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Comparison of complications after transfemoral coronary angiography between mechanical and manual closure techniques

Megan Bontrager¹ and Sam Abraham^{1*}

Abstract: Cardiovascular disease continues to be the leading cause of death in the United States. Coronary angiography is one of the most commonly used diagnostic tools in the identification of coronary artery disease, and it remains a prime treatment option for significant coronary artery stenosis. The widely used femoral approach to coronary angiography does not come without significant risk for access site complications, patient complaints of pain, and lengthy bedrest durations. With these concepts in mind came the evolution and implementation of multiple vascular closure devices. The purpose of this study was to compare complication rates after coronary angiography via the femoral approach between mechanical and manual closure techniques, the pain associated with each, and the duration of bedrest employed using a systematic review of the literature. Upon conclusion of the literature review, evidence has shown to provide significant data supporting the use of mechanical closure devices while reducing access site complications, pain, and lengthy bedrest durations when used in appropriate patients.

Subjects: Cardiovascular Imaging; Interventional Cardiology; Medical-Surgical Nursing

Keywords: coronary angiography; femoral approach; closure techniques; bedrest; pain; access site complications



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PUBLIC INTEREST STATEMENT

In the United States, the femoral approach remains the most widely used access site for coronary angiography. This important tool in diagnosing and treating coronary artery disease does not come without possible complications. During this inquiry, the complications among the femoral approach to coronary angiography were looked at between two types of closure methods. This article describes the important factors considered for each patient undergoing coronary angiography, the pros and cons to each closure method, and the many complications that can occur. These are important facts that anyone undergoing coronary angiography, or involved in cardiovascular care, need to be aware of and consider. It is hopeful that with more education and awareness these complications can be reduced. Understanding these findings and their impact can save time, money, and valuable resources for everyone involved.

1. Introduction

As the femoral approach to coronary angiography remains the most widely used access site in the United States, mechanical closure techniques and the development of new closure devices have emerged. As cardiovascular disease (CVD) persists to take its toll on mortality rates in the United States, coronary angiography and percutaneous coronary interventions remain a foundation in the diagnosis and treatment of coronary artery disease (CAD). Although advancements have been made with the use of the radial artery as an alternative approach to coronary angiography, the femoral approach continues to be the most frequently used access site in the United States (Schulz-Schüpke et al., 2014; p. 1982). Caputo et al. (2011) affirmed that transradial arterial catheterization is currently much more frequent in Europe and Asia. Unfortunately, the femoral approach used in the United States imposes the risk of significant access site complications and can prolong the bedrest duration post procedure. The purpose of this literature review was to compare the incidence of access site complications and bedrest duration between manual and mechanical closure techniques following transfemoral coronary angiography. The research question used to guide this study was: Do vascular closure devices (VCD) reduce bedrest duration and access site complications more than manual compression in patients undergoing coronary angiography via the femoral approach?

2. Literature review

2.1. Methods

The literature review was performed with thorough exploration and investigation using the Cumulative Index of Nursing and Allied Health Literature (CINAHL), PubMed, and Ovid databases. Using the search terms *cardiac catheterization*, *femoral approach*, and *manual and mechanical closure techniques*, an abundance of peer-reviewed, scholarly journal articles were readily available. The literature chosen for review were published from 2013–2017, meticulously analyzed, and methodically pieced for proper evidence-based review, using only the top four tiers of evidence hierarchy, as summarized in Appendix A.

There is little defined data supporting the specific use for mechanical closure or manual closure in any given patient following cardiac catheterization. Hence, the widely variable use of manual and mechanical closure techniques. Regardless of closure technique used, however, a variable but specific bedrest duration will be implemented post cardiac catheterization to further decrease the risk of access site complications. Numerous studies were reviewed to find a correlation among closure technique, bedrest duration, and access site complications following transfemoral coronary angiography.

2.2. Mechanical closure vs. manual compression

One of the many challenges associated with coronary angiography via the femoral approach is the struggle and labor-intensive course of manual compression to the common femoral artery (CFA) to achieve hemostasis. This process and technique can take anywhere from ten to thirty minutes to achieve hemostasis and comes with a lengthy bedrest duration to follow it. Before the development of VCDs, the manual technique was the only option to achieve hemostasis to the CFA following transfemoral cardiac catheterization.

The use of VCD is a form of mechanical closure technique. Since the mid-1990s, VCDs have been initiated into practice with the goal to improve efficacy and the safety of endovascular procedures (Schulz-Schüpke et al., 2014, p. 1982). There have been multiple studies comparing the differences among many types of VCDs and the outcomes they achieved. “Increased efficacy, in comparison to manual compression (i.e. reduced time to hemostasis and early ambulation), has been a consistent finding across different trials of VCDs” (Schulz-Schüpke et al., 2014, p. 1982).

2.3. ISAR-CLOSURE randomized trial

The ISAR-CLOSURE randomized clinical trial was an open-label clinical trial that enrolled 4,524 patients undergoing coronary angiography with the use of a 6 French sheath in the CFA. The main

outcomes and measures were access site related complications at 30 days and evaluation of time to hemostasis, repeat manual compression, and VCD malfunction (Schulz-Schüpke et al., 2014, p. 1981). Of the 4,524 patients, 3,015 underwent mechanical closure technique, and 1,509 underwent manual compression technique. Time to hemostasis was significantly reduced utilizing mechanical closure when compared to manual closure (1, 10 min, respectively). Access site complications were assessed with duplex sonography before hospital discharge, “the primary endpoint was observed in 208 patients (6.9%) assigned to VCD and 119 patients (7.9%) assigned to manual compression” (Schulz-Schüpke et al., 2014, p. 1981). In conclusion, of the study, VCDs were found non-inferior to manual closure technique in patients who undergo transfemoral coronary angiography utilizing a 6 French sheath in regards to their primary endpoints of time to hemostasis and access site complications (Schulz-Schüpke et al., 2014, p. 1981).

The ISAR-CLOSURE trial was performed using only diagnostic cardiac catheterization patient populations. Among that population was additional exclusion criteria, such as CFA <5 mm, VCD within the last 30 days, symptomatic leg ischemia, prior vascular surgery to the CFA, planned invasive diagnostic or interventional procedure in the following 90 days, heavily calcified vessel, active bleeding, severe arterial hypertension (SBp > 220), local infection, autoimmune disease, allergy to reabsorbable suture, and pregnancy (Schulz-Schüpke et al., 2014, p. 1982). Those excluded patient populations are at an even greater risk for post-procedure access site complications. In further analysis of the study, it was identified that earlier ambulation was allowed in patients who underwent mechanical closure technique vs. manual closure technique (2 vs. 6 h, respectively). The rate for repeat compression was higher (1.8% for manual compression vs. 0.7% for mechanical closure), and time to hemostasis was significantly shortened with mechanical closure (Schulz-Schüpke et al., 2014, p. 1985).

2.4. CLOSE-UP study

Holm et al. (2014) conducted a study to compare the safety and efficiency of the FemoSeal VCD vs. manual compression (MC) after femoral access coronary angiography. Over the course of 13 months and with over a 1,000-patient population, they concluded that closure of femoral access after cardiac catheterization by the FemoSeal VCD was safe and significantly reduced in-hospital large hematomas when compared to manual compression closure (Holm et al., 2014, p. 190). It was interesting to note that this trial used both one hour of bedrest for both closure techniques. “The combined endpoint of 14-day adverse vascular events occurred in 1.0% in the MC group vs. 0.6% in the FemoSeal VCD group” (Holm et al., 2014, p. 183). It was also relevant to note that Holm et al. (2014) point out that multiple punctures during access were identified as an independent predictor of adverse events and large hematomas.

2.5. Complications with Angio-Seal VCD compared with manual compression

The study conducted by Gregory, Midodzi, and Pearce (2013) assessed and compared access site complications in diagnostic and interventional cardiac catheterization patients using the Angio-Seal™ vs. manual compression closure technique. This study conducted a secondary data analysis to further compare femoral access-related complications outcomes in patients who underwent cardiac procedures via the femoral route. Of the reviewed 11,897 procedures, 7,063 of them used a VCD. It was stated that vascular complications arised in 2% of diagnostic cardiac catheterizations and 2.7% of interventional cardiac catheterizations (Gregory et al., 2013, p. 630). Concluding that a “low incidence” of vascular complications was observed with the use of an Angio-Seal VCD when compared to mechanical closure for both techniques (Gregory et al., 2013, p. 630).

Gregory et al. (2013) used both diagnostic and interventional procedural populations who underwent transfemoral cardiac catheterizations. Exclusion criteria were limited to patients under the age of 19 years old and patients who were treated with any other closure technique besides the Angio-Seal VCD or manual compression (Gregory et al., 2013, p. 631). Another interesting fact regarding this particular study is that the vascular management was performed only by experienced interventionists, not trainees such as fellows or residents (Gregory et al., 2013, p. 631). “The decision to use a VCD and the type of VCD uses is left to the operator; however, Angio-Seal is used almost exclusively

in out-patients, particularly out-patient PCIs, to allow for quicker ambulation” (Gregory et al., 2013, p. 631). Upon further conclusion, low incidence of vascular complications does exist with Angio-Seal VCD relative to manual closure techniques, and more trials are needed to further explore these complication rates (Gregory et al., 2013, p. 637).

2.6. Bedrest duration and complications

The femoral approach to coronary angiography, although the predominantly used site, does not present without risk of complications such as bleeding, groin hematoma, pseudo-aneurysm, stenosis, arterial closure, pain, and discomfort. Additional precautions and care are taken to help alleviate these issues. With a goal to decrease vascular access site complications, VCDs also aim to decrease the painful and often irritable lengthy bedrest duration following manual compression technique. Many comparisons, trials, and studies of VCDs and manual compression techniques show mixed results regarding safety, efficiency, and comfort (Sindberg et al., 2014, p. 221).

2.7. CLOSE-UP pain sub-study

The aim of this study was to compare pain and discomfort after femoral artery closure by manual compression vs. a particular VCD called the FemoSeal. It was a sub study to the widely known CLOSE-UP study that was discussed earlier. This sub-study looked directly into the pain and discomfort associated with the insertion of the FemoSeal VCD in comparison to sheath removal followed by manual compression. It assessed pain in the patients using a numerical pain scale immediately following sheath removal, at discharge, and again 14 days post procedure. In conclusion of the study, it was found that femoral access closure after coronary angiography was associated with a significantly higher amount of pain and discomfort than manual compression (Sindberg et al., 2014, p. 226). This pain was significantly increased at sheath removal; there was no increased pain in the following assessment times at discharge or 14 days post-procedure. Of particular interest with this study, bedrest duration for mechanical and manual closure technique was both one hour, and patients were allowed to have the head of the bed elevated up to 45° (Sindberg et al., 2014, p. 222).

2.8. MOBS study

The MOBS study looked into the fact that regardless of closure technique, mechanical or manual, immobilization and bedrest are implemented into post-cardiac catheterization regimens. The aim of this study was to compare bleeding complications after coronary angiography via the femoral approach in two cohorts: MOBS I (diagnostic angiogram patients) and MOBS II (percutaneous coronary intervention patients [PCI]) following a bedrest duration of one or two hours, respectively, against immediate mobilization after angiography. In conclusion, it was shown that immediate mobilization after diagnostic or interventional coronary angiography with the femoral access site closed with the Angio-Seal VCD was not associated with any increased bleeding risk when compared to the standard bedrest duration used in the study (Larsen, Hansen, Thayssen, & Jensen, 2014, p. 471). Patients were excluded from this trial if they were treated with the commonly used drugs during cardiac catheterizations such as heparin, glycoprotein IIb/IIIa receptor blockers, or bivalirudin (Larsen et al., 2014, p. 467).

2.9. THREE CATH trial

The objective of this trial was to compare the incidence of vascular complications in patients following coronary angiography via the femoral approach followed by a three hour and five-hour bedrest period. In this trial, a fairly small control with only 367 patients in the intervention group (3 h bedrest) and 363 patients in the control group (5 h bedrest) were used. The hematoma was the most common complication in both groups and accounted for 3% of patients who were treated with five hours of bedrest and in 4% of patients who were treated with three hours of bedrest (Matte, Hilário, Reich, Aliti, & Rabelo-Silva, 2016, par. 1). In conclusion, reducing bedrest durations from five hours to three hours did not increase complications. Again, in this study, only diagnostic coronary angiography patients were used and exclusion included use of Coumadin anticoagulants, body mass index (BMI) > 35 kg/m², hypertension with a systolic blood pressure (SBP) > 180 mmHg or diastolic blood pressure (DBP) > 110 mmHg (Matte et al., 2016, par. 6).

2.10. Early ambulation systematic review

The study Mohammady, Heidari, Sari, Zolfaghari, and Janani (2014) conducted was a systematic review and meta-analysis that assessed the effects of the duration of bedrest after transfemoral coronary angiography on the prevention of vascular access site complications and general discomfort. Upon completion, it was concluded that patients could be ambulated after two to three hours following cardiac catheterization and that early ambulation has no significant effect on the incidence of vascular complication and may reduce pain and discomfort following the procedure (Mohammady et al., 2014, p. 39). This study was unique from the rest in this literature review, where is used patient populations from not only cardiac catheterizations but also many other catheterizations such as mesenteric, renal, carotid, and upper extremities. It excluded patients who underwent electrophysiology studies and percutaneous coronary intervention. It also used multiple sheath sizes and many different VCDs.

3. Summary of research evidence

To decrease the length of bedrest duration and possibly reduce the risk of access site complications following femoral coronary angiography, multiple VCDs have been developed. The aim of this systematic review was to look at the comparison between the use of mechanical closure and manual closure techniques following transfemoral coronary angiography and their effects, along with bedrest duration, that they have on access site complications. Although more research is strongly needed to help providers determine the best closure approach and bedrest duration, it is evident that in select patients VCDs can not only decrease bedrest duration and pain but also help alleviate vascular access site complications such as bleeding, hematoma, pseudo aneurysm, and arterial closure.

Kandarpa, Machan, and Durham (2016) pointed out many advantages and disadvantages of both manual compression and VCDs. Kandarpa et al. (2016) noted that manual compression is the gold standard, has a limited learning curve, and is very cost effective (p. 36). However, manual compression can increase patient discomfort, delay time to hemostasis, delay time to ambulation, and decrease department workflow. Kandarpa et al. (2016) go on to reiterate VCDs advantages of immediate hemostasis, decreased time to ambulation, improved patient comfort, and improved department workflow (p. 36). Unfortunately, each VCD has its own learning curve and has the potential for severe complications (Kandarpa et al., 2016, p. 36).

It is clear that there is beneficial data suggesting appropriate use criteria for VCDs in specific patient populations. After analyzing the literature, it is important to point out the populations identified in many exclusion criteria, as in the ISAR-CLOSURE trial and THREE CATH trial, which are very similar to the relative contraindications listed in published text and handbooks. Kandarpa et al. (2016) point out possible contraindications to VCDs as severe calcified atherosclerotic peripheral artery disease in the CFA, small CFA <5 mm, multiple puncture attempts during access, double wall puncture technique, prior interventional work on the CFA, uncontrolled hypertension, and morbid obesity (p. 38). With that said, it is evident that some VCDs are better suited than others for certain clinical applications and patient populations. There are many VCDs on the market. The keys to successful VCD deployment and positive patient outcomes are familiarity with the concepts, mechanisms, and instructions for each device used in one's practice and the specific patient and case characteristics of each closure method (Kandarpa et al., 2016, p. 49).

It is clear that the femoral approach to coronary angiography remains the most widely used access site in the United States. However, the transradial approach used in Europe and Asia is associated with less major bleeding complication than transfemoral, and this is translated into a reduction in a major adverse cardiovascular event (Ando & Capodanno, 2016). Furthermore, transradial access seems associated with a reduction in the incidence of post-procedural acute kidney injury, which is a common complication after cardiac catheterization (Ando et al., 2015).

4. Recommendations & implications for practice

Reviewing all the data gathered in this single literature review, it can be concluded that among specific populations and criteria, VCD can safely reduce access site complications and bedrest duration

among transfemoral coronary angiography patients, in both diagnostic and interventional. Complete knowledge and understanding of the many VCDs out there, their indications for use, instructions, and patient selection criteria are imperative for successful implementation of mechanical closure devices. Each closure technique decision requires an in-depth awareness of patient-specific implications. Therefore, closure technique and bedrest duration following should be based upon each patient selection with their unique factors assessed along with case specific variables.

5. Conclusion

Coronary angiography via the femoral approach remains a highly common procedure. Mechanical closure technique and manual closure technique are both viable options. For providers, it is imperative that they familiarize themselves with the large array of VCDs available and the indications for each of their use. These devices can provide a practical option for ideal candidates to reduce vascular complication rates and decrease bedrest duration following cardiac catheterization and interventions via the femoral route. The studies and trials examined for this literature review conclude multiple perspectives and a wealth of relevant data. Understanding that patient criteria, characteristics, and provider expertise play a large role in successful implementation of each closure method is crucial. Evidence has shown to provide significant data supporting the use of mechanical closure devices while reducing access site complications, improving outcomes, and reducing lengthy bedrest durations when used in appropriate patients. However, further specific studies should be conducted to analyze the details linking bedrest duration following closure technique with each particular VCD.

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Competing Interests

The authors declare no competing interest.

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Cover image

Goshen Hospital - New EP room addition in the Cardiovascular Lab.

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Appendix A. Research evidence summary table

Author/s	Type of study	Number of subjects	Major findings	Conclusions
Gregory, D., Miodazi, W., & Pearce, N. (2013). <i>Journal of Interventional Cardiology</i>	Complications with Angio-Seal Vascular Closure Devices Compared with Manual Compression after Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention; Secondary data analysis of a population-based multiyear cohort database was conducted	The study population consisted of 11,987 CATHs with or without PCI using femoral approach. (Of the 11,987 procedures, 7,063 (59.4%) used a VCD. Newfoundland and Canada	Vascular complications occurred in 174/8,796 (2.0%) of CATHs and 82/3,004 (2.7%) of PCIs. In the CATH sample, the odds of vascular complications occurred were 57% lower if a VCD was used. For the PCI sample, the risk was 49% lower if a VCD was used	A low incidence of vascular complications was observed with the use of Angio-Seal VCD relative to MC for both procedures
Holm, N., Sindberg, B., Schou, M., Maeng, M., Kalltoft, A., Bottcher, M., ... Lassen, J. (2014). <i>EuroIntervention</i>	Randomized Comparison of Manual Compression and FemoSeal Vascular Closure Device for Closure After Femoral Artery Access Coronary Angiography: The closure devices used in everyday practice (CLOSE-UP) study; randomized trial	Over 13 months, 1,014 patients entered but only 1,001 were analyzed	Bedrest for one hour after was recommended for both groups. The primary endpoint of incidences of large groin hematoma was 6.7% in mechanical closure group vs. 2.2% in FemoSeal group; Multiple punctures were identified as independent predictors of adverse events and hematomas	Closure of femoral access after coronary angiography by the FemoSeal vascular closure device was safe, faster, and associated with significantly fewer in-hospital large hematomas when compared manual closure technique
Larson, E., Hansen, C., Thayssen, P., & Jensen, L. (2014). <i>European Journal of Cardiovascular Nursing</i>	Immediate Mobilization After Coronary Angiography or Percutaneous Coronary Intervention Following Hemostasis with AngioSeal Vascular Closure Device (The MOBS Study). Block- randomized, Quantitative Study	In the MOBS I cohort, (100 patients were mobilized immediately, and 100 patients followed standard care). In the MOBS II cohort after PCI, (158 patients were mobilized immediately, and 161 patients followed standard care.) Department of Cardiology, Odense University Hospital, Denmark	No major bleeding complications were seen between the groups. Baseline characteristics did not differ between the groups	Immediate mobilization after coronary angiogram of PCI with the femoral access site closed by the closure device AngioSeal was not associated with increased bleeding risk compared to standard care with bed rest of 1 or 2 h
Matte, R., Souza Hilario, T., Reich, R., Aliti, G., & Rabelo-Silva, E. (2016). <i>Revista Latina-Americana de Enfermagem</i>	Reducing Bed Rest Times from Five to Three Hours Does not Increase Complications After Cardiac Catheterization: The THREE CATH Trial; Randomized clinical trial	The study sample comprised of adult outpatients who underwent transfemoral diagnostic cardiac catheterization with 6F sheath. Sample n = 367 patients in the IG (intervention group) and n = 363 patients in the CG (control group); Latin America	Based on the results of the RCT, reducing the duration of bedrest from 5-3 h in patients undergoing transfemoral diagnostic cardiac catheterization with a 6F sheath did not increase the rate of arterial puncture-related complications during OU stay over at 24, 48, and 72 h telephone follow-up	The results of this trial show that reducing bed rest times to 3 h after elective cardiac catheterization is safe and does not increase complications as compared with a 5 h rest

(Continued)

Appendix A. (Continued)

Author/s	Type of study	Number of subjects	Major findings	Conclusions
Mohammady, M., Heidari, K., Sari, A., Zolfaghari, M., & Janani, L. (2014). <i>International Journal of Nursing Studies</i>	Early Ambulation After Diagnostic Transfemoral Catheterization: A systematic review and meta-analysis; Blinded and unblinded randomized controlled trials and quasi-randomized controlled trials that used two different durations of bed rest after angiography before ambulation was permitted	Twenty studies involving a total of 4,019 participants with a mean age of 59.5 years were included. The studies considered periods of bedrest ranging from 2–24 h, which were compared in three main categories	There were no statistically significant differences between categories in the incidence of bleeding, hematoma, bruising, pseudo aneurism, thrombus, or arteriovenous fistula. Back pain intensity was assessed in the four studies. Patients had significantly less back pain in after 2–4 h of bedrest than compared to the 6 h. In addition, reduced bed rest times may significantly decrease the costs of hospital care	The systematic review suggests that patients can be ambulated 2–3 h following transfemoral catheterization and that early ambulation had no significant effect on the incidence of vascular complications and may reduce back pain and urinary discomfort
Schupke, S., Helde, S., Gewalt, S., Ibrahim, T., Linhardt, M., Haas, K., ... Kastrati, A. (2014). <i>The Journal of the American Medical Association</i>	Comparison of Vascular Closure Devices - Manual Compression After Femoral Artery Puncture: The ISAR-CLOSURE Randomized Clinical Trial; Randomized, large-scale, multicenter, open-label clinical trial	4,524 patients undergoing coronary angiography with a 6F sheath via the common femoral artery from April 2011 through May 2014 in four centers in Germany	Of the 4,524 enrolled patients, 3,015 were randomly assigned to VCDs, and 1,509 patients were randomly assigned to manual compression. Time to hemostasis was significantly shorter in patients with VCDs vs. manual compression. The incidence of hematoma was lower in patients assigned to the VCDs compared with manual compression	In patients undergoing transfemoral coronary angiography, VCDs were noninferior to manual compression in terms of vascular access-site complications and reduced time to hemostasis. The principle reasons for using VCDs are to reduce time to homeostasis, facilitate earlier mobilization after sheath removal, and enhance patient comfort
Sindberg, B., Schou, M., Hansen, L., Christiansen, K., Jorgensen, K., Soltoft, M., ... Lassen, J. (2014). <i>European Journal of Cardiovascular Nursing</i>	Pain and Discomfort in Closure of Femoral Access Coronary Angiography. The Closure Devices Used in Everyday Practice (CLOSE-UP) Pain sub-study; a randomized, single center sub study comparison of FemoSeal VCD vs. manual compression after CAG	Consecutive patients scheduled for elective or sub-acute diagnostic CAG were included on all-comers basis. The inclusion criteria were eligibility for femoral access, age over 18 years, the ability to provide written consent, and the use of a 6F sheath. The sample was $n = 1004$; and the study was conducted by the Department of Cardiology, Aarhus University Hospital, Skejby, Denmark	1,014 patients were included, and 1,001 patients entered the analysis. In-hospital follow-up was obtained for all patients and a 14-day follow-up was completed for 96% of patients. Pain and discomfort score at the procedure was significantly higher in the FemoSeal VCD group. No differences in pain and discomfort were detected after leaving the catheterization lab	Closure of femoral access after CAG by the FemoSeal VCD was associated with significantly more pain and discomfort compared with closure by manual compression. No difference was found at follow-up



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