Effectiveness of the vascular closure devices after angiography through the femoral artery.

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SUMMARY

Effectiveness of the vascular closure devices after angiography through the femoral artery.
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Aim of the study. Evaluation of the effectiveness of the vascular closure devices after angiography through the femoral artery.

Objective. 1. To evaluate frequency of different complications after angiography. 2. To evaluate different procedure management of complications.

Material and Methods. A systematic literature review was conducted to identify relevant studies reporting data on various vascular closure devices used nowadays and their complications rate. The data was extracted from the selected papers. The following key words or their combinations were used during searching: vascular closure devices, femoral artery, early discharge, suture mediated vascular closure devices. The search was performed through "PubMed" and was restricted to English language articles, published from 2011 to 2017.

Results. A total 621 of articles were identified after initial search and 15 publications were enrolled in the systematic review in which the vascular closure devices are effective, giving highly patient comfort after the procedure and decrease bleeding rate from the access site.

Conclusion. Vascular closure devices are effective among the patients who undergoing percutaneous intervention procedure. The closure devices (Angioseal, Mynxgrip) are safe and feasible with high successful rate. It achieves fast hemostasis, high comfort level, early discharge compared to traditional manual compression.

Key words. vascular closure devices, femoral artery, early discharge, same day discharge, suture mediated vascular closure devices
Conflict of interest

The authors report no conflicts of interest
Abbreviations

VCD - vascular closure device
MC - manual compression
DD - delayed discharge
AS - Angioseal
SC - Starclose
MTH- mild therapeutic hypothermia
CFA - common femoral artery
PFA – profound femoral artery
SFA - superficial femoral artery
AVF - arteriovenous fistula
AV - arteriovenous
BAV- balloon aortic valvuloplasty
FST - fascia suture technique
BGCs - balloon guide catheters
OHCA - out of hospital cardiac arrest
PCI- percutaneous intervention
**Introduction**

Arterial access is a major site of bleeding complications after cardiovascular invasive procedure.
Vascular closure device-(VCD) is a medical device which is used to close arteries for ex: femoral artery, the place which is usually used after cardiovascular procedure such as angioplasty.
VCD introduced in the early 1990 and it results in fast hemostasis, early discharged post procedure and better healing after closing of the femoral interventional site compared to manual compression (MC) which is used prior to VCD. MC is taking longer to achieve hemostasis by compression at the interventional site up to 30 minutes and it takes longer healing process and delayed discharge (DD).
VCD consist of two types in clinical use include collagen hemostatic puncture closure device and suture mediated devices.
Hemostatic puncture closure device consists of an absorbable plug component and delivery system. The plug has a lactide and glycolide anchor attached to a 24 to 28 mg collagen sponge by an absorbable suture.
Perclose Proglide closure device is achieving femoral access site closure by a non-absorbable suture on the other hand, there is Angioseal closure device which is consist of intravascular anchor that is connected to an extravascular collagen material by a self-tightening absorbable suture. To achieve a haemostasis, the device should be inserted into the access site, and by sandwiching the intravascular anchor and the extravascular collagen plug the haemostasis is achieved [1].
Methodology and Methods

Aim and Objectives: evaluation of the effectiveness of the vascular closure device after angiography through the femoral artery. The research process is established in order to: (1) Evaluate frequency of different complications after angiography (2) Evaluate different procedure management of complications.

Methods:

Literature search strategy

Literature was selected through “PubMed”. In this website, a variety number of articles can be found according the key word/ phrase that should be typed in the search box. The key words were: vascular closure devices, femoral artery, early discharge, same day discharge, suture mediated vascular closure devices. The comprehensive search was restricted to English language articles, published from 2011 to 2017. In the results, it was shown approximately 258 publications (abstracts). If full publications were not accessible without purchasing, they were excluded. 50 articles were analyzed, of which 15 consistent with the subject of this review were qualified. Citations were read and verified. Articles related to the theme were qualified. After all information’s having collected and exclusions that have been made, the gathering information was sufficient and efficient for the research project. One investigator carried out the selection and evaluation of articles.

According to the PRISMA guidelines, we conducted an electronic search using MEDLINE (PubMed) database and google scholar to locate articles concerning effectiveness of vascular closure devices after angiography through the femoral artery (Figure 1).

Inclusion and exclusion criteria

Inclusion criteria for the selection were the following:

- Publications written in English language.

- Studies performed on humans only.
- Articles familiar to topic effectiveness of vascular closure devices after angiography through the femoral artery

- Randomized / non-randomized controlled clinical studies and prospective / retrospective observational studies

**Exclusion criteria for the selection were the following:**

- Abstracts

- Conference proceedings.

- Commentaries.

- Practice guidelines.

- Studies performed on animals
Figure 1 illustrates by a flow chart the process of filtering.

**Figure 1 - PRISMA flow diagram**

- **Records identified through database searching** (n = 621)
- **Additional records identified through other sources** (n = 0)
- **Records after duplicates removed** (n = 300)
- **Records screened** (n = 258)
  - **Records excluded** (n = 35)
  - **Full-text articles assessed for eligibility** (n = 50)
    - **Full-text articles excluded, with reasons** (n = 35)
  - **Studies included in qualitative synthesis** (n = 15)
  - **Studies included in quantitative synthesis (meta-analysis)** (n = 15)
Literature review

vascular closure devices have been used more often in the past two decades after surgical maneuvers such as femoral angiography or percutaneous coronary intervention (PCI), as a better substitute for manual compression by reducing ambulation time and increasing patients' comfort. VCDs were proved to be linked with decreased rate of vascular complications such as: hematoma, pseudoaneurysm, Arteriovenous fistula, bleeding and groin infection [2].

Most VCDs based on technologies involving a suture (Perclose) or a collagen plug (Angio-Seal) [3].

The Perclose VCD deployment is presented in Figure 2 [4].

Figure 2: Suture mediated closure device Perclose Proglide.

VCDs are classified to active vs. passive, foreign body vs. none, extraluminal versus intraluminal, temporary vs. permanent.

In active VCDs- the arteriotomy site is actively approximated by usage of anchor and collagen plug (Angio-Seal), suture (Perclose), or a nitinol clip (Starclose).

In passive VCDs- the arteriotomy is closed passively by a sealant (gel foam) or thrombin, which promotes formation of blood clot.
foreign body versus none, depends if a foreign object such as: suture, clip, sealant, anchor or plug is left inside the body.

Extraluminal (no foreign object left inside the artery) versus intraluminal (foreign object is left inside the artery).

Temporary (foreign object is absorbed) versus permanent (foreign object stays) [5].

Angio-seal is a type of VCD most widely used these days as a different method for MC hemostasis. Although its effectiveness and safety was demonstrated, their possible complications after procedure make their usage controversial in comparison to traditional manual compression methods [6].

The mechanism of Starclose VCD is presented in Figure 3 [7].

Figure 3: Starclose mechanism.

A) The vessel locator wings are placed in the the arteriotomy site; B) The clip delivery tube transports the clip to the arteriotomy; C) The trigger is pushed down and the clip is discharged; D) The tines of the clip holds the tissue and obstruct the arteriotomy

Ideal closure device would avoid use of permanent intravascular implants, reduce trauma to the arteriotomy, have a minimal influence on platelet activation, non-inflammatory, absorbed fast, allow repeated entry at the same site, easy manipulation and result in anticipated
outcomes independently of manipulator technique skills levels and the degree of anticoagulation or platelet inhibition [8].

VCDs have few iatrogenic complications which are practically exclusive to VCDs. Infection complication is rare though extremely serious, and femoral obstruction producing acute limb ischaemia or retroperitoneal haemorrhage [9].

VCD failure is rare, however when it happens, it is related to an increase in risk of vascular complications [10].
Results

Analysis was done in 15 articles that published between 2013 until 2017. In these studies, 10 different VCDs were use: Angioseal, Starclose, Mynxgrip, Femostop, Vascade, Exoseal, Prostar XL, Axera 2, Perclose Proglide, FST. It appears that Angioseal is the most common vascular closure device used for managing treatment after angiography [11][12][13].

Starclose closure device were used 3 times in the analysed articles, as well as Mynxgrip closure device used twice and all the other closure devices were used once (Exoseal, Axera 2, Prostar XL, FST, Vascade).

In this systematic review, the evaluation of different complications after use of vascular closure device can show that the most common complication is vascular access site hematoma [6] as seen in Table 1.

Table 1. Main characteristic of analyzing studies.

<table>
<thead>
<tr>
<th>Researches</th>
<th>Type of study</th>
<th>Number of patients</th>
<th>Complications</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeni H et al, 2016 [11]</td>
<td>Prospective</td>
<td>620 patients</td>
<td>Hematoma, Pseudoaneurysm, Arteriovenous fistula</td>
<td>No significant difference between VCDs and MC</td>
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<tr>
<td></td>
<td></td>
<td>210: with AS</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>196: with SC</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>214: with MC</td>
<td></td>
<td></td>
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<tr>
<td>Wu PJ et al, 2015 [6]</td>
<td>Prospective</td>
<td>130 patients:</td>
<td>MC group without complication. Hematoma in 5 patients</td>
<td>There is no significant difference in complication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>65 Angioseal.</td>
<td></td>
<td>rate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>65 MC.</td>
<td></td>
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<tr>
<td>Hermiller JB et al, 2015 [14]</td>
<td>Prospective</td>
<td>420 patients:</td>
<td>Access site bleeding: 1 patient with Vascade use.</td>
<td>In this study, the Vascade VCD was safe compared to</td>
</tr>
<tr>
<td></td>
<td></td>
<td>278 with Vascade</td>
<td>10 patients with MC. Hematoma &gt;6 cm: 1 patient with</td>
<td>MC.</td>
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<tr>
<td></td>
<td></td>
<td>VCD.</td>
<td>Vascade.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>142 with MC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leclercq F et al, 2015 [15]</td>
<td>Prospective</td>
<td>180 patients:</td>
<td>Pseudoaneurysm &amp; AV fistula:</td>
<td>In this study, the use of VCD after</td>
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<tr>
<td>Study Authors</td>
<td>Study Type</td>
<td>Group 1</td>
<td>Group 2</td>
<td>Complication</td>
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</tr>
<tr>
<td>Christ M et al, 2015 [12]</td>
<td>Prospective</td>
<td>75 patients with Angioseal. 105 patients with MC or FemoStop.</td>
<td>5 patients in group 1(VCD) 2 patients in group 2 (MC).</td>
<td>BAV (balloon aortic valvuloplasty) Increase the complication rate compared to MC.</td>
</tr>
<tr>
<td>Shah VA et al, 2016 [13]</td>
<td>Retrospective</td>
<td>26 patients with Angioseal 16 patients with MTH. 10 patients without MTH.</td>
<td>Hemoglobin relevant bleeding (5 patient) with MTH. Arterial occlusion (1 patient) with MTH.</td>
<td>Angioseal appear to be safe in patients who treated without MTH (mild therapeutic hypothermia)</td>
</tr>
<tr>
<td>Taha A et al, 2013 [8]</td>
<td>Retrospective</td>
<td>472 patients with different VCDs, the main VCD used was Angioseal. (in 443 patients)</td>
<td>1 patient with Groin hematoma and pseudoaneurysm. 1 patient with only groin hematoma.</td>
<td>In this study, very low rate of complication with 0.4%.</td>
</tr>
<tr>
<td>Hutchings D et al, 2016 [16]</td>
<td>Retrospective</td>
<td>53 patients with MynxGrip</td>
<td>Small hematoma (less than 3 cm in diameter) In 1 patient</td>
<td>The Mynx VCD is highly successful device with</td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Patients/Technique</td>
<td>Details</td>
<td>Results</td>
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<tr>
<td>Grandhi R et al, 2015 [17]</td>
<td>Prospective</td>
<td>98 patients with Exoseal</td>
<td>Minor vessel stenosis, (average of the stenosis 21%) in 7 patients.</td>
<td>Exoseal appear to be VCD with high successful rate</td>
</tr>
<tr>
<td>Spiliopoulos S et al, 2016 [18]</td>
<td>Prospective</td>
<td>30 patients with Starclose</td>
<td>Minor complication: 2 patients with small superficial hematoma. No major complications.</td>
<td>In this prospective study, there is high successful rate with 100%</td>
</tr>
<tr>
<td>Chakfé N et al, 2015 [19]</td>
<td>Prospective</td>
<td>84 patients with 154 percutaneous access with Prostar XL</td>
<td>Femoral cutdown in order to achieve adequate hemostasis in 10 cases. During 1 year follow up 4 late complications were seen: 2 cases significant CFA stenosis. 1 false aneurysm. 1 occlusion of the endograft limb.</td>
<td>The Prostar XL VCD is safe and feasible with 93.5% successful rate</td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Patients</td>
<td>Access Site</td>
<td>Complications</td>
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</tr>
<tr>
<td>Sartorius B et al, 2017 [21]</td>
<td>Prospective</td>
<td>95 patients with Angioseal. The puncture site: 39 patients CFA (Common femoral artery). 37 patients at Femoral bifurcation. 19 patients at PFA (profound femoral artery) or SFA (superficial femoral artery).</td>
<td>Bleeding consisting small hematoma in 53% of overall patients. CFA: 61.5% Femoral bifurcation: 41% PFA and SFA: 58%. Complicated access site bleeding 2.1% AV-dissection 2.1% Aneurysm 1.1%</td>
<td>There is no significant difference in bleeding rate in different access site.</td>
</tr>
<tr>
<td>Grandhi R et al, 2015 [22]</td>
<td>Prospective</td>
<td>13 patients with AXERA 2</td>
<td>Minor complication: Groin hematoma in 1 patient. Major complication: Dissection and femoral artery occlusion in 2 patients.</td>
<td>In this study of small series used AXERA 2 VCD there are serious complication rate.</td>
</tr>
<tr>
<td>Hamid T et al, 2015 [23]</td>
<td>Prospective</td>
<td>100 patients with Perclose VCD.</td>
<td>Pseudoaneurysm in 2 patients. Mild access site oozing in 5 patients (requiring manual compression).</td>
<td>Perclose VCD appear to be safe and effective with minor risk of vascular complications.</td>
</tr>
</tbody>
</table>

The effectiveness of different closure devices and manual compression is presented in table 1. The complications rate is different in each study and it shows: In the study performed by Yeni H et al.[11] 620 patients were selected randomly, 210 patients were treated with Angioseal, 196 with Starclose and the rest of the patients (214)
with Manual compression. It shows that there were not any major complications in different types of procedures but there are minor complications, which include Hematoma in different sizes from the smallest <3cm in diameter up to the largest size >6 cm in diameter.

Hematoma <3 cm: 89 patients with AS, 76 patients with SC and 83 patients with MC.
Hematoma 3-6 cm: 25 patients with AS, 23 patients with SC and 36 patients with MC.
Hematoma >6 cm: 11 patients with AS, 10 patients with SC and 14 patients with MC.

Pseudoaneurysm in AS group (10 patients), in SC group (6 patients), and MC group (10 patients). Arteriovenous fistula in AS group (1 patient), SC group (4 patients), MC group (2 patients). There was not difference in the complications rate between VCD and MC.

Wu PJ et al. [6] carried out a study in 2015 showing the comparison between MC and VCD Angioseal. The total number of patients participated in this study was 130, in which 65 patients treated with Angioseal and 65 patients treated with MC. In manual compression group, there weren't any complications after procedure but in the Angioseal group there were 5 patients who experienced complications: 3 patients had oozing after catheter removal and 2 other patients got hematoma. In this study, there is no statistically significant difference in the rate of complications between MC and VCD groups.

On the other hand, Hermiller JB et al. [14] also compared between VCD and MC. In this study, they used a new VCD which is called Vascade. A total of 420 patients were participated, in which 278 patients treated with Vascade closure device and 142 patients treated by manual compression. There weren’t any major complications in both groups, but there were minor complications. 3 patients experienced complications in Vascade group and 10 patients in MC group. In MC group 10 patients had related interventional site bleeding which required more than 30 minutes to achieve hemostasis. In Vascade group 1 related interventional site bleeding, 1 patient with related hematoma >6cm, 1 patient with related access site neuropathy in the lower extremity of the interventional side which is not requiring any surgical procedure to repair it.

In this trial, the VCD Vascade is safe and effective compared to MC.

In a prospective study which made in France by Leclerce F et al, 2015[15] they use to treat either with MC and Angioseal VCD after BAV (balloon aortic valvuloplasty) procedure. 180 consecutive patients who receive BAV, participated in the analysis. 75 patients were treated with Angioseal closure device and 105 patients were treated with MC or mechanical groin
compression (FemoStop). Overall 180 patients didn’t get heparin during the procedure. Different complications were shown in this article: Arteriovenous Fistula and Pseudoaneurysm had in 7 patients, 5 patients in Angioseal group, 2 patients in MC group. Groin Infection in 3 patients with Angioseal group. Acute limb ischemia in 6 patients, 5 patients in Angioseal group and 1 patient in MC group. Dissection in 4 patients, 2 patients in angioseal group and 2 patients in MC group. Major bleeding appears in 16 patients, 11 patients in Angioseal group and 5 patients in MC group. More than 1 pack RBC transfusion in 11 patients, 9 patients in Angioseal group and 2 patients in MC group. 1 patient from Angioseal group got retroperitoneal hematoma. In this study, the comparison between VCD and MC may show that the use of VCD after BAV procedure may increase the complication rate compare to MC.

Angioseal closure device is the most common device in the analyzed articles. The mechanism of the device is seen in figure 4: [24].

Figure 2: Angioseal mechanism.

A. Locate the artery  B. Set the anchor  C. Seal the puncture

Angioseal closure device in some articles can show high effectivity with low rate of complications and in some articles high rate of complications.

26 patients were treated with Angioseal closure device after OHCA (out-of hospital cardiac arrest) in the study of Christ M et al, 2015 [12].
16 patients out of 26 patients treated with MTH (mild therapeutic hypothermia), whereas 10 patients without MTH. Totally 6 patients got complications, those 6 patients were treated with MTH. The complications are: Hemoglobin relevant bleeding in 5 patients. 3 patients were treated with transfusion, 1 patient with conservative therapy and 1 patient treated with transfusion + operation. 1 patient had arterial occlusion which was treated with operation.

This study can show that the use of Angioseal closure device without MTH is safe and effective.

In other retrospective study which published at 2016 by Shah VA et al.[13] a total of 472 patients who received mechanical thrombectomy due to acute ischemic stroke with BGCs (balloon guide catheters). 443 patients (93.9%) out of 472 were treated with Angioseal closure device, the rest 29 patients treated with other closure devices or MC. 2 patients get complicated: 1 patient with groin hematoma and pseudoaneurysm and 1 patient with groin hematoma. This study shows the effectiveness of VCDs with very low complications rate.

The Mynxgrip closure device used in analyzed 2 retrospective studies performed by Taha A et al. [8] and Hutchings D et al. [16]. Both of the studies show that the Mynxgrip closure device has high successful rate with very mild complication rate. In Taha A et al.[8] participated 53 patients in which only one patient got complicated with mild hematoma compared to Hutchings D et al.[16] study where 432 patients participated, there were 3.2% complicated patients with hematoma. Mynxgrip closure device appear to be safe and feasible closure device.

There are different types of vascular closure devices which were used in the analyzed articles, some of them have high success rate. For example, in Grandhi R et al.[17] study which 98 patients were participated with Exoseal closure device, 7 patients got complicated with minor vessel stenosis, stenosis size was <21%. The device Exoseal has high successful rate.

A total of 30 obese patients were treated with Starclose closure device in Spiliopoulos S et al. [18] study. This analyzed study shows 100% of successful with Starclose closure device without any complications.
Another study that published at 2015 in France by Chakfé N et al.[19] shows the success rate of the use of Prostar XL closure device. 84 patients participated with 154 percutaneous accesses.

The complication: In 10 cases, they performed femoral cutdown in order to achieve adequate hemostasis. During 1 year follow up, 4 late complications occure. CFA (Common femoral artery) stenosis in 2 cases, 1 false aneurysm and 1 occlusion of the endograft limb. The Prostar closure device appear to be safe and feasible with 93.5% successful rate.

On the other hand, in the study of Larzon T et al.[20] they used Prostar closure device versus FST (fascia suture technique). 99 randomized patients were treated either with Prostar or FST. 51 patients with Prostar closure device and 48 with FST. The complications were: Peri-operative: bleeding in 2 FST patients and 9 Prostar patients. Post-operative: bleeding in 2 FST patients, thrombosis in 2 FST patients, stenosis in 1 Prostar patient. In this randomized trial, there is no difference in complication rate between Prostar and FST.

Sartorius B et al, 2017 [21] analyzed 3 different access sites: common femoral artery, femoral bifurcation and superficial or deep femoral artery. 95 patients underwent the procedure with Angioseal closure device. The outcome found that there is no significant difference in complications rate at different access site.

Another small series study that published at 2015 by Grandhi R et al. [22], there participated 13 patients with Axera 2 closure device. In this study 3 patients get complicated. 1 patient with groin hematoma and 2 patients had dissection plus femoral artery occlusion. In this small trial were serious complications but this closure device should be further evaluated.

Another type of closure device called Perclose was used in the study performed by Hamid T et al.[23], 100 consecutive patients were participated with Perclose, suture mediated closure device. Mild complications were observed, pseudoaneurysm in 2 patients and mild access site oozing which required manual compression in 5 patients. Perclose is safe and effective with minor risk of vascular complications.
VCDs has advantages such as: patient comfort, early ambulation, fast in achieving hemostasis, early discharge. On the other hand, it has also disadvantages which is characterized by complications during or post procedure. The complications and their treatment is seen in figure 5 [25].

Figure 5: Complications and their treatment.


**Discussion**

Analysis of different studies show, that there are different types of vascular closure devices for achieving proper hemostasis after cardiovascular procedure with angiography. The devices are classified as active and passive. Active vascular closure device be made up out of collagen based (Angioseal), suture based (Perclose Proglide), or clip based (Starclose). Passive vascular closure devices be made up out of hemostatic pads (Chitoseal) and devices which compressed (Femostop) [26].

Hemostasis can be achieved either by VCDs or MC. Angiography allows to get a proper view of the anatomical site of access [27]. Angiography used to visualize the lumen of the blood vessels. In case of complications the angiography used to see the exact point of the complication such as thromb formation inside the lumen or arterial dissection after interventional procedure.

Recently VCDs are more often use than MC. Its main advantages are: achieving fast hemostasis, early discharge and ambulation for comfort of the patient that’s shows the effectivity of the device compared to manual compression. In most of the studies it also shows less complication rates [27].

In retrospective study which have done at 1470 places across USA there were included 2,056,585 patients who underwent transfemoral percutaneous intervention and treated either with vascular closure device or with manual compression. There was low rate of complications with vascular closure device compared to MC. The use of VCDs decrease the risk of access site bleeding by 0.36% [28].

Some studies reported no significant difference in the complication rate between VCD and traditional manual compression, but the use of VCD was more convenient for patients than MC [11] [6].

The most common complication of the access site is hematoma, usually its small hematoma that doesn’t need any further treatment, sometimes large hematoma which needs blood transfusion. Some studies show the effectiveness of VCDs (Exoseal, Mynxgrip, Starclose, Angioseal) with safety and successful with very low complication rate such as small hematoma in 3.2% of patients out of 432, or 2 cases with hematoma in the study of 472 patients [13] [8] [16] [17] [18].
Conclusion

Vascular closure devices are effective among the patients who undergoing percutaneous intervention procedure. The closure devices (Angioseal, Mynxgrip) are safe and feasible with high successful rate. It achieves fast hemostasis, high comfort level, early discharge compared to traditional manual compression.
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