb arterial endovascular revascularization. The study also included the materials and techniques. The primary outcome was technical success 5 hours after the VCD intervention, which was defined as the establishment of hemostasis without the requirement for a follow-up intervention at the access site and without a reduction in hemoglobin of more than 2 g/dL. Between the months of December 2017 and April 2019, a total of 113 patients were allotted to the FemoSeal® group, whereas 117 patients were placed in the ProGlide® group. VCD interventions were technically effective for 90 patients with FemoSeal®, which is 80% of the total, and for 58 patients with ProGlide®, which is 50% of the total (odds ratio, 3.98; 95% CI, 2.22 to 7.14; p 0.0001). This disparity in success rates between FemoSeal® and ProGlide® can be partially explained by the fact that the latter group resorted to manual compression more frequently (FemoSeal®: n = 19; ProGlide®: n = 45) and utilized an extra VCD more frequently (FemoSeal®: n = 0; ProGlide®: n = 23). 87% of patients with FemoSeal® and 69% of patients with ProGlide® were able to resume walking after 5 h (odds ratio: 3.07; 95% confidence interval: 1.93 to 6.15; p = 0.0016). In patients who were undergoing lower-limb artery endovascular revascularization, we found that FemoSeal® was more effective than ProGlide® in terms of the technical success of the procedure.

Junquera et al., (2021) conducted a study in order to determine the clinical significance of VCDs for secondary femoral access hemostasis during transcatheter aortic valve replacement surgeries (44). This was a multicenter study that included 4031 patients who had undergone transcatheter aortic valve replacement (mean age, 81 8 years; mean Society of Thoracic Surgeons score, 4.9 [interquartile range, 3.3-7.6]), and had a secondary femoral access. The patients had a mean age of 81 8 years and a mean score of 4.9 on the Society of Thoracic Surgeons scale. After thirty days, the clinical outcomes were evaluated using a propensity-matched, multivariable, logistic regression model. The evaluation was done according to the method of femoral access-site hemostasis (MC vs. VCD) and according to the type of VCD (Perclose [Abbott Cardiovascular] vs. Angio-Seal [Terumo Interventional Systems]). Manual compression was used in 941 of the patients (23.3%), while VCDs were used in 3090 of the patients (76.7%); Perclose was used in 1549 of the patients (38.4%), and Angio-Seal was used in 1541 of the patients (38.2%). The results showed that for secondary femoral access hemostasis, VCDs were used in 3090 of the patients (76.7%); Perclose was used in 1549 of the patients (38.4%); There were 162 patients who developed vascular complications as a result of the secondary access site. This represents 4% of the total number of patients. In patients who underwent MC, the incidence of these complications was significantly higher (7.2%), compared to patients who underwent VCD hemostasis (3%); the adjusted p-value was significantly higher than 0.0001. In the VCD group, using Angio-Seal rather than Perclose was associated with a higher rate of vascular complications (3.7% vs 2.4%, respectively; adjusted p-value = 0.02), femoral artery pseudoaneurysm (1.3% vs 0.4%, respectively; adjusted p-value = 0.01), invasive treatment requirement for treating vascular complications and thrombin (surgery: 0.8% vs 0.3%, respectively; adjusted The use of VCDs was discovered to be a safer and more effective alternative to manual compression for secondary femoral access-site hemostasis in patients undergoing transcatheter aortic valve replacement procedures, and the Perclose VCD was linked with the lowest risk of vascular problems. This research was conducted on patients who were undergoing procedures to replace their aortic valves.

Kuno et al., (2021) conducted a study to determine whether or not employing VCDs during percutaneous coronary intervention for left main coronary artery disease was risky and whether or not it was effective (45). In this study, the results from the EXCEL

study in patients with left main coronary artery disease who had percutaneous coronary intervention done through transfemoral access with or without VCD were evaluated. These patients had participated in the EXCEL trial. The primary endpoint was a composite measure that included either mortality, myocardial infarction, or stroke. Bleeding that was classified by the Bleeding Academic Research Consortium as type 2-5 at 30 days was also evaluated. We utilized a matching analysis based on propensity scores. The study showed that 423 (61%) of 694 patients with left main coronary artery disease who underwent transfemoral access-percutaneous coronary intervention were given VCDs (collagen plugs: 320 [75.7%], suture-mediated: 55 [13.0%], and others: 48 [11.3%]). Both patients who used VCDs and patients who did not use VCDs had comparable 30-day rates of Bleeding Academic Research Consortium type 2-5 bleeding (5.0% vs 6.7%, respectively; p-value = 0.30), as well as Bleeding Academic Research Consortium type 3-5 hemorrhage (2.1% vs 3.7%, respectively; p-value = 0.20). At 30 days (4.7% vs 4.1%, respectively; p-value = 0.74) or at 5 years (20.3% vs 24.2%, respectively; p-value = 0.16), there were no statistically significant changes in the rates of death, myocardial infarction, or stroke between patients who used VCDs and those who did not use VCDs. After making the necessary adjustments, these results remained the same. In the EXCEL study, left main coronary artery disease percutaneous coronary intervention by TFA employing VCD was linked with equivalent early and late significant adverse cardiovascular events, as well as similar 30-day rates of bleeding. This was in comparison to manual compression.

Mayer et al., (2021) conducted a study to compare between VCDs and MC in the treatment of vascular access-site problems in patients who are receiving chronic oral anticoagulation and who are undergoing diagnostic coronary angiography (46). This is a sub-analysis of 604 patients who had undergone transfemoral diagnostic coronary angiography. The VCDs included in this analysis were intravascular FemoSeal VCD and extravascular EXOSEAL VCD. The primary objective was a composite score measuring vascular problems related to the access site after 30 days. Time to hemostasis and repeat MC were considered to be secondary goals. The study showed that patients who were given VCDs had a comparable rate of vascular access-site problems as those who were given MC (8.2% vs 10.6%; p-value = 0.33). There was no interaction between the effects of the therapy and chronic oral anticoagulation (the p-value = interaction value was 0.59). VCDs were associated with a significantly decreased

incidence of pseudoaneurysms (0.8% versus 3.2%; p-value = 0.02). When compared to MC, the time it took for VCDs to stop bleeding was considerably less (one minute with an interquartile range of 0.5 to 2.0 min versus 12 min with an interquartile range of 10-15 min; p-value = 0.001). There was no significant difference between the two groups in terms of the frequency of repeat MC (VCD 1.5% vs. MC 0.5%; p-value = 0.23). When compared with the extravascular VCD, the intravascular VCD had a shorter time to hemostasis (0.5 [0.2-1.0] min, versus 2.0 [1.75-2.0] min; p-value = 0.001) and a lower rate of closure device failure (3.7% vs 17.2%; p-value = 0.001) than the extravascular VCD. The usage of VCDs was comparable to that of MC in terms of the primary composite outcome of vascular access-site associated problems in patients who were chronically taking chronic oral anticoagulation and who were undergoing transfemoral diagnostic coronary angiography. The development of pseudoaneurysms and the amount of time needed to achieve hemostasis was sped up by the use of VCDs.

Thurner et al., (2021) conducted a study to determine the efficacy and safety of the novel Celt ACD® VCD following antegrade and retrograde punctures of the common femoral artery in order to treat peripheral artery disease in a patient collective that presents a number of unique challenges (e.g. calcifications, obesity, and anticoagulation) (47). In the period between October 2019 and December 2020, a total of 208 VCDs, consisting of 100 antegrade and 108 retrograde devices, were installed in a tertiary referral interventional radiology department. 52 of the devices had dimensions that were too small in comparison to the introducer sheath (up to 2 Fr). During the immediate post-operation time as well as the clinically subsequent 24 hours, both the technical success of the procedure and any VCD-related problems were examined. Before the patients were allowed to go home, further duplex ultrasounds were conducted in 68% of the cases. The findings showed that the rate of overall technical success was 97%. An excessively acute access angle (less than sixty degrees) was the cause of the technical failures that occurred after an antegrade approach. This angle made it impossible to insert the applicator tip into the sheath lumen. According to the results of a subgroup study of technical success (p-value = 0.004), significant calcification is another important condition that prevents VCD use. It was determined that there was no statistically significant difference between identically sized and undersized device selection (p-value = 0.196), direction of approach (p-value = 0.265), or body mass index (p-value = 0.184). There was a total of five major complications

that occurred during the procedure (2%, or 5/208): two device migrations; 4%, or 4/100), four antegrade (i.e., one false aneurysm, one vessel laceration with retroperitoneal hemorrhage, and one following retrograde access (i.e., a hematoma larger than 6 centimeters; 1%, or 1/108). Manual compression or other interventional methods were both effective in successfully managing the complications. The results of the study showed that the innovative clip-based VCD was successful and had a low complication rate that was connected to VCDs.

Bhat et al., (2021) conducted a study to compare the results of using the suture-mediated vascular closure device known as Perclose Proglide with those obtained using MC in coronary interventions (48). This investigation was conducted from January 2018 to September 2019 at a single center and was retrospective in nature. Patients who were undergoing interventions through transfemoral access one after the other were split into two groups: the Perclose Proglide group and the MC group. Those who had a follow-up time of less than three months were disqualified. The characteristics of both groups at the beginning of the study as well as numerous problems at 24 h and 30 days were compared. The findings showed that the Perclose Proglide group comprised a total of 1343 patients while the MC group comprised a total of 400 individuals. Both groups had similar characteristics at the beginning of the study, including sheath size and the usage of antiplatelet and anticoagulant medication. At 24 hours, the Perclose Proglide group experienced a statistically significant reduction in the incidence of both hematoma (p-value = 0.0007, CI: 0.95-5.10) and mild bleeding (p-value = 0.01, CI: 0.34-4.03). At 30 days, the Perclose Proglide group had significantly fewer instances of mild bleeding (p-value = 0.0001, CI: 0.97-4.25), hematoma (p-value = 0.0002, CI: 1.05-4.93), and pseudo-aneurysm (p-value = 0.0095, CI: 0.03-1.18) than the control group did. Both hypertension (odds ratio = 2.41, 95% CI: = 1.12-5.19) and obesity (odds ratio = 3.5, 95% CI = 1.29-9.49) were linked with an increased risk of mild bleeding at 24 h. The rate of malfunctioning hardware was 2.38%. In conclusion, the Perclose Proglide device is both safe and effective in the treatment of coronary interventions, and it is associated with a lower risk of complications than MC. The rate of failure of the device is low. Both obese and hypertensive individuals have an increased risk of experiencing even modest bleeding complications.

Barrette et al., (2020) compared the safety and effectiveness of these devices in antegrade and retrograde patient groups who were having percutaneous intervention (49). Over the course of five years, 107 limbs in 84 patients underwent VCD arteriotomy closure after percutaneous revascularization. This procedure was performed in a series that was consecutive (VCD-A). The time to ambulation, success of device use, and complication rates were compared to a contemporaneous control group of 401 limbs in 305 patients who underwent closure after retrograde access during revascularization or embolization procedures. The control group consisted of patients who had previously undergone closure following retrograde access (VCD-R). The following devices were utilized in an effort to achieve closure in the 35 Perclose, VCD-A: 53 StarClose, and 19 Angio-Seal. Hemostasis was accomplished in 86 out of 107 (80.4%) limbs without the use of any supplementary manual compression. It was attempted to close the VCD-R using 215 StarClose devices, 119 Perclose devices, and 67 Angio-Seal devices. Hemostasis was achieved in 357 out of 401 limbs (89.0%). Regardless of the specific device type, device deployment failure occurred in 7/107 (6.5%) of VCD-A and 20/401 (5.0%) of VCD-R (p-value = 0.52). A femoral pseudoaneurysm formed in 1/107 and 1/401 of the VCD-A and VCD-R, respectively (p-value = 0.31), and a small hematoma developed in 3/107 and 8/401 of the VCD-A and VCD-R, respectively (p-value = 0.61). In the VCD-A group, the mean time to ambulation was 204.1 min, but in the VCD-R group, it was 204.8 min (p-value = 0.97). Similar to retrograde femoral closure, antegrade femoral closure was linked with high rates of technical success and low complication rates. Despite higher heparin doses in the antegrade patients, there was no difference in the amount of time it took for either group to be able to walk.

Sharma et al., (2021) conducted a study to assess efficacy of the SiteSeal® VCD in terms of attaining hemostasis mortality (50). Following diagnostic cardiac catheterization, a single-center, prospective case-control research was conducted to evaluate the safety and efficacy of SiteSeal® VCD in comparison to standard MC. This study was done to compare the two methods. Forty patients were recruited for the trial, and they were randomly assigned to receive either the SiteSeal® device or MC (20 in each group). Patients in the SiteSeal® group achieved hemostasis in a significantly shorter time than those in the MC group (4 2.4 vs. 19 2.4 min, p-value = 0.001), had shorter time from hemostasis to ambulation (95 44 vs. 388 63 min, p-value = 0.001),

and significantly earlier device deployment to discharge time compared to the MC group (4.7 1.1 vs. 8.9 In the SiteSeal® group, there was one minor bleeding incident that took place more than 24 h after the patients were discharged from the hospital. This event was handled conservatively. There was no clinical or Doppler ultrasound indication of major or mild vascular problem in the remaining device patients. Additionally, the remaining patients reported good overall patient comfort at discharge, 7 days, and 30 days following the procedure. The SiteSeal® VCD delivered safe and efficient hemostasis, allowing for earlier ambulation, and facilitated speedier discharge compared to MC in this first clinical experience.

Natale et al., (2020) conducted a study to evaluate the safety and effectiveness of the VASCADE MVP Venous Vascular Closure System (VVCS) device in comparison to MC for the purpose of closing multiple access sites following catheter-based electrophysiology procedures (51). The VASCADE MVP VVCS is intended to deliver earlier ambulatory hemostasis than MC does after catheter-based treatments. This is because of the system's architecture. The AMBULATE trial was a multicenter, RCT of device closure versus MC in patients who underwent ablation. The trial compared VVCS to MC in the closure of multiple femoral venous access sites in sheath sizes ranging from 6Fr to 12 Fr. Total post-procedure time, major and minor problems after 30 days, time to discharge eligibility, time to ambulation, time to hemostasis, patient-reported outcomes, and amount of pain medication used were all considered outcomes. The results showed that a total of 204 patients were randomly assigned to either the device arm (n = 100; 369 access sites) or the MC arm (n = 104; 382 access sites) at 13 different locations. Comparatively speaking, each group had comparable baseline characteristics. The device group experienced significant reductions in mean time to ambulation, total post-procedure time, time to discharge eligibility, and time to hemostasis (respective declines of 54%, 54%, 52%, and 55%; all p-value = 0.0001) The number of people who used opioids dropped by 58% (p-value = 0.001) There were no significant difficulties encountered at the access site. There were no significant differences in the incidence of mild problems between the device arm and the MC arm (p-value = 0.45). The patient satisfaction levels in the device group were 63% and 36% higher with regard to the duration of and comfort during bedrest, respectively (both p-value = 0.0001). Overall patient satisfaction with the device was found to be 25% higher (p-value = 0.001), and satisfaction with bedrest pain was found to be 40% higher

(p-value = 0.002) in patients who had previously had ablation. The use of the closure device for multiple access ablation procedures resulted in significant reductions in time to ambulation, total post-procedure time, time to hemostasis, and time to discharge eligibility as well as opiate use. Additionally, there was a rise in patient satisfaction and there was no increase in the number of problems.

Han et al., (2018) conducted a study to report their 17-month experience with employing ExoSeal VCDs to close the puncture site at the femoral artery during angiographic operations (52). Using a common femoral arterial approach, 179 diagnostic and interventional angiographic procedures were carried out between November 2015 and April 2017. For the purpose of achieving hemostasis in 125 patients, the ExoSeal VCD was applied at the puncture site. The success rates of the ExoSeal VCDs in terms of both the technical and procedural aspects of the procedure, as well as any difficulties that arose and the factors that affected how long it took for the hemostasis to take effect were investigated. The findings showed that both the technical and procedural goals, in 176 cases (98.0%) and 128 cases (71.5%) respectively, were successfully accomplished. Failure of the device happened in 3 of the cases (1.7%). A minor hematoma formed in one patient (0.6%), but other than that, there were no serious problems. A low platelet count, history of drinking alcohol, and high prothrombin time-international normalized ratio values were the statistically significant predictors of the need for longer MC among the hemostasis-relevant variables. There was no significant difference in the success rates of the repeat ExoSeal procedure groups and the single ExoSeal procedure groups, and the repeated use of the ExoSeal did not influence the amount of time it took for the wound to become hemostatic. The ExoSeal VCD is a successful method for achieving hemostasis, with just a little risk of complications. If the patient drinks alcohol, has a low PLT count, and has high PT-INR readings, a longer light MC may be required.

Su et al., (2019) et al conducted a study to evaluate the effectiveness of VCDs in terms of maintaining hemostasis after transfemoral percutaneous coronary procedures (PCIs) (53). This two-group pre-post-test observational study with purposive sampling enrolled 73 patients between January 2014 and February 2015, and the study was conducted between January 2014 and February 2015. Patients were randomly assigned to either the intervention group (the vascular closure devices group, with a total of 34 participants)

or the control group (the MC group, with 39 participants). They were given questionnaires to fill out so that their demographic and clinical characteristics, vascular problems, pain score on a visual analogue scale, and level of discomfort could be determined. Before and after the percutaneous coronary procedures, the patient's level of pain and discomfort was recorded. The study showed that vascular problems occurred in 13 (33.3%) patients who had MC and 15 (44.1%) patients who had VCD, but there was no significant difference between the two groups. On the other hand, individuals with VCD had a higher relative risk of experiencing bruising and hematomas, in addition to requiring additional therapy. After the percutaneous coronary procedures, the patients in both groups reported significantly higher levels of discomfort and pain; however, the VCD patients reported significantly lower levels of all of these symptoms, including less effective hemostasis, less pain, and less physical and psychological discomfort (lower-limb numbness, shoulder pain, restlessness, and worrying about walking ability, being unable to lift heavy objects in the future, and taking time off from work). It appears that the VCDs are superior than the MCs because they provide more effective hemostasis, less pain and discomfort, and earlier ambulation following a transfemoral percutaneous coronary procedures. These findings assist clinical nurses in understanding the risk of vascular complications, discomfort, and pain that are associated with the use of VCDs for the purpose of improving the quality of clinical care. Additionally, these findings assist clinicians in determining the appropriate hemostatic method for patients undergoing a transfemoral percutaneous coronary procedures, particularly in the Chinese population.

Gabrielli et al., (2018) conducted a study to assess the usage of the FemoSeal® artery closure device in terms of safety and efficacy in patients who were about to undergo a transfemoral peripheral operation and to determine the risk factors for complications (54). A retrospective analysis was performed to compare two different specialists and techniques with systematic implantation of FemoSeal® VCD in a cohort of vascular patients treated by endovascular procedure with femoral artery access site over a two-year period and sheaths ranging from 6F to 8F. The patients were treated over the course of the study. During the procedure, all of the patients were given heparin in addition to continuing their antiplatelet treatment. In order to seal the common femoral arteries, the FemoSeal® was inserted. In both groups of patients, 20 to 24 hours following VCD deployment, as well as 1 and 6 weeks after the surgery, clinical visits

and ultrasound duplex scans were used to check for access site complications. These exams were performed on all patients. A number of complications, including small and significant hematomas, the creation of pseudoaneurysms, the blockage or dissection of blood vessels, and infections, were documented. During the course of the trial, a total of 130 FemoSeal® devices were implanted in 114 patients. Of those, 102 were used in the VS group, and 28 were used by interventionalists. The mean age was 57 years with a standard deviation of 24 years. In terms of the prevalence of comorbidities, there was not a discernible difference between the two groups. The duration of the patient follow-up ranged from 1 to 15 months. It was possible to successfully deploy all but three of the FemoSeal® devices (all 3 cases in group 2). Following the interventions, the mobilization time was between 6 and 4 hours, and the discharge time after the procedure ranged anywhere from 6 hours to 7 days. The difference between the number of patients who were discharged early (within six hours) in group 1 and group 2 was statistically significant (p-value = 0.008). On the first postoperative day, delayed discharge was attained in 74% of group 1 (67 patients), while it was acquired in 70% of group 2 (18 patients) (p-value = 0.47). 99 percent of group 1 and 93 percent of group 2 were successful from a technical standpoint (p-value = 0.87). There were no deaths during the perioperative period. In both groups, there were no statistically significant differences in the occurrence of mild bleeding problems (p-value = 0.21), infections, or the requirement for blood transfusions (p-value = 0.06). Complications caused by FemoSeal® occurred in 6 patients, one of whom was in group 1 and the other five were in group 2 (p-value = 0.0017). All of the problems manifested themselves after the therapeutic intervention with the 6F sheath introducer. According to the findings of a subgroup analysis on peripheral arterial disease, the incidence of complications was significantly greater in group 2 in terms of the formation of pseudoaneurysms (p-value = 0.0001) and the requirement for transfusions (p-value = 0.03). (Rutherford 3-5). The only factor that was demonstrated to be an independent predictor of problems caused by VCD usage was chronic limb ischemia. The findings lead to the conclusion that the device is risk-free, effective, and simple to implement, and that it paves the way for early ambulation and discharge when simple guidelines are followed. On the other hand, relevant randomized clinical trials could shed light on the best guideline to follow in order to reduce the risk of complications.

Ben-Dor et al., (2018) conducted a study to determine whether or not using MynxGrip® to close the common femoral vein is safe (55). This was a prospective, multicenter, randomized trial of 208 patients who were scheduled to undergo diagnostic or interventional procedures via femoral venous access. The patients were randomly assigned to receive either saline or contrast solution in their femoral veins. Patients were assigned a one-to-one chance of receiving either venous hemostasis with MynxGrip® (n = 104) or manual compression (n = 104) utilizing sheaths with a 5, 6, or 7 Fr diameter. The calf and thigh circumferences of both legs were measured in a sequential fashion. Patients were monitored all the way to their discharge from the hospital. When comparing the two groups' baseline characteristics, there was no discernible difference between them. The study showed that there was no significant difference in the rate of venous thrombosis between the two groups (0%, p-value = 1). The access site calf diameter did not significantly alter (0.18 1.38 cm, p-value = 0.18), nor did the thigh diameter (0.33 2.86 cm, p-value = 0.81). None of the patients in either group experienced any severe or mild vascular problems, infections at the access site, injuries to the nerves, or bleeding at the access site that required a transfusion. In the manual compression group, the pre- to post-procedure decline in hemoglobin was -0.51 1.1 g/dL, whereas in the MynxGrip® group, it was -0.64 1.3 g/dL, and the significance level for this difference was p-value = 0.59. When compared to the group that used manual compression, the time it took for the MynxGrip® group to achieve hemostasis was significantly shorter at 0.12 0.89 min, while the manual compression group took 7.6 5.7 minutes (p-value = 0.001). In conclusion, the use of the MynxGrip® extravascular sealant for the closure of the femoral venous access site is both safe and effective.

Owens et al., (2017) conducted a study to study the complication rates of the Catalyst VCD to the complication rates after MC (56). This was done in order to determine which method was associated with a lower risk of complications. The sample consisted of 1,470 patients, the majority of whom were men, who were undergoing diagnostic coronary and peripheral angiography. In 1,034 (70.3%) of the patients, MC was applied, while catalyst closure devices were utilized in 436 (29.7%) of the patients. Those in the first group were allowed to walk around after two hours, while those in the second group were allowed to go around after six hours. (odds ratio [OR]: 0.67, 95% confidence interval [CI]: 0.22-2.1, p-value = 0.49). Patients who had a Catalyst device experienced major complications in just 4 (0.9%) cases, while patients who had MC

experienced major complications in 14 (1.4%) cases. A Catalyst closure device was used on 51 patients (11.7%), while MC was used on 64 patients (6.2%) (OR: 2, CI: 1.4-3, p-value = 0.01) Any problems were experienced by 51 patients (11.7%) who had a Catalyst closure device. Even after adjusting for other variables and for a propensity score that reflected the probability to receive the closure device, the association of major complications with the use of the closure device remained not significant (OR: 0.54, 95% CI: 0.17-1.7, p-value = 0.29), whereas the association of any complications with the use of the Catalyst device remained significant (OR: 1.9, 95% CI: 1.3-2.9, p-value = 0.01). In comparison to MC, the use of the Catalyst device was related with a higher risk of any issues, but it was not connected with an increased risk of serious groin complications. Patients who were given the closure device were able to walk more quickly.

1.6 Problem statement

Despite the increasing popularity of transradial access approach to cerebral angiography, transfemoral access approach is commonly used for diagnostic and therapeutic interventions in many settings around the world including those in Palestine. Although VCDs are popularly used to help achieve hemostasis, MC remains the gold standard. Little is known on the postinterventional complications among patients undergoing transfemoral cerebral angiography when MC and VCDs were used.

1.7 Hypotheses

- The null hypothesis (H_0) in this study was: there is no difference in the incidence of postinterventional complications among patients who undergo transfemoral cerebral angiography when MC or a VCD (Angio-Seal VIP) are used.

- The alternative hypothesis (H_1) in this study was: there is a difference in the incidence of postinterventional complications among patients who undergo transfemoral cerebral angiography when MC or a VCD (Angio-Seal VIP) are used.

1.8 Objectives

This study was conducted to assess and compare postinterventional complications occurring among patients who underwent transfemoral cerebral angiography when MC or a VCD (Angio-Seal VIP) were used.

1.9 Significance of the study

Findings of this study can inform decision makers and planners of healthcare for patients who are scheduled for transfemoral cerebral angiography. Decision makers and planners of care delivery might benefit from the findings of this study in balancing the goals of patient comfort, potential postinterventional complications, availability of healthcare personnel, availability of hospital and intensive care unit (ICU) beds, and possibility of early ambulation. Although VCDs are expensive, MC is labor-intensive. Little is known on which method could be cost-effective. Findings of this study might be used by decision makers and healthcare costs forecasters to determine which method would be the most cost-effective to be used in Palestinian healthcare settings.

Chapter Two

Methods

This section describes the methods used in the study. The methods section contains the following subsections: 1) Study Design, 2) Study Setting, 3) Population, 4) Sample Size, 5) Eligibility Criteria, 6) Study Interventions, 7) Study Measures/Variables, 8) Data Collection Procedure, 9) Statistical Analysis, 10) Confidentiality, and 11) Ethical Approval.

2.1 Study Design

This was a retrospective cohort study in which patients who underwent cerebral angiography and for whom MC or a VCD (Angio-Seal VIP) were used (57-59). The study was conducted at An-Najah National University Hospital in the time period between March 2019 and November 2020. All patient information and clinical data were collected from their clinical and medical records.

2.2 Study Setting

The study was conducted at An-Najah National University Hospital which is a major academic non-for-profit referral hospital in the North of the West Bank of Palestine. The hospital was established in 2013 and has 120 beds in its general and intensive care units. An-Najah National University Hospital is the only teaching hospital in Palestine and has recently received accreditation from the Joint Commission International (JCI). Accreditation by the JCI indicated that the study site adhered to the international procedures followed in caring for patients (60).

2.3 Population

The study population in this study was all patients who underwent cerebral angiography using the transfemoral access for whom MC or a VCD (Angio-Seal VIP) were used during the study period.

2.4 Sample Size

The sample size needed for this analysis was calculated to identify potential differences between the two study cohorts (MC vs. Angio-Seal VIP). To compute the sample size needed for this analysis, the following formula was used (61):

$n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1-p_1) + p2(1-p_2)) / (p_1-p_2)^2$

Where, n is the sample size, $Z_{\alpha/2}$ 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_{β} 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 p_1 and p_2 are the expected sample proportions of the two groups. In this study, 100 patients in each group were needed.

2.5 Eligibility criteria

The eligibility criteria used in this study was as follows:

2.5.1 Inclusion criteria

The patients in this study were included when they met the following inclusion criteria:

- Receiving a diagnosis with cervical or intracranial vascular disease
- Being 18–75 years
- Undergoing cerebral angiography via the transfemoral access

2.5.2 Exclusion criteria

Patients were excluded from this study when they had one or more of the following criteria:

- Having abnormal lung, kidney, or liver function
- Having hyperthyroidism
- Having coagulation disorders
- Having a mental illness
- Having unstable hemodynamics

2.6 Study interventions

2.6.1 Manal compression

Despite the introduction of VCDs, MC remains the gold standard in achieving hemostasis in many settings (18, 19). Although MC could be effective in helping achieve hemostasis, the technique has many disadvantages. In this study, MC was performed by a specialized team.

2.6.2 VCDs

VCDs are gaining more popularity in percutaneous vascular interventions (24, 25). The use of these devices has improved achieving hemostasis.

2.7 Study Measures/Variables

2.7.1 Independent variables

In this study, the independent variables were: the use of MC and the use of a VCD (Angio-Seal VIP).

2.7.2 Dependent variables

The main dependent variables in this study were:

- Postinterventional complications
- Postinterventional patient comfort
- ICU stay
- In hospital stay
- Need for mechanical ventilation
- Postinterventional pain
- The need for prolonged bed rest

2.8 Data Collection Procedure

After obtaining ethical approval for the study from the Institutional Review Board (IRB) of An-Najah National University and the committee of An-Najah National

University Hospital, the clinical files and records of the patients were reviewed for data collection. The data were collected into a data collection form that was designed specifically for this study.

2.8.1 The data collection form

The data collection form was designed after reviewing the relevant literature. The content validity of the data collection form was established following a review by a panel of experts. The experts were two intensivists, one anesthesiologist, and three critical care nurses. All items in the data collection form were reviewed for relevance and suitability of inclusion. The panelists commented on the contents of the data collection form. All comments of the panelists were considered when the final data collection form was revised. The panelists approved the final data collection form that was used in this study. The form collected demographic and clinical variables of the patients age, weight, height, gender, comorbidities, laboratory findings, procedural variables, postinterventional complications and patient comfort. The data collection form is provided in Appendix A.

2.9 Statistical Analysis

Height and weight were used to calculate the body mass index (BMI). The data collected in this study were entered into Excel Spreadsheets and then were transferred into IBM SPSS v.21.0. for Windows. Normality of distribution was assessed using Kolmogorov-Smirnov test. Because the data were not normally distributed, medians with the corresponding interquartile range (IQR) (lower quartile “Q1”, upper quartile “Q3”) were used. Categorical data were compared using Chi-squared/Fisher’s exact tests, Kruskal-Wallis tests, and/or Mann-Whitney U tests as appropriate. A p-value of < 0.05 indicated statistical significance.

2.10 Confidentiality

The data collected in this study were for the purpose of scientific research. No information leading to the identity of the patient was collected. The data collected were coded and anonymized before analysis. The filled data collection forms were kept in a safe place throughout the study.

2.11 Ethical Approval

The Institutional Review Board (IRB) of An-Najah National University approved this study. Approval from the IRB is shown in Appendix B. Additionally, the Research Ethics Committee of An-Najah National University provided approval to collect the data needed for this study. The study was conducted in adherence to the international ethical principles in the Declaration of Helsinki and those followed at An-Najah National University and An-Najah National University Hospital.

Chapter Three

Results

3.1 Demographics and clinical variables of the patients included in the two groups

In this study, a total of 166 patients were included. Of those, 89 had MC and 77 had Angio-Seal VIP. The median age of the patients was 46.0 years with an IQR of 37.0 to 60.0 years. The median weight was 75.0 kg with an IQR of 68.8 to 90.3 kg. The median height was 1.96 m with an IQR of 1.60 to 1.75 m. The median BMI was 27.7 kg/m^2 with an IQR of 23.9 to 30.8 kg/m^2.

When compared, the patients in both MC and Angio-Seal VIP groups were not different in terms of weight, height, and BMI (p-value > 0.05). However, patients in the Angio-Seal VIP group were older than those in the MC group (p-value = 0.004). Details of age, weight, height, and BMI of the patients stratified by method of compression are show in Table 3.1.

Table 3.1

Age, weight, height, and BMI of the patients stratified by method of compression

Variable	Method of compression	Q1	Median	Q3	p-value
Age (years)	MC	36.0	41.0	47.0	0.004
	Angio-Seal VIP	37.0	55.0	64.0	
Weight (kg)	MC	65.5	75.0	86.5	0.326
	Angio-Seal VIP	68.5	78.0	91.0	
Height (m)	MC	1.6	1.7	1.8	0.263
	Angio-Seal VIP	1.6	1.7	1.8	
BMI (kg/m^2)	MC	23.3	27.7	29.6	0.228
	Angio-Seal VIP	24.5	28.1	31.4	

BMI: body mass index, MC: manual compression, Q1: lower quartile, Q3: upper quartile

None of the patients used immunosuppressive therapy or had carotid stenosis of more than 70%. Patients were similarly distributed in both groups in terms of gender, BMI, history of hypertension, history of cerebrovascular accidents, history of hemodialysis, history of groin scar, undergoing a previous angiography, access site crossover, and previous stage access site. On the other hand, more patients were 50 years and older,

had a history of diabetes mellitus, history of transient ischemic attacks, hyperlipidemia, and history of peripheral artery disease in the Angio-Seal VIP group compared to those in the MC group. However, more patients were smokers and were in their 1st and 2nd stages of their treatment in the MC group compared to those in the Angio-Seal VIP group. Details of the demographics and clinical variables of the patients in both groups are shown in Table C.1 in Appendix C.

The difference in creatinine, white blood cells, and hemoglobin levels were not statistically significant among patients in both groups. On the other hand, patients in the MC group had significantly higher prothrombin time (p-value = 0.009), partial thromboplastin time (p-value < 0.001), and international normalized ratio (p-value < 0.001). On the other hand, patients in the Angio-Seal VIP group had significantly higher platelet counts (p-value < 0.001). Details of the laboratory findings of the patients in both groups are shown in Table 3.2.

Table 3.2

Laboratory findings of the patients in both groups

Variable	Method of compression	Q1	Median	Q3	p-value
Prothrombin time (sec)	MC	14.0	14.0	22.0	0.009
	Angio-Seal VIP	13.0	14.0	15.0	
Partial thromboplastin time (sec)	MC	29.0	39.0	60.0	< 0.001
	Angio-Seal VIP	25.0	29.0	50.7	
International normalized ratio	MC	0.9	1.0	1.1	< 0.001
	Angio-Seal VIP	0.6	1.0	1.0	
Creatinine (mg/dL)	MC	0.6	0.8	1.0	0.520
	Angio-Seal VIP	0.5	0.7	1.0	
White blood cells (cells/mL)	MC	4.0	8.0	11.8	0.860
	Angio-Seal VIP	5.5	7.0	12.3	
Hemoglobin (g/dL)	MC	10.0	13.0	14.0	0.164
	Angio-Seal VIP	10.0	11.0	13.0	
Platelets (1,000 per μl)	MC	155.0	177.0	245.0	< 0.001
	Angio-Seal VIP	226.5	245.0	287.0	

MC: manual compression, Q1: lower quartile, Q3: upper quartile

3.2 Procedural variables

Device failures were not reported in both MC and Angio-Seal VIP. Both procedures were similar in terms of indication, sheath size, use of nimodipine, clopidogrel, and result of the catheterization. On the other hand, Angio-Seal VIP was associated with more puncture attempts (p-value = 0.003), significantly shorter time to hemostasis (p-value < 0.001), lidocaine use (p-value = 0.012), use of acetylsalicylic acid (p-value = 0.001), and use of tirofiban (p-value < 0.001). However, MC was associated with more contrast use (p-value < 0.001). Details of the procedural variables are shown in Table C.2 in Appendix C.

There was no statistical difference in the duration of both procedures. On the other hand, the puncture duration, number of stents used, and number of balloons used were significantly higher among patients who received Angio-Seal VIP compared to those who received MC. On the other hand, the length of MC and amount of lidocaine used were significantly higher among patients who received MC compared to those who received Angio-Seal VIP. Comparison of those variables are shown in Table 3.3.

Table 3.3

Comparison of continuous procedural variables among patients in both groups

Variable	Method of compression	Q1	Median	Q3	p-value
Puncture duration (sec)	MC	30.0	40.0	40.0	0.015
	Angio-Seal VIP	40.0	45.0	50.0	
Procedure duration (min)	MC	127.5	180.0	240.0	0.487
	Angio-Seal VIP	120.0	180.0	180.0	
Amount of lidocaine used (mL)	MC	10.0	10.0	10.0	0.018
	Angio-Seal VIP	5.0	10.0	10.0	
Length of MC	MC	10.0	15.0	15.0	< 0.001
	Angio-Seal VIP	10.0	15.0	15.0	
Number of stents used	MC	0.0	1.0	1.0	< 0.001
	Angio-Seal VIP	0.0	0.0	1.0	
Number of balloons used	MC	0.0	0.0	0.0	0.046
	Angio-Seal VIP	0.0	0.0	0.0	

MC: manual compression, Q1: lower quartile, Q3: upper quartile

3.3 Postinterventional complications

With the exception of diastolic blood pressure, respiration rate, heart rate, systolic blood pressure, temperature, and oxygen saturation were similar among patients in both groups as measured on day 1 and day 2 following the procedures. Details of these variables are shown in Table 3.4.

Table 3.4

Respiration rate, heart rate, blood pressure, temperature, and oxygen saturation measured on day 1 and day 2 following the procedures

	Variable	Method of compression	Q1	Median	Q3	p-value
Day 1	Respiration rate (breaths/min)	MC	13.0	16.0	22.0	0.256
		Angio-Seal VIP	13.0	14.0	21.0	
	Heart rate (beats/min)	MC	46.0	58.0	77.8	0.257
		Angio-Seal VIP	45.0	54.0	70.0	
	Systolic blood pressure (mmHg)	MC	120.0	128.0	140.0	0.330
		Angio-Seal VIP	118.0	122.0	143.5	
	Diastolic blood pressure (mmHg)	MC	60.5	80.0	90.0	0.036
		Angio-Seal VIP	50.0	80.0	80.0	
	Temperature (º)	MC	36.0	36.0	36.0	0.314
		Angio-Seal VIP	36.0	36.0	36.1	
	Oxygen saturation (SPO_2) (%)	MC	96.0	96.0	96.0	0.754
		Angio-Seal VIP	96.0	96.0	96.0	
Day 2	Respiration rate (breaths/min)	MC	14.0	16.0	21.0	0.651
		Angio-Seal VIP	14.0	16.0	21.0	
	Heart rate (beats/min)	MC	52.5	60.0	69.8	0.273
		Angio-Seal VIP	50.0	55.0	70.0	
	Systolic blood pressure (mmHg)	MC	122.0	136.5	140.0	0.498
		Angio-Seal VIP	122.0	133.0	145.0	
	Diastolic blood pressure (mmHg)	MC	60.0	80.0	87.5	0.104
		Angio-Seal VIP	54.5	70.0	80.0	
	Temperature (º)	MC	36.7	37.0	37.0	0.335
		Angio-Seal VIP	36.0	37.0	37.0	
	Oxygen saturation (SPO_2) (%)	MC	95.0	95.0	97.0	0.333
		Angio-Seal VIP	95.0	96.0	97.0	

MC: manual compression, Q1: lower quartile, Q3: upper quartile

None of the patients had excessively prolonged time to hemostasis, acute ipsilateral leg ischemia, retroperitoneal bleeding, distal embolization, and occurrence of spasms following the procedures in both groups.

Patients in both groups were similar in terms of occurrence of femoral bleeding, leg ischemia, thrombosis, ecchymosis, systemic infections, local infections, need for vascular repair, and access site related major bleeding. On the other hand, more patients had local hematomas and needed repeated compression in the MC group compared to those in the Angio-Seal VIP group. Details of the postinterventional complications are shown in Table C.3 in Appendix C.

3.4 Postinterventional patient comfort

Occurrence of in hospital mortality and the need for mechanical ventilation was similar for patients in both groups. However, more patients in the MC group reported discomfort at discharge compared to patients in the Angio-Seal VIP group (p-value = 0.001). Comparison of the need for mechanical ventilation, in hospital mortality, and discomfort at discharge are shown in Table 3.5.

Table 3.5

Need for mechanical ventilation, in hospital mortality, and discomfort at discharge among patients in both groups

	Method of compression					
	MC		Angio-Seal VIP			
Variable	n	%	n	%	Chi-Square/Fisher's exact test	p-value
Mechanical ventilation needed						
No	63	70.8	58	75.3	0.43	0.600
Yes	26	29.2	19	24.7		
In hospital mortality						
Yes	2	2.2	2	2.6	0.02	0.633
No	87	97.8	75	97.4		
Discomfort at discharge						
Yes	37	41.6	14	18.2	10.61	0.001
No	52	58.4	63	81.8		

MC: manual compression

Preprocedural pain was statistically non-significant between the patients in both groups. On the other hand, patients in the MC group stayed significantly longer duration in the ICU (p-value < 0.001), in the hospital (p-value < 0.001), needed longer mechanical ventilation hours (p-value = 0.030), reported higher postinterventional pain (p-value = 0.011), and needed prolonged bed rest hours (p-value = 0.007) compared to patients in the Angio-Seal VIP group. Details of the intensive care unit stay, hospital stay, mechanical ventilation needed, preprocedural pain, postinterventional pain, and prolonged bed rest are shown in Table 3.6.

Table 3.6

Intensive care unit stay, hospital stay, mechanical ventilation needed, preprocedural pain, postinterventional pain, and prolonged bed rest for patients in both groups

Variable	Method of compression	Q1	Median	Q3	p-value
ICU stay (day)	MC	6.0	10.0	14.0	< 0.001
	Angio-Seal VIP	3.0	5.0	7.0	
In hospital stay (day)	MC	7.0	10.0	16.0	< 0.001
	Angio-Seal VIP	4.0	5.0	8.0	
Mechanical ventilation needed (hours)	MC	24.0	24.0	48.0	0.030
	Angio-Seal VIP	2.0	7.0	48.0	
Preprocedural pain (1-10 scale)	MC	8.0	8.0	10.0	0.166
	Angio-Seal VIP	8.0	8.0	10.0	
Postinterventional pain (1-10 scale)	MC	7.0	7.0	8.0	0.011
	Angio-Seal VIP	6.0	7.0	8.0	
Prolonged bed rest (hours)	MC	48.0	72.0	144.0	0.007
	Angio-Seal VIP	24.0	48.0	126.0	

MC: manual compression, Q1: lower quartile, Q3: upper quartile

Chapter Four

Discussions and Conclusions

4.1 Summary of the key findings

Cerebral angiographies are common in different healthcare settings worldwide (6, 62). Complications following cerebral angiographies have attracted considerable attention (63). This retrospective cohort study was conducted to assess and compare postinterventional complications that occur among patients who undergo transfemoral cerebral angiography when MC or Angio-Seal VIP were employed. The use of Angio-Seal VIP significantly reduced the time to hemostasis, reduced complications leading to patient discomfort at discharge, longer stay in the ICU, longer in hospital stay, higher postinterventional pain, and longer prolonged bed rest. To the best of our knowledge, this is the first study of its nature in the Palestinian practice. Findings of this study could inform decision makers and providers of postinterventional care for patients who underwent cerebral angiographies in the Palestinian practice and in similar healthcare systems.

4.2 Diversity in the demographics and clinical history of the patients in both groups

The patients included in this study were diversified in terms of their gender, smoking status, age groups, height, weight, body mass index, and presence of comorbidities. The diversity of the sample included could have mirrored the diversity of the demographics and clinical characteristics seen among patients who undergo cerebral angiography (64). This diversity must have imparted more validity to the findings of this study (65, 66). In this study, there were no statistical differences in distribution of patients into gender, BMI, history of hypertension, history of cerebrovascular accidents, history of hemodialysis, history of groin scar, undergoing a previous angiography, access site crossover, and previous stage access site groups. Additionally, levels of creatinine, white blood cells, and hemoglobin were not statistically different between the patients in both groups. These similarities in the baseline characteristics should have permitted comparing the effects of the interventions.

It has been argued that older age, history of diabetes mellitus, transient ischemic attacks, hyperlipidemia, and peripheral artery disease, and being in the 3rd stage of treatment

would be expected to result in higher incidence of postinterventional complications, longer ICU stay, hospital stay, higher postinterventional pain, and postinterventional discomfort. In this study, patients in the Angio-Seal VIP group were significantly older, had history of diabetes mellitus, transient ischemic attacks, hyperlipidemia, peripheral artery disease, and were in the 3rd stage of treatment compared to the patients in the MC group. These differences could have been in the disadvantage of the patients in the Angio-Seal VIP group.

4.3 Comparison of the procedural variables

The procedures used in this study were not different in terms of indications for the cerebral angiography, sheath size, use of nimodipine, clopidogrel, and result of the catheterization. Findings of this study were consistent with those reported in previous studies in which patients who underwent angiographies received heparin/anticoagulants and antiplatelets (30). In this study, the patients in the Angio-Seal VIP group received significantly more puncture attempts, lidocaine, acetylsalicylic acid, and tirofiban. This should have been in the disadvantage of the patients in the Angio-Seal VIP group in terms of bleeding time. However, findings of this study showed that patients in the Angio-Seal VIP group had significantly lower prothrombin time, partial thromboplastin time, and international normalized ratio compared to those in the MC group. These results indicated that patients in the Angio-Seal VIP group achieved hemostasis in significantly lower time compared to patients in the MC group. These findings were confirmed by a significantly shorter time to hemostasis among the patients in the Angio-Seal VIP group compared to those in the MC group. Findings of this study were consistent with those reported among patients who underwent coronary and peripheral vascular interventional procedures using Angio-Seal VIP (30). It is noteworthy mentioning that VCDs were originally introduced to help achieve hemostasis in shorter time compared to classical methods like MC (36).

Despite the findings that patients in the Angio-Seal VIP received more stents and balloons, the durations of the cerebral angiographies were not statistically significant when either MC or Angio-Seal VIP were used. These findings were consistent with those reported in a systematic review with meta-analysis (29).

4.4 Comparison of postinterventional complications

In general, heart rate, respiration rate, blood pressure, and temperature measured on day 1 and day 2 following the intervention were comparable among patients in both groups. Occurrence of femoral bleeding, leg ischemia, thrombosis, ecchymosis, systemic infections, local infections, need for vascular repair, and access site related major bleeding was comparable between the patients in both groups. On the other hand, patients in the MC group experienced more local hematomas and needed more repeated compression compared to those in the Angio-Seal VIP. The meta-analysis performed by Das et al showed no statistical differenced in the occurrence of postinterventional complications among patients who underwent interventional radiological procedures using MC or Angio-Seal VIP (29). However, when ACDs were pooled, marginally fewer postinterventional complications occurred compared to MC, but the differences were not statistically significant (odds ratio = 0.87, 95% CI of 0.52 to 1.48, p-value = 0.130).

4.5 Comparison of postinterventional patient discomfort

In hospital mortality and the need for mechanical ventilation were similar in both groups. However, patients in the MC group received longer hours of mechanical ventilation, when needed. Patients in the MC group reported higher postinterventional pain, stayed longer duration in the ICU, in the hospital, needed longer bed rest, and reported discomfort at discharge more frequently compared to those in the Angio-Seal VIP group. Findings of this study indicate that Angio-Seal VIP could help reduce postinterventional complications that can lead to extended immobility, longer stays in the ICU, in the hospital, postinterventional pain, and discomfort (29, 30, 36).

4.6 Strengths and limitations

A number of strength points could be attributed to this study. The strength points were:

- This was the first comparison of the use of MC and Angio-Seal VIP among patients who underwent transfemoral cerebral angiographies in Palestine. Little evidence exists on the postinterventional complications when MC and Angio-Seal VIP for patients who undergo transfemoral cerebral angiographies. Findings of this study could add to the existing literature in the field.

- Different postinterventional complications were compared when MC and Angio-Seal VIP were used. Globally, comparative studies draw considerable attention of stakeholders. Therefore, findings of this study are informative to clinicians, nurses, and planners of healthcare for patients who are scheduled for transfemoral cerebral angiographies.

On the other hand, the study has a number of limitations. These limitations include:

- This study used a retrospective design. Compared to prospective designs, retrospective designs produce less reliable findings.
- Although a commonly used formula was used to calculate the sample size needed for this study at an adequate power, the sample size was relatively small. Using a larger sample size could have generated more reliable data and could have identified more complications that could be analyzed and compared.
- The study was conducted in a single center. Compared to multicenter studies, single center studies might produce less generalizable findings.
- In this study, one type of VCDs was used. Comparison of different VCDs could have generated more interesting and informative results.

4.7 Conclusions

In conclusion, findings of this study indicated that Angio-Seal VIP was associated with less postinterventional complications compared to MC for patients undergoing transfemoral cerebral angiographies. Although both methods could be safe and effective in helping achieve hemostasis, Angio-Seal VIP could reduce postinterventional complications that can lead to longer mechanical ventilation hours, higher postinterventional pain, longer stays in the ICU, in hospital, longer bed rest, and higher patient discomfort at discharge.

4.8 Recommendations

- In clinical practice, planners of patient care might consider using Angio-Seal VIP for patients undergoing transfemoral cerebral angiographies.
- More studies are still needed to compare postinterventional complications when different VCDs other than Angio-Seal VIP are used. These studies might allow

recommending the use of the most effective VCDs in helping achieve hemostasis and reduce postinterventional complications.

List of Abbreviations

Abbreviation	Meaning
BMI	Body mass index
ICU	Intensive care unit
IQR	Interquartile range
IRB	Institutional Review Board
JCI	Joint Commission International
MC	Mechanical compression
Q1	Lower quartile
Q3	Upper quartile
VCDs	Vascular closure devices

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Appendices

Appendix A

The data collection form

Age:	Sex:	History:	Diabetes : **Y N** Hypertension: **Y N** CVA (Stroke) : **Y N** TIA : **Y N** Hemodialysis: **Y N** Groin scar: **Y N** Smoking : **Y N**	Immunosuppressive therapy : **Y N** Carotid stenosis >70%: **Y N** Hyperlipidemia : **Y N** Peripheral artery disease: **Y**	
BMI:					
Weight:	Height:				
Stage of current treatment : 1st 2nd 3rd Previous angiograph : **Y:---- N** Cross over (if none state no) : **Y :..... N** Previous stage access site : **Y :----- N** Puncture duration (from first attempt) :------- -- Number of puncture attempt :-------- Procedure duration: (from the point of successful puncture attempt): ----- Amount of lidocaine 1% : ------ Method of compression: *** manual compr** *** VIP** Device failure : **Y N** Sheath size : **4 FR 5FR 6 FR 7FR** Length of manual compression applied. **Time :** Time to hemostasis: *<2 min *2-5 min >10 min Result of Cath : *** diagnostic * therapeutic** #Used of stent #used of balloons: Femoral bleeding : **Y N** Ischemia of the leg : :* pale *coldness *pulseless *weakness Using contrast : **Y N** Send to radiology for ultra sound if bleeding or vascular complication was occurred :**Y N**		**Drug :** Heparin dose : Y------ N Nimodipine : Y ----- **N** ASA: **Y ----- N** Beta Blocker: **Y ----- N** Clopidogrel: **Y ----- N** Aggrastat: **Y ----- N** Antiplatelet: **Y ----- N**	**Indication:** O Cerebrovascular diseases O Tumor O Subarachnoid hemorrhage O Aneurysm O Arteriovenous malformation O Seizure	
			PT >>>>> ... **PTT >>>>** ... **INR >>>>** ... **Creatinine** ... **WBC >>>> Hg >>>>>** ... **PLT >>>>>**	**Post OP. test :** **Obser , Day 0** **RR :** …… **HR :** …… **B/P :** …… **Temp :** …… **SPO2 :** ……	
Post- operative Complication :			**Length of stay :**		
Day 0 Day 1 Day 2 ICU Length of Stay					
Local: Hematoma (regardless of size or excessive tenderness at the puncture site)					
]					
Hospital length of stay					
Thrombosis				MV Need: **Y : ------hours**	
Ecchymosis more than 30 min to hemostasis					
Infection				**Pain Assessment :**	
Need for vascular repair				Pre procedure:	
Local infection				Post procedure:	
Repeat manual compression					
Time to hemostasis, min				In-hospital mortality:	
Lack of hemostatic control				**Y N**	
Acute ipsilateral leg ischemia				**Patient Satisfaction:**	
Access site–related major bleeding				Prolonged bed rest: **:----- hours ---**	
Retroperitoneal bleeding				Discomfort at time of discharge:	
Distal embolization				**Y N**	
Occurrence of spasm					

Appendix B

Approval from the Institutional Review Board (IRB)

An-Najah National University
Faculty of medicine Sciences Health
Institutional Review Board

جامعة النجاح الوطنية
كلية الطب وعلوم الصحة
لجنة اخلاقيات البحث العلمي

Ref: N.G.S. Aprill *2021/9*

IRB Approval Letter

Study Title:

Comparison of vascular closure devices versus manual compression in terms of postoperative complications among patients undergoing cerebral angiography:A hospital-based observational study

Submitted by:
Duaa Faraj

Supervisor:
Saed Zyoud, Waqael Sadaqa

Date Approved:
14h Aprill 2021

Your Study "**Comparison of vascular closure devices versus manual compression in terms of postoperative complications among patients undergoing cerebral angiography:A hospital-based observational study**" viewed by An-Najah National University IRB committee and was approved on 14th Aprill 2021.

Hasan Fitian, MD

IRB

IRB Committee Chairman
An-Najah National University

Appendix C

Tables of Study

Table C.1

Demographics and clinical variables of the patients stratified by method of compression

	Method of compression					
	MC		Angio-Seal VIP			
Variable	n	%	n	%	Chi-Square/Fisher's exact test	p-value
Age (years)						
< 50	66	74.2	28	36.4	24.01	< 0.001
≥ 50	23	25.8	49	63.6		
Gender						
Male	64	71.9	49	63.6	1.30	0.317
Female	25	28.1	28	36.4		
BMI (kg/m^2)						
< 25	44	49.4	50	64.9	4.04	0.059
≥ 25	45	50.6	27	35.1		
History of diabetes mellitus						
Yes	23	25.8	36	46.8	7.88	0.006
No	66	74.2	41	53.2		
History of hypertension						
Yes	53	59.6	42	54.5	0.42	0.533
No	36	40.4	35	45.5		
History of cerebrovascular accident						
Yes	3	3.4	2	2.6	0.09	1.000
No	86	96.6	75	97.4		
History of transient ischemic attack						
Yes	0	0.0	5	6.5	5.92	0.020
No	89	100.0	72	93.5		
History of hemodialysis						
Yes	3	3.4	2	2.6	0.08	1.000
No	86	96.6	75	97.4		

History of groin scar						
Yes	1	1.1	1	1.3	0.01	1.000
No	88	98.9	76	98.7		
History of hyperlipidemia						
Yes	1	1.1	8	10.4	6.87	0.013
No	88	98.9	69	89.6		
History of peripheral artery disease						
Yes	0	0.0	6	7.8	7.15	0.009
No	89	100.0	71	92.2		
Smoking status						
Yes	48	53.9	27	35.1	5.93	0.019
No	41	46.1	50	64.9		
Stage of current treatment						
1st	76	85.4	66	85.7	5.32	0.044
2nd	13	14.6	7	9.1		
3rd	0	0.0	4	5.2		
Previous angiography						
Yes	12	13.5	7	9.1	0.79	0.467
No	77	86.5	70	90.9		
Access site crossover						
Yes	4	4.5	6	7.8	0.79	0.516
No	85	95.5	71	92.2		
Previous stage access site						
Yes	11	12.4	5	6.5	1.63	0.292
No	78	87.6	72	93.5		

BMI: body mass index

Table C.2

Comparison of the procedural variables

	Method of compression					
	MC		Angio-Seal VIP			
Variable	n	%	n	%	Chi-Square/Fisher's exact test	p-value
Indication						
Cerebrovascular disease	0	0.0	1	1.3	3.95	0.393
Tumor	11	12.4	5	6.5		
Subarachnoid hemorrhage	68	76.4	57	74.0		
Aneurysm	5	5.6	7	9.1		
Arteriovenous malformation	5	5.6	7	9.1		
Number of puncture attempts retried						
None	85	95.5	63	81.8	10.37	0.003
Once	3	3.4	12	15.6		
Twice	0	0.0	2	2.6		
Trice	1	1.1	0	0.0		
Lidocaine use						
No	68	76.4	44	57.1	6.98	0.012
Yes	21	23.6	33	42.9		
Sheath size						
5Fr	2	2.2	2	2.6	3.59	0.181
6Fr	26	29.2	33	42.9		
7Fr	61	68.5	42	54.5		
Time to hemostasis (min)						
< 2	4	4.5	21	27.3	26.43	< 0.001
2-5	68	76.4	55	71.4		
> 5	17	19.1	1	1.3		
Use of contrast						
Yes	66	74.2	22	28.6	34.44	< 0.001
No	23	25.8	55	71.4		
Nimodipine use						
No	30	33.7	22	28.6	0.51	0.506
Yes	59	66.3	55	71.4		
Acetylsalicylic acid						

No	64	71.9	36	46.8	10.91	0.001
Yes	25	28.1	41	53.2		
Clopidogrel use						
No	53	59.6	38	49.4	1.72	0.213
Yes	36	40.4	39	50.6		
Tirofiban use						
No	85	95.5	58	75.3	14.09	< 0.001
Yes	4	4.5	19	24.7		
Result of the catheterization						
Diagnostic	23	25.8	20	26.0	0.00	1.000
Therapeutic	66	74.2	57	74.0		

MC: manual compression

Table C.3

Postinterventional complications

	Method of compression					
	MC		Angio-Seal VIP			
Variable	n	%	n	%	Chi-Square/Fisher's exact test	p-value
Femoral bleeding						
Yes	5	5.6	3	3.9	0.27	0.726
No	84	94.4	74	96.1		
Leg ischemia						
None	74	83.1	72	93.5	6.70	0.063
Coldness	3	3.4	1	1.3		
Pulseless	9	10.1	1	1.3		
Weakness	3	3.4	3	3.9		
Local hematoma						
Yes	33	37.1	8	10.4	15.81	< 0.001
No	56	62.9	69	89.6		
Thrombosis						
Yes	4	4.5	0	0.0	3.53	0.124
No	85	95.5	77	100.0		
Ecchymosis						
Yes	3	3.4	0	0.0	2.63	0.249
No	86	96.6	77	100.0		
Systemic infection						
Yes	1	1.1	0	0.0	0.87	1.000
No	88	98.9	77	100.0		
Local infection						
Yes	3	3.4	0	0.0	2.63	0.249
No	86	96.6	77	100.0		
Need for vascular repair						
Yes	1	1.1	0	0.0	0.87	1.000
No	88	98.9	77	100.0		
Repeated MC						
Yes	26	29.2	2	2.6	20.86	< 0.001
No	63	70.8	75	97.4		

Access site related major bleeding						
Yes	1	1.1	0	0.0	0.87	1.000
No	88	98.9	77	100.0		

MC: manual compression

جـامعـــة النجاح الوطنية

كليـــة الدراســـات العليـــا

مقارنة أجهزة إغلاق الأوعية الدموية مع الضغط اليدوي من حيث دورها في التقليل من مضاعفات ما بعد إجراء القسطرة الدماغية: دراسة قائمة على الملاحظة في المستشفى

إعداد

دعاء أحمد حسين فرج

إشراف

د. سائد زيود

د. وائل صدقة

قدمت هذه الرسالة استكمالا لمتطلبات الحصول على درجة الماجستير في تمريض العناية المكثفة من كلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس– فلسطين.

2022

مقارنة إغلاق الأوعية الدموية والضغط اليدوي ودورها في التقليل من مضاعفات ما بعد إجراء القسطرة الدماغية: دراسة قائمة على الملاحظة في المستشفى

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الملخص

خلفية الدراسة: عادة ما يتم إجراء تصوير الأوعية الدماغية الشوكي عبر شريان الفخذ في أماكن رعاية صحية مختلفة حول العالم، لذا تُستخدم أجهزة إغلاق الأوعية الدموية وطرق الضغط الميكانيكي لوقف نزيف الدم.

أهداف الدراسة: أجريت هذه الدراسة لتقييم ومقارنة مضاعفات ما بعد خضوع المرضى لتصوير الأوعية الدماغية عبر الفخذ عند إستخدام أجهزة إغلاق الأوعية الدموية وطرق الضغط الميكانيكي لوقف نزيف الدم.

منهجية الدراسة: أجريت هذه الدراسة بمقارنة مجموعتين بأثر رجعي تم فيها إستخدام سجلات المرضى الذين خضعوا لتصوير الأوعية الدماغية في جامعة النجاح الوطنية.

نتائج الدراسة: أجريت الدراسة على 166 مريضاً (89 بإستخدام الضغط الميكانيكي و77 بإستخدام أجهزة إغلاق الأوعية الدموية). إحتاج مرضى الضغط الميكانيكي لوقت أطول لوقف النزيف، كما وعانوا من آلام بشكل أكبر، وإستخدموا كميات أكبر من المخدر الموضعي (ليدوكائين)، ومكثوا لفترات أطول في المستشفى، ووحدة العناية المكثفة، وإحتاجو لأوقات راحة أطول مقارنةً بمرضى أجهزة إغلاق الأوعية الدموية.

خلاصة الدراسة: أشارت نتائج هذه الدراسة إلى أن إستخدام أجهزة إغلاق الأوعية الدموية كان مرتبطًا بمضاعفات أقل مقارنةً بإستخدام الضغط الميكانيكي للمرضى الذين يخضعون لتصوير الأوعية الدماغية عبر الفخذ. على الرغم من أن كلتا الطريقتين يمكن أن تكون آمنة وفعالة في المساعدة على تحقيق وقف النزيف،إلا أن إستخدام أجهزة إغلاق الأوعية يمكن أن يقلل من مضاعفات ما بعد إجراء تصوير الأوعية الدماغية الشوكي عبر شريان الفخذ.

كلمات مفتاحية: القسطرة، تصوير الأوعية الدماغية، شريان الفخذ، وقف النزيف، الضغط الميكانيكي، جهاز إغلاق الأوعية الدموية.