Early sheath removal after percutaneous coronary intervention using Assiut Femoral Compression Device is feasible and safe. Results of a randomized controlled trial

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Hemostasis;
Vascular complications

Abstract  Objective:  This study was performed to evaluate the feasibility and safety of early sheath removal after percutaneous coronary intervention (PCI) using a locally designed Assiut Femoral Compression Device (AFCD2) vs. manual compression (MC).

Background:  Due to antithrombotic therapy before, during, and after PCI, the arterial femoral sheath is generally not removed early after PCI.

Patients and methods:  This was a randomized, controlled trial. We enrolled all patients undergoing PCI at Assiut University Hospitals from September, 2013 to December, 2013. At the end of PCI, the arterial hemostasis method was randomly assigned 1:1 to AFCD2 vs. MC. The sheaths were removed 2 h after PCI, instead of conventional 6 h, in the AFCD2 arm.

Results:  The trial assigned 100 patients (mean age 57 ± 9 years, 75% men) to AFCD2 (n = 50) vs. MC (n = 50). Both groups were comparable regarding baseline characteristics. Concerning the primary effectiveness end point, there was significantly shorter mean time-to-ambulation with AFCD2 (8.2 ± 1.42 h) vs. MC (12.02 ± 0.22 h; p = <0.001). This was directly reflected on shorter time for hospital discharge eligibility in AFCD2 (11 ± 1 h) vs. MC (15 ± 1 h; p = <0.001). As regards safety, none of our research population experienced major adverse events. The use of AFCD2 was associated with similar occurrence of minor complications, mainly ecchymosis and oozing, compared with MC.
1. Introduction

Percutaneous coronary intervention (PCI) is inevitably associated with the risk of access site complications as high as 16%, especially with the aggressive antithrombotic treatment required for stenting. Although trans-radial coronary angioplasty has been shown to be safe and to decrease the rate of access site complications, it has not gained wide popularity and most of the procedures are currently performed via the femoral route at Assiut University Hospitals (AUH). After a transfemoral PCI procedure, the arterial sheath is usually removed after 4–6 h in order to wait for heparin reversal. Then, a period of bed rest of a minimum of 6 h is advised, and this period of immobilization makes the procedure more uncomfortable for the patient. Assiut Femoral Compression Device (AFCD1) is a locally designed femoral compression system with proven safety and efficacy compared to manual compression (MC) on 206 patients undergoing coronary angiography.

At AUH, we use only conventional MC to achieve hemostasis in high risk patients undergoing PCI. After our primary report, we collaborated with Mechatronic Engineering Department, to develop AFCD2 with improved quality and efficacy.

At this second report, we evaluated the efficacy and safety of early sheath removal after PCI using AFCD2 compared to MC in a randomized controlled trial.

2. Methods

2.1. Trial design and patient selection

We performed a randomized, controlled, nonblinded trial with parallel assignment and 1:1 allocation, at the catheterization laboratory of Assiut University Hospitals. Patients between 18 and 85 years of age, scheduled to undergo an elective PCI via arterial puncture of common femoral artery were eligible for enrollment in the study. Elective PCI was defined as any coronary revascularization in a low-risk patient who presents to the facility for a planned PCI or for a coronary angiogram followed by ad hoc PCI. Patients were excluded from the trial if the patient has any procedural complication: included prolonged chest pain, transient closure, no-flow or slow-flow phenomenon, hemodynamic instability, persistent electrocardiographic changes, side-branch occlusion of >1.5 mm, or an angiographically suboptimal result, arterial access other than the right or left femoral artery, vascular perforation, thrombosis during procedure, patients with high risk of puncture site complications as: bleeding diathesis, international normalized ratio >1.5, recent thrombolysis, low platelet count, lower limb atherosclerosis, previous iliofemoral artery surgery or any peripheral vascular surgery, previous femoral artery complication from angiography, and uncontrolled hypertension at time of procedure (>180/>110).

2.2. Study groups and protocol

From September, 2013 to December, 2013, 150 patients who underwent elective PCI via arterial puncture of common femoral artery were assessed for eligibility. 50 patients were excluded (Fig. 1). 100 patients were randomized into two groups with 1:1 allocation concealment using daily numbered, sealed envelopes: 50 patients used AFCD2 and 50 patients used MC for arterial hemostasis. The trial protocol was reviewed and approved by the institutional review committee, and all patients granted their informed consent to be included in the trial. The demographic and clinical data were collected using a standardized “procedural datasheet”.

2.2.1. PCI procedure

PCI was performed using femoral approach in all our patients using 6 F guiding catheters. All patients had detailed history and clinical examination to exclude bleeding diathesis with complete blood picture before procedure. All patients were pre-treated with aspirin 150 mg and clopidogrel 600 mg orally before the procedure. The anticoagulation protocol included intravenous heparin bolus 10,000 U. No activated clotting time (ACT) was measured during or after intervention. Glycoprotein IIb/IIIa inhibitors were used according to the operator discretion. Stent implantation was at the discretion of the primary operator. None of our patients received protamine sulfate for reversal of anticoagulation.

2.2.2. Vascular access management

The intra-arterial sheaths were removed 6 h after PCI in the MC group according to the standard local protocols. However for the AFCD2 group, the sheaths were removed 2 h after PCI instead of conventional 6 h. To standardize compression times, AFCD2 was applied to patient and complete femoral artery compression was applied for 5 min, followed by a gradual release of pressure till distal pulse is palpated. Each patient received a minimum of 13 min of compression, with further compression applied only if full hemostasis had not been achieved at that point with maximum of 30 min.

2.2.3. Post-procedure care

Immediately after achieving hemostasis, arterial access site was carefully inspected for evidence of hematoma formation or other vascular problems. Then a pressure dressing using bandage was applied to maintain hemostasis. After PCI, patients were observed in the department ward by staff that is well trained to manage post-PCI complications. Post-interventional therapy included 150 mg/day of aspirin and 75 mg/day of

Conclusion: Our results indicate that AFCD2 is a simple and effective alternative to MC for hemostasis following PCI. Early sheath removal 2 h post PCI is feasible, safe, and improves the patient’s comfort.

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clopidogrel for 1 month in case of a bare-metal stent and for 1 year in case of a drug eluting stent.

2.2.4. Ambulation
Uniform verbal instructions of immobility were given to each patient with bed rest for 6 h after the procedure. All dressings were removed and all patients were strongly encouraged to ambulate 6 h after sheath removal. Vital sign check, vascular access site, and distal vascular bed examination by ultrasonography were done immediately after ambulation for a comprehensive analysis before discharge.

2.2.5. Pre-discharge evaluation
Suitability for discharge required freedom from symptoms, absence of electrocardiogram changes, absence of puncture site abnormalities and successful ambulation. Written instructions and oral explanation of all possible events were given to all patients. Before discharge, patients were instructed on how to achieve hemostasis by local pressure for puncture-related bleeding. All patients received pre-discharge counseling on diet and lifestyle modification. The management of medication compliance was repeatedly highlighted by the interventionalist and residents directly involved in the patient care. With successful ambulation, patients were instructed to climb only 1 flight of stairs and not to lift heavy objects for 3 days after the procedure.

2.3. Device description

The first version of Assiut Femoral Compression Device (AFCD1) has been described in detail in our primary report. Dissimilarity between AFCD1 and the second version AFCD2 used in this trial is presented in Fig. 2: (a) The material used for the arch is Galvanized Steel Sheet which is more powerful than

![Figure 1](Image 1)

Flow of patients through the trial. AFCD = Assiut Femoral Compression Device.

![Figure 2](Image 2)

Assiut Femoral Compression Device 2 Design. (1) White textile belt (2 m) with adhesive stickers on both sides, (2) Galvanized Steel Sheet, (3) Metallic screw (19 cm) with more snails and (4) Wood with flat surface pressure dome.
Plexiglass used in AFCD1, (b) More potent pressure dome that is made of wood with flat surface rather than plexiglass with cone shaped surface in AFCD1, (c) Longer metallic screw: 19 cm (instead of 15 cm in AFCD1) with more snails for rapid screw movements, (d) Longer and stronger belt made of 2 m (instead of 1.5 m in AFCD1) of white strong textile with adhesive stickers on both sides (instead of black fabric with plastic fastener in AFCD1) and no elongation kit (Fig. 2).

Our AFCD total cost is around 15 $ once. It can be reused with discard of the sterile disposable gloves positioned over the dome.

2.4. Study end points

2.4.1. The primary efficacy end point of the study was

1- Time-to-ambulation (TTA), measured in hours.
TTA was measured from the time the introducer sheath was removed to the time of ambulation. Ambulation was defined as patient standing and walking at least 6 m (20 feet) without re-bleeding or significant oozing requiring manual compression.

2- Time the patient is deemed eligible for hospital discharge

Measured from the time of access site closure to the time when the patient was judged by the attending physician to be ready for discharge from the hospital. Hospital discharge decision was at the discretion of the primary operator and the attending physician irrespective of the patient’s assignment to one of the hemostasis techniques.

2.4.2. The secondary efficacy end point of the study was

1. Time-To-Hemostasis (TTH), measured in minutes
TTH was measured from the time the introducer sheath was removed to the time hemostasis was achieved. Hemostasis was defined as no or minimal subcutaneous oozing and the absence of expanding or developing hematoma.10 The entry site was revised for signs of active bleeding (acknowledged as failure of closure strategy). In case of failure, the compression was restored manually for additional 2–5 min. and observed thereafter until bleeding stops.

2. Device success

This was defined as easy application of the device with good fixation and stability and achieving final hemostasis. Time for device deployment was measured from the beginning to position the belt under the patient till the removal of the femoral sheath. Device stability was defined as the absence of tilt and/or mobility after application of the device on top of the patient groin. Assessment of the device application was performed using a questionnaire with a scale of three grades; “Easy”, “Difficult” and “Requires Improvement”. Assessment of stability and fixation of the device was performed on a scale defined as “Very Good”, “Good” and “Bad”.

3. Procedure success

This was defined as hemostasis achieved by the assigned method, without the occurrence of a closure-related major adverse event (MAE). MAE was defined as symptomatic bleeding associated with hemoglobin drop ≥ 5 g/dL requiring blood transfusion, fatal bleeding that directly results in death, a pseudoaneurysm or arteriovenous fistula, distal arterial embolism, infections requiring administration of IV antibiotics or debridement, and the need for vascular surgery.10,11

2.4.3. The primary safety end point was defined as the absence of MAE on discharge

2.4.4.1. The secondary safety end points included.

1. Minor complications
Any oozing (leakage of blood from the puncture site requiring digital pressure), ecchymosis (bleeding into subcutaneous tissue planes causing bluish-purple discoloration > 4 cm in diameter), hematoma (non pulsatile mass ≥ 1 cm in diameter), and infections treatable with oral antibiotics.11,12

2. Patient discomfort

Patients were asked about the intensity of pain during the hemostasis procedure. Patient discomfort was assessed based on a short form of the McGill Pain Questionnaire using a Present Pain Intensity (PPI) scale that rated pain from 0 (no pain) to 5 (excruciating).11

3. Vasovagal manifestations (sweating, bradycardia, nausea and vomiting): were recorded

2.5. Sample size calculation

The trial was designed to have a 95% power to detect a 5.5 h difference in time-to-ambulation (TTA) with an overall type I error rate of 0.05 (two sided). Sample size was calculated to be at least 50 patients in each arm. Mean TTA was estimated to be 8 h in the AFCD2 group and 12 h in the MC group with a common standard deviation (sigma) of 5.5 h.13

2.6. Randomization process

At the completion of PCI, patients were randomly assigned to AFCD2 vs. MC, using sealed envelopes in a 1:1 allocation sequence. The assignment was based on simple randomization of procedure on daily basis. The enrollment period of the trial lasted 3 months, and the patient clinical follow-up was 24 h.
post procedure. Data were collected by resident attending the PCI, and were managed and analyzed by a blinded statistician. If all the criteria for entry in the trial were satisfied, an envelope was opened to randomly assign the patient to AFCD2 or MC.

2.7. Statistical analysis

Categorical data were presented as counts and proportions (percentages) and compared by Pearson chi-square analysis or Fischer’s exact test if the expected cell count for a 2×2 table was <5. Normal distribution of continuous data was tested using a Kolmogorov–Smirnov test. Continuous and normally distributed data are presented as mean ± standard deviation and were compared by two-tailed unpaired t-test. These comparisons were performed using the SPSS version 16.0 software package (SPSS Inc., Chicago, IL), and a p value of ≤0.05 was considered to be significant.

3. Results

3.1. Patient characteristics

The baseline demographic and clinical characteristics of the 2 trial groups are summarized in Table 1. The two groups were comparable with no significant differences in baseline and procedural characteristics. Approximately three-quarters of patients in each group were men. Obese patients with a body mass index >30 kg/m² tend to be higher in the AFCD2 group (36%) compared to 28% of patients in the MC groups (p = NS). Procedural variables are shown in Table 1 with no difference in use of GP2B/3A, neither number nor type of stents used.

3.2. Analysis of efficacy

Concerning the primary effectiveness end point, the mean TTA was significantly shorter in the AFCD2 group compared to the MC group with a mean difference of around 4 h (8.2 ± 1.42 vs. 12.02 ± 0.22 h; p = <0.001). This was directly reflected on shorter time for hospital discharge eligibility in the AFCD2 group (Fig. 3). On the other hand, the mean TTH was longer in the AFCD2 group compared to the MC group (27.3 ± 4.3 vs. 22.3 ± 5.4 min; p = <0.001). However, the mean difference was only 5 min. The duration of hospital stay did not differ between groups (Table 2).

The procedure success was observed in 48 (96%) patients of the AFCD2 group and all patients of the MC group. None of our research population experienced a MAE.

The device success was observed in 48 patients of the AFCD2 group with mean device deployment time of

<table>
<thead>
<tr>
<th>Variable</th>
<th>MC (N = 50)</th>
<th>AFCD2 (N = 50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>56 ± 10</td>
<td>57 ± 9</td>
<td>NS</td>
</tr>
<tr>
<td>Male gender n (%)</td>
<td>38 (76%)</td>
<td>37 (74%)</td>
<td>NS</td>
</tr>
<tr>
<td>Smoking n (%)</td>
<td>31 (62%)</td>
<td>37 (74%)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension n (%)</td>
<td>21 (42%)</td>
<td>23 (46%)</td>
<td>NS</td>
</tr>
<tr>
<td>Dyslipidemia n (%)</td>
<td>30 (60%)</td>
<td>31 (62%)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus n (%)</td>
<td>22 (44%)</td>
<td>16 (32%)</td>
<td>NS</td>
</tr>
<tr>
<td>PAD</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic renal impairment</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>4 (8%)</td>
<td>1 (2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>3 (6%)</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80 ± 13</td>
<td>77 ± 12</td>
<td>NS</td>
</tr>
<tr>
<td>Height (m)</td>
<td>165 ± 9</td>
<td>164 ± 7</td>
<td>NS</td>
</tr>
<tr>
<td>Body mass index n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From 18.5 to 25 kg/m²</td>
<td>12 (24%)</td>
<td>11 (22%)</td>
<td>NS</td>
</tr>
<tr>
<td>From 25 to 30 kg/m²</td>
<td>24 (48%)</td>
<td>21 (42%)</td>
<td>NS</td>
</tr>
<tr>
<td>&gt;30 kg/m²</td>
<td>14 (28%)</td>
<td>18 (36%)</td>
<td>NS</td>
</tr>
<tr>
<td>Previous femoral puncture</td>
<td>17 (34%)</td>
<td>13 (26%)</td>
<td>NS</td>
</tr>
<tr>
<td>Prothrombin concentration %</td>
<td>94 ± 7</td>
<td>92 ± 10</td>
<td>NS</td>
</tr>
<tr>
<td>INR</td>
<td>1 ± 0.1</td>
<td>1 ± 0.1</td>
<td>NS</td>
</tr>
<tr>
<td>Hemoglobin (mg/dl)</td>
<td>12 ± 2</td>
<td>12 ± 2</td>
<td>NS</td>
</tr>
<tr>
<td>Platelets (u/L)</td>
<td>272 ± 87</td>
<td>261 ± 66</td>
<td>NS</td>
</tr>
<tr>
<td>INR impaired n (%)</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Warfarin before hospital admission</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic aspirin therapy</td>
<td>47 (94%)</td>
<td>50 (100%)</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic clopidogrel therapy</td>
<td>22 (44%)</td>
<td>28 (56%)</td>
<td>NS</td>
</tr>
<tr>
<td>Number of diseased vessels</td>
<td>1.6 ± 0.5</td>
<td>1.6 ± 0.5</td>
<td>NS</td>
</tr>
<tr>
<td>Number of stents</td>
<td>1.6 ± 0.5</td>
<td>1.6 ± 0.5</td>
<td>NS</td>
</tr>
<tr>
<td>Number of DES</td>
<td>22 (44.9%)</td>
<td>17 (35.4%)</td>
<td>NS</td>
</tr>
<tr>
<td>Need GP 2hb/3a</td>
<td>0</td>
<td>1 (2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Complicated procedure</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard deviation, number (%) of patients. MC = manual compression; AFCD = Assiut Femoral Compression Device; IHD = ischemic heart disease; NS = not significant; PAD = peripheral arterial disease; PCI = percutaneous coronary intervention; IND = international normalized ration; DES = drug eluting stents; GP 2hb/3a = glycoprotein 2hb/3a inhibitors.
3 ± 2 min. Easy device application was reported in 40 patients (80%) while device fixation was very good in 47 patients (94%). Only two patients experienced device failure; these patients crossed over to MC without further vascular complication because of a device failure. In the first case, failure was due to the development of vasovagal reaction related to pain so the device was removed and MC was used to complete hemostasis. In the second case, the device was applied for the maximum time but hemostasis was not completed and we needed MC for another 10 min without further vascular complication.

3.3. Regarding safety
No complication was new or unanticipated, and the type of complication did not differ between the 2 trial arms. None of our study population reported any MAE.

Some secondary adverse events occurred in each study group, without statistically significant differences among the groups. The incidence of minor complications was comparable in both groups (Table 2). These minor complications were mainly ecchymosis and oozing in both groups. Large hematoma >5 cm was noted in 1 pts. (1.8%) in the MC arm vs. non in the AFCD2 arm ($p = 0.3$). Size of hematoma in the MC arm was bigger compared to the AFCD2 arm; however this difference was not statistically significant (Table 2).

3.4. Regarding pain
The tolerance of the hemostasis procedure was good with both techniques without significant difference between the two groups. The scores of pain assessment scale for each group are presented in Fig. 4. Patients did not report a significant difference in the pain score in the AFCD2 group compared with the MC group ($p = NS$). The incidence of vagal episodes was slightly higher in the AFCD2 arm compared to the MC arm (12% vs. 2%; $p = 0.056$). However, all of these episodes resolved spontaneously without medications but one patient in each group needed CCU admission for severe pain and vagal collapse (Table 2).

4. Discussion
In this randomized controlled trial of a new locally developed Femoral Compression Device, we could demonstrate a high procedural success rate, with a significantly 4 h shorter time-to-ambulation and time to hospital discharge eligibility after

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MC (N = 50)</th>
<th>AFCD2 (N = 50)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to ambulation (h)</td>
<td>12.02 ± 0.22</td>
<td>8.2 ± 1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Eligibility for hospital discharge (h)</td>
<td>15 ± 1</td>
<td>11 ± 1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time to Hemostasis (min)</td>
<td>22.3 ± 5.4</td>
<td>27.3 ± 4.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospital discharge (h)</td>
<td>23 ± 9</td>
<td>23 ± 5</td>
<td>0.96</td>
</tr>
<tr>
<td>Vagal episodes</td>
<td>1 (2%)</td>
<td>6 (12%)</td>
<td>0.036</td>
</tr>
<tr>
<td>Hematoma size &lt; 5 cm</td>
<td>7 (14%)</td>
<td>4 (8%)</td>
<td>0.33</td>
</tr>
<tr>
<td>Hematoma 1 cm</td>
<td>1 (2%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hematoma 2 cm</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Hematoma 3 cm</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
<td></td>
</tr>
<tr>
<td>Hematoma 4 cm</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Hematoma &gt; 5 cm/major bleeding</td>
<td>1 (2%)</td>
<td>0</td>
<td>0.31</td>
</tr>
<tr>
<td>Ecchymosis</td>
<td>16 (32%)</td>
<td>14 (28%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Oozing</td>
<td>2 (4%)</td>
<td>5 (10%)</td>
<td>0.24</td>
</tr>
<tr>
<td>Peripheral ischemia</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Retroperitoneal hematoma</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Pseudo aneurysm</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>AV fistulae/bruit</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Site infection</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Major adverse events</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard deviation, number (%) of patients or median. MC = manual compression; AFCD2 = Assiut Femoral Compression Device; AV = arterio-venous; NS = not significant.
PCI in the AFCD2 group. There was no significant difference in the complication rate between the study groups. None of our trial population reported any MAE, confirming that AFCD2 is a simple, safe and effective alternative to MC for hemostasis 2 h. following PCI.

Few large studies have compared vascular access strategies in patients undergoing elective coronary procedures. Several devices have been developed to aid in the closure of the femoral arteriotomy, including, extravascular plug devices (VasoSeal, AngioSeal, ExoSeal), percutaneous suture closure devices (Perclose, StarClose), and mechanical compression devices. Mechanical compression devices most commonly used are the C-clamp or Compressor (Advanced Vascular Dynamics, Portland, OR) and pneumatic Femostop device (Radi Medical Systems, Uppsala, Sweden). All these devices including our AFCD provide the application of constant pressure while maintaining limb perfusion monitored by only one nurse and free up the operator. However, increased cost per patient of both Femostop (75–150 $) and C-clamp (50–100 $) compared with MC was identified as a disadvantage. Our AFCD total cost is around 15 $ once.

The C-clamp and Femostop devices were compared to MC in a number of studies, which generally reported equal efficacy with no significant differences regarding femoral vascular complication rates.

Regarding efficacy of AFCD2 by measuring TTA there was a great decrease (about 4 h) in the AFCD2 group in contrast to the MC group (8.20 ± 1.42 h vs. 12.02 ± 0.22 h, p < 0.001). This was the main driving factor for 4 h reduction in time for hospital discharge eligibility in the AFCD2 group which allows early movement of patients, and reduces patient discomfort by long bed rest following PCI. Our findings are in accordance with Jaspers et al. who also reported a 4 h reduction in TTA after Femostop application but immediately after PCI in 339 patients. Also Wong et al. reported a 3.7 h reduction in TTA in the ExoSeal closure device group compared to manual compression.

Regarding ability to obtain full hemostasis, our trial showed equal efficacy with a five min. shorter TTH in the MC group compared to the AFCD2 group (22.3 ± 5.4 vs. 27.3 ± 4.3 min, p < 0.001), in accordance with Bogart who demonstrated that mean TTH was 22 min for MC and 31 min for mechanical device compression. The increase in TTH in the AFCD2 group can be explained by early sheath removal 2 h. after PCI as intended by the trial protocol.

On the other hand, Walker et al. showed that TTH was much shorter in the MC group than the Femostop group. This can be explained by the difference in the trial design, where Femostop application protocol was extended for 30 min.

Device failure rate in our trial was 4%, which was in agreement with Femostop device failure rate. Bogart reported that 13% of cases with compressor device were switched to MC which is an accepted failure rate.

Concerning patient comfort, the pain level at the time of sheath removal did not differ significantly between our AFCD2 group compared with the MC group. This was in agreement with Benson et al. who reported that the mean pain level in the MC group was 1.9 ± 0.5 while in the Compressor group it was 2.1 ± 0.5. On the other hand, Norderhaug et al. showed that there was more discomfort with Femostop device than with MC as the device application was for 1 h in all patients compared to 12 min for MC. Also, Lehmann et al. presented that there was more discomfort with Femostop use (3.1 ± 2.1) compared with MC (1.9 ± 1.9) or C-clamp (2.2 ± 2.0) (p < 0.001).

Conflicting results were also noted regarding safety issue. Siddher et al. showed lower complication rate in the Femostop device group compared with the MC group. On the other hand, Lehmann et al. concluded that the use of the Femostop device leads to longer compression times, greater discomfort, more bleeding, and larger hematomas. In a metaanalysis of 16 randomized clinical studies comparing the rates of access site complications (excluding hematoma) associated with vascular closure devices (VCD) vs. MC in over 5000 patients, Vaitkus reported a lower risk of vascular complications associated with VCD. Two other meta-analyses comparing the safety of VCD with MC, published in 2004 and found similar rates of periprocedural, access site complication with VCD and MC, whether the procedure was diagnostic or interventional.

In our trial, no complication was new or unanticipated. Neither the type nor the incidence of complication differs between the 2 groups. None of our trial population reported any MAE. The incidence of small hematoma < 5 cm was 8% in the AFCD2 group vs. 14% in the MC group in accordance with Lehmann et al. who showed that the frequency of hematoma formation was statistically similar between MC (10%) and mechanical compression (11% for C-clamp and 13% for Femostop). However, Walker et al. showed that prevalence of hematoma was higher in the Femostop group (18.1%) than in the MC group (9.1%). On the other hand, Norderhaug et al. showed that prevalence of hematoma was less in the Femostop group 7% vs. 11% in the MC group. Also, Semler reported that the incidence of hematoma was 2% using the Compressor compared with 6% for MC. Non of the AFCD2 group had a large hematoma, however one patient in the MC group had a large hematoma > 5 cm.

Our trial represents a similar incidence of ecchymosis between MC (32%) and AFCD (28%) in accordance with Lehmann et al. who showed that the frequency of ecchymosis formation was statistically similar between MC (38%) and mechanical compression (34% for C-clamp and 29% for Femostop).

The results of this trial signify oozing frequency to be statistically similar between MC (4%) and AFCD (10%) in accordance with Lehmann et al. that represent similar bleeding rate between MC (8%) and mechanical compression (6% for C-clamp and 12% for Femostop). On the other hand, Benson et al. showed more significant rebleeding 7/61 (11%) in mechanical compression compared to zero/30 in the MC group, which can be attributed to the lack of clear definition of rebleeding in the MC group. This trial had several limitations; The ACT was not monitored in the current study.

However, as the patients were randomized, the intensity of the anticoagulation during the procedure should have been similar in the two arms of the trial. The nature of the trial precluded blinding of treatment strategy for either patient or treating physician, though most outcomes were evaluated without knowledge of the assigned technique. Cost-effectiveness has not been examined in this trial, however, it is well
known that locally developed device costs much less than any commercially available one. Improvement of device design with a C-shaped belt free device is a point for improvement in the device for further easy and rapid application.

5. Conclusions

Our results indicate that AFCD2 is a simple and effective alternative to MC for hemostasis following PCI. Early sheath removal 2 h. post PCI is feasible, safe, and improves the patient’s comfort.

6. Future prospective

Next step is to develop AFCD3 with C-shaped belt free design and use it in patients undergoing PCI. Aim is to study cost effectiveness regarding expenses of the procedure and hospital stay and also to study the feasibility of immediate sheath removal post PCI.

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Conflict of interest

None.

References


