Access site complications of manual compression versus closure devices after lower limb revascularization: a systematic review

Maitham S. Alabduljabbar1*, Bader S. Alhamdan1, Mustafa A. Alabdrabalnabi2

ABSTRACT

Annually, around 7 million percutaneous procedures are performed worldwide. However, the common femoral artery is still utilized for most of them, despite radial access becoming increasingly prevalent. This is an updated systematic review of studies discussing access site complications of manual compression versus closure devices after lower limb (LL) revascularization between 2017 and 2022. The PubMed and Google scholar databases were used to explore studies regarding our subject. The keywords included “access site, complications, manual compression, closure devices, LL, and revascularization” and were used in various combinations. The inclusion criteria were original studies that reported the access site complications of manual compression (MC) versus closure devices after LL revascularization and full-text articles. Though 300 articles were obtained, only 7 of them met the inclusion criteria. The studies included 85,806 participants; 5 were prospective, 1 retrospective study, and 1 multicenter randomized clinical trial. The present systematic review indicated that vascular closure devices (VCDs) were independently related to forming fewer hematomas when MC and VCD were compared. Percutaneous endovascular operations’ feasibility, safety, and efficacy were excellent, with very little conversion and complication. Lesion therapy was technically successful in 98.2% and 100% of cases. When patients were undergoing endovascular revascularization of the LL s, FemoSeal® was recommended as the first-line hemostasis treatment. Technically, VCD interventions were successful for both FS and PG patients, and hemostasis was accomplished with complete success. EXOSEAL arm has a greater success rate. The combination treatment of two VCDs with routine ultrasonography guiding access showed excellent efficacy and safety results for individuals who underwent the endovascular treatments operation.

Keywords: Access site, complications, manual compression, closure devices, lower limb, revascularization.

Introduction

Vascular surgery has dramatically changed in the last several decades, moving away from traditional open surgery and toward an increasing variety of percutaneous endovascular treatments (EVT) [1]. Percutaneous access via the common femoral artery has grown in popularity since the interventional radiologist Sven Ivar Seldinger first described the Seldinger technique in 1953 [2]. This is accurate for both therapeutic and diagnostic vascular operations. Over 7 million percutaneous operations are carried out annually throughout the world. While radial access is becoming increasingly popular, the common femoral artery is still used for most of them [3].

The “gold standard” for achieving hemostasis has continued to be manual compression (MC). Still, this

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procedure can be time-consuming and labor-intensive (20-30 minutes or more of MC), requires extended bed rest after completion (up to 4-8 hours), and can be uncomfortable for the patient and the provider [4]. Additionally, due to the continued rise in obesity, the number of patients using anticoagulants and antiplatelet medications, and the sizes of percutaneous devices (such as thoracic endovascular aortic repair and endovascular aneurysm repair), MC is becoming less useful and occasionally insufficient to achieve adequate hemostasis [5].

Peripheral vascular treatments have increased tenfold since 1995. Vascular access site problems, which have been shown to occur in 1%-11% of cases undergoing percutaneous operations, account for a sizable amount of morbidity. The frequency of access site difficulties has decreased in recent years. According to Ortiz et al. [6], the rate in 2014 was 3.5%, of which 74.4% were mild, 9.7% were moderate and required a transfusion, 5.4% were moderate and required thrombin injection, and 10.5% were severe and required surgery. This results in a longer hospital stay, greater discharge rates to nursing homes and rehabilitation centers compared to discharge home, and much higher hospital expenses. The 30-day mortality rate was also greater in patients with severe access site complications, and the 1-year mortality rate was 12.1% (vs. 5.7% without complication) in those with mild complications requiring transfusion [6].

Early in the 1990s, vascular closure devices (VCDs) made their debut. They were made to achieve hemostasis by closing the arteriotomy during percutaneous access [7,8]. Reduced bleeding time from the artery puncture site, quicker ambulation, and increased patient comfort are the main goals of VCDs. VCDs have had exponential growth in the market since their introduction. The market was estimated to be close to $1 billion in 2013. VCDs are worth more and more when percutaneous procedures’ boundaries are pushed [9]. Consequently, the present systematic review seeks to evaluate the current literature on the access site complications of MC versus closure devices after lower limb (LL) revascularization.

Method and Search Strategy

This systematic review complies with the PRISMA checklist guidelines for systematic reviews and meta-analyses [10]. Two databases were used for searching purposes: PubMed and Google scholar databases. The two databases were utilized to survey for studies on our main topic, “access site, complications, MC, closure devices, LL, and revascularization.” The studies were published between 2017 and 2022. The searching process involved using various keywords, including “access site, complications, MC, closure devices, LL and revascularization.” In addition, the involved keywords were employed to collect all relevant articles. This initial exploration resulted in the revision of all titles.

Eligibility criteria

Only papers focusing on the access site complications of MC versus closure devices after LL revascularization were included after reviewing the titles of the retrieved articles. In contrast, articles on the same topic before 2017 were excluded. The second step included reviewing the abstract of the remaining articles to select only original articles and those written in English. In contrast, review articles, editor letters, and case reports were excluded. The final step included original articles written in English and reported articles; these articles were further explored to exclude non-available full-text articles, duplicate articles, and articles with unsatisfying content, such as those with overlapped or incomplete data. The full description of the search strategy is shown in Figure 1.

Data reviewing and analysis

Articles were reviewed for abstracts and the full text to extract the data of interest and transfer data into a pre-designed excel sheet. The selected data were then revised through the excel sheet, and then the data were transferred to one table to summarize the chosen data to facilitate the analysis of data.

Results

Seven studies met the eligibility criteria for this systematic review [11-17] (Table1). The included studies were published in 2017 [17] or 2019 [16] or 2020 [15] or 2021 [12,14], or 2022 [11,13]. Five studies were prospective [11,13-16], while one study was retrospective [17], and one was a multicenter randomized clinical trial [12]. The included studies involved 85,806 patients undergoing lower-limb arterial endovascular revascularization. Three studies were conducted on patients undergoing MC [11,13,16]. In comparison, three studies were carried out on patients undergoing VCDs [12,15,17], and in one study [14], the procedure was not specified. The types of VCDs used were: FemoSeal® (FS) in two studies [12,15], ProGlide® (PG) in two studies [15,17], and EXOSEAL in one study [17].

Two studies compared perioperative outcomes between MC and VCDs after Peripheral vascular interventions [11,14]. Four studies assessed the efficacy and safety of VCDs to achieve hemostasis following LL revascularization [12,15-17]. One study evaluated the security and efficacy of MC in patients with endovascular revascularization [13].

One study assessed the safety and outcomes of endovascular procedures in an ambulatory practice [14]. The common femoral artery (52%), superficial femoral artery (24%), and humeral artery (21%) were the preferred vascular accesses for the operations. Only one serious complication, the non-fatality complication, was found despite the worldwide complication rate.
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Records identified from databases and registers:

- Databases (n=200)
- Registers (n=100)
- Total n=300

Records removed before screening:
- Duplicate records removed (n=170)
- Records marked as ineligible by automation tools (n=50)
- Records removed for other reasons (n=30)
- Total removed n=250

Records screened (n=50)

Reports sought for retrieval (n=17)

Reports assessed for eligibility (n=11)

- Reports excluded:
  1. Review article studies (n=1)
  2. Systematic reviews (n=2)
  3. Incomplete outcome retrieved (n=1)

Studies included in review (n=7)
- Reports of included studies (n=7)

Figure 1. Planning of eligibility criteria.

being 19%. Arterial dissection was the most frequent complication (8.3%), and none of them interfered with blood flow. In the same study [14], the 1-year amputation rate was 6.7%, and the 1-year mortality rate was 3.0%. Female sex, hypertension, and dyslipidemia were significantly associated with procedure complications.

In one study, MC was found to be feasible and safe for same-day discharge after Lower extremity arterial disease (LEAD) revascularization with a 5F sheath femoral approach [13]. Mainly femoropopliteal lesions were treated (70%), and the technical success was 97%. No re-hospitalization was carried out within 24 hours after discharge. No major cardiovascular event, including death, was observed. In addition, the patients were significantly improved in terms of clinical status and hemodynamics compared to baseline.

By comparing MC with VCD, it was found that VCDs were independently associated with the development of fewer hematomas in one study [11]. The occurrence of access site stenosis/occlusion was comparable to the use of either VCD or MC. Percutaneous endovascular procedures were feasible, safe, and effective with very low conversion and complication rates in one study [16]. In this study [16], unilateral femoral access was performed in 75.4% of procedures, with a 6-French sheath in 80.7%. Balloon Percutaneous transluminal angioplasty (PTA) alone was performed in 17.3% and stent placement in 82.7% of treated segments. The technical success of lesion treatment was 98.2% in one study [16], while it was 100% in another [15]. In the first study [15], closure devices were used in 55.4% of procedures. Conversion and readmission rates were 1.8% and 0.6%, respectively.
### Table 1. Selected studies.

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<th>Author and publication year</th>
<th>Study design</th>
<th>Population, sample size, and characterization</th>
<th>Main points</th>
<th>Results and main findings</th>
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<tr>
<td>Cheng et al. [11]</td>
<td>Prospective study</td>
<td>There were 84,172 lower extremity PVI s found in total. Of them, 52,159 (62%) and 32,013 (38%) had used VCDs.</td>
<td>Compare perioperative outcomes between MC and four VCDs following PVI in a multicenter context.</td>
<td>The use of any VCD and the specific VCDs compared to MC were independently related to producing fewer hematomas, according to multivariable analysis. In addition, the incidence of access site stenosis/occlusion was similar between any VCD and MC. The matched analysis revealed similar findings.</td>
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<td>Gouëffic et al. [12]</td>
<td>Multicenter randomized clinical trial</td>
<td>Patients are undergoing lower-limb arterial endovascular revascularization. The primary endpoint was a technical success 5 hours after the VCD intervention.</td>
<td>Compare the effectiveness of the LL arterial endovascular revascularization FS and PG VCDs in attaining hemostasis at the femoral access site.</td>
<td>FS group received 131 patients, whereas the PG group (FS) received 117 patients (PG). VCD treatments were technically successful for 90 FS patients (80%) and 58 PG patients (50%). This disparity in success rates between FS and PG can be partially attributed to the latter group’s more frequent use of MC and insertion of a VCD. 87% of FS and 69% of PG patients were still ambulatory after 5 hours. In patients undergoing LL arterial endovascular revascularization, FS was superior to PG in terms of technical success.</td>
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<td>Gouëffic et al. [13]</td>
<td>National multicenter, prospective study</td>
<td>114 patients were included with symptomatic LEAD (Rutherford 2-5) and eligible for same-day discharge. The primary outcome was the overall hospital admission rate, which also considers overnight monitoring and the 1-month rehospitalization rate.</td>
<td>Examine the safety and effectiveness of same-day discharge following MC in patients receiving 5F sheath treatment for LEAD endovascular revascularization.</td>
<td>Mainly femoropopliteal lesions were treated (178, 70%), and the technical success was 97%. No rehospitalization was carried out within 24 hours after discharge. No major cardiovascular event, including death, was observed. In addition, the patients were significantly improved in terms of clinical status and hemodynamics compared to baseline. FREEDOM OP showed that MC is feasible and safe for same-day discharge after LEAD revascularization with a 5F sheath femoral approach.</td>
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<td>Carvas et al. [14]</td>
<td>Prospective study</td>
<td>134 patients were admitted to an ambulatory unit for an endovascular procedure for 1 year for lower limb (LL) arterial occlusive disease.</td>
<td>To analyze the safety and outcomes of endovascular procedures in ambulatory practice.</td>
<td>134 individuals underwent a total of 168 operations. The common femoral artery (52%), superficial femoral artery (24%), and humeral artery (21%) were the preferred vascular accesses for the operations. Only one serious complication, the non-fatal complication, was found despite the worldwide complication rate being 19%. Atheroma dissection was the most frequent complication (8.3%), and none of them interfered with blood flow. The 1-year amputation rate was 6.7%, while the 1-year mortality was 3.0%. Female sex, hypertension, and dyslipidemia were significantly associated with procedure complications.</td>
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<td>Tagliaferro et al. [15]</td>
<td>Retrospective study</td>
<td>The study reviewed the hemostatic outcome achieved with FS in 103 consecutive patients that had undergone 111 antegrade common femoral artery accesses for percutaneous LL revascularization using 5- to 8-Fr vascular sheaths. The primary outcome was a technical success, which meant achieving complete hemostasis without immediate complications.</td>
<td>To retrospectively assess the efficacy and safety of FS VCDs to achieve hemostasis following antegrade common femoral artery puncture after LL revascularization using vascular sheaths from 5 to 8 Fr.</td>
<td>Hemostasis was achieved in all 111 puncture sites (100% technical success). Only eight (7%) puncture site minor complications (hematomas) were observed; none affected the patients' outcome, required different therapies, or increased the hospital stay. The study found high safety and efficacy of FS VCDs in antegrade common femoral artery puncture site hemostasis when using vascular sheaths ranging from 5 to 8 Fr. Therefore, FS could be considered as a first-line hemostasis strategy in such cases.</td>
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<td>Malekzadeh et al. [16]</td>
<td>Retrospective study</td>
<td>A total of 498 consecutive patients were included. The clinical profile, procedure details, and technical success were reviewed. In addition, complications, conversion rate, readmission rate, and long-term follow-up were evaluated.</td>
<td>To assess the viability and safety of peripheral percutaneous endovascular procedures in many peripheral artery disease outpatients.</td>
<td>Unilateral femoral access was performed in 75.4% of procedures, with a 6-French sheath in 80.7%. Balloon PTA alone was performed in 17.3% and stent placement in 82.7% of treated segments. Technical success of lesion treatment was 98.2%. Closure devices were used in 55.4% of procedures. Rates of conversion and readmission were, respectively, 1.8% and 0.6%. 386 target lesions had a long-term follow-up, and the 5-year restenosis rate was 20.5%. It was concluded that percutaneous endovascular procedures were feasible, safe, and effective with very low conversion and complication rates.</td>
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<td>Fujihara et al. [17]</td>
<td>Retrospective study</td>
<td>Endovascular treatment (EVT) was performed on 513 patients using femoral artery access, and VCDs were used to achieve hemostasis (406-patient EXOSEAL arm and 107-patient PG arm). The main objective was to achieve hemostasis without periprocedural or 30-day incidence of major or minor access site-related problems.</td>
<td>In patients receiving EVT through femoral access, evaluate the effectiveness and safety of routine ultrasound-guided puncture and VCD.</td>
<td>91.6% of the cases (470/513) in which the primary endpoint was reached were successful, with the EXOSEAL arm having a greater success rate (93.6%). Major problems were seen in 5 patients (0.9%) in the overall cohort and 3 patients (0.7%) treated with EXOSEAL arm versus 2 patients (1.8%) with PG arm ($p = 0.32$). For patients with the EVT operation, combined treatment of two VCDs with regular ultrasonography guiding access demonstrated great effectiveness and safety results.</td>
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**Vascular closure devices (VCDs).**  
**Manual compression (MC).**  
**Peripheral vascular interventions (PVIs).**  
**Lower extremity arterial disease (LEAD).**  
**Peripheral arterial disease (PAD).**
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Long-term follow-up was obtained in 386 target lesions, and 5-year restenosis of the lesion was 20.5%.

Three types of VCDs were used in three studies [12,15,17]. FS in two studies [12,15], PG in two studies [15,17], and EXOSEAL in one study [17]. FS was regarded as a first-line hemostasis technique in situations of LL revascularization in patients having lower-limb artery endovascular revascularization in three studies [12,15,17]. In one study, VCD interventions were technically successful for 90 FS and 58 PG patients [12].

The variation in success rates between FS and PG can be partially attributed to the latter group’s more frequent use of MC and insertion of a VCD. After 5 hours, 87% of FS and 69% of PG patients resumed ambulation.

In another study [15], hemostasis was achieved with 100% technical success. Only eight (7%) puncture site minor complications (hematomas) were observed; none affected the patients’ outcome, required further therapies, or increased the hospital stay. In one study [17], the primary endpoint was achieved in 91.6% of the cases, with a higher success rate in the EXOSEAL arm. Major complications were observed in 0.9% of patients, and 0.7% were treated with the EXOSEAL arm versus 1.8% with the PG arm. For patients who underwent the EVT procedure, combined treatment of two VCDs with regular ultrasonography guiding access demonstrated great effectiveness and safety results.

Discussion

According to their mode of operation, VCDs may be divided into two primary categories: active approximators and passive approximators. The term “external hemostatic devices” or “aided compression devices” refers to a distinct class of devices that provide hands-free MC [2]. Active approximators are tools that employ a nitinol clip or a suture to physically seal the arteriotomy site. Three commercially available active approximators have received Food and Drug Administration (FDA) approval [18]. EXOSEAL is a passive approximator that introduces a man-made, biodegradable polyglycolic acid plug to the extravascular space next to the arteriotomy site. Retracting the delivery shaft causes the plug to be released. According to Instructions for Use (IFU), the EXOSEAL is authorized to close arteriotomy sites from 5F to 7F. Both diagnostic and therapeutic approaches including it have received approval.

Compared to MC, it has a higher technical success rate and a lower risk of vascular complications [19,20].

The plugs in FS, an active VCD, hydrolyze within 90 days and are made up of two fully resorbable polymer discs with inner discs measuring 10 by 5 mm and outside discs measuring 5 mm in diameter. This approach is recommended when employing vascular sheaths up to 7 Fr in size. Although St. Jude Medical does not advise against using this device for antegrade common femoral access in its “Instruction for usage,” various papers have shown its safety and effectiveness compared to MC. Any type of arterial sealing will inevitably result in complications; as a result, the effectiveness of any hemostasis device should be carefully evaluated [21-24]. Another active approximator called Perclose PG percutaneously deploys a suture on each side of the arteriotomy site. A lever deploys “feet” within the lumen and is drawn back to abut the wall when the device is placed over a wire until blood verifies intraluminal location. At this point, a needle is released, and a suture loop is established. The suture loop is tightened to seal the arteriotomy. The technical success rate for closing 5F to 21F arteriotomy sites has been authorized for the Perclose PG. There is a chance of distal embolization and arterial infection due to the intraluminal anchor. However, the incidence of vascular problems is generally minimal [25-27]. The goal of this review was to provide an up-to-date comparison between the access site complications of MC versus closure devices after LL revascularization.

In this systematic review, Gouëffic et al. [13] found MC feasible and safe for same-day discharge after LEAD revascularization with a 5F sheath femoral approach. Mainly femoropopliteal lesions were treated (70%), and the technical success was 97%. No re-hospitalization was carried out within 24 hours after discharge. No major cardiovascular event, including death, was observed. In addition, the patients were significantly improved in terms of clinical status and hemodynamics compared to baseline. Similarly, a single-center study by Antonsen et al. [28] assessed the outcomes of same-day-discharge percutaneous coronary interventions with femoral access. They showed that except for one patient who underwent target lesion revascularization as PCI 4 days after the surgery, there were no significant adverse cardiac and cerebral events within 24 hours or 30 days. Two patients were readmitted within 24 hours due to access-site hematomas managed with MC and bedrest regimens in three patients with bleeding/vascular problems. After the treatment, one patient experienced a pseudoaneurysm within 12 hours. They concluded that when patients are carefully selected, same-day discharge following straightforward PCI utilizing femoral access is safe. Future health expenditures may decrease thanks to the plan. Cheng et al. [11] found that VCDs were independently associated with developing fewer hematomas by comparing MC with VCD. When either VCD or MC was used, the incidence of access site stenosis/occlusion was similar. In support of these results, Yi et al. [29] showed that in a previous cohort study included 617 patients (NFACD, n = 308 against MC, n = 309). Time to hemostasis and time to ambulation, the two main endpoints, were significantly shortened in the NFACD group compared to the MC group. There were not many more complications in either group. Additionally, no significant variations were found in the NFACD and MC group’s time to hospital discharge. Percutaneous endovascular procedures were feasible, safe, and effective with very low conversion and complication rates, as shown by Malekzadeh et al. [16]. They also noted that unilateral femoral access was performed in 75.4% of procedures, with a 6-French sheath in 80.7%. Balloon PTA alone was performed in 17.3% and stent
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guiding access demonstrated great effectiveness and safety results. 400 and one patients undergoing diagnostic or interventional cardiovascular procedures were randomly assigned to EXOSEAL or MC closure in the multicenter ECLIPSE study by Wong et al. [19]. No severe problems were reported in this research, and the mean times for hemostasis and ambulation were considerably shorter in the EXOSEAL arm.

Conclusion

This systematic review indicated that VCDs were independently related to forming fewer hematomas when MC and VCD were compared. The occurrence of access site stenosis/occlusion was comparable when either VCD or MC was used. Percutaneous endovascular operations’ feasibility, safety, and efficacy were excellent, with very little conversion and complication. Lesion therapy was technically successful in 98.2% and 100% of cases. About 55.4% of operations used closure devices. Rates of conversion and readmission were, respectively, 1.8% and 0.6%. FS, PG, and EXOSEAL were the three types of VCDs utilized. When patients were undergoing endovascular revascularization of the LL s, FS was recommended as the first-line hemostasis treatment. Technically, VCD interventions were successful for both FS and PG patients. Due to the latter group’s frequent usage of MC and VCD insertion, the difference in success rates between FS and PG can be partially explained. About 87% of FS and 69% of PG patients were still ambulatory after 5 hours. Technically, hemostasis was accomplished with complete success. The main endpoint was met in 91.6% of the patients, with the EXOSEAL arm having a greater success rate. In 0.9% of patients, there were major problems, and 0.7% of those patients had treatment with EXOSEAL versus 1.8% with PG. The combination treatment of two VCDs with routine ultrasonography guiding access showed excellent efficacy and safety results for individuals who underwent the EVT operation.

List of Abbreviations

LEAD Lower extremity arterial disease
MC Manual compression
VCD Vascular closure devices

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