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ORIGINAL ARTICLE

A new femoral compression device compared with manual compression for bleeding control after coronary diagnostic catheterizations



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KEYWORDS

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Abstract *Objective:* This study was performed to evaluate the safety and efficacy of a locally designed assiut femoral compression device (AFCD) versus manual compression (MC).

Background: Femoral compression devices have been developed through the past decades without being strongly implemented in the catheterization laboratory. Their limited adoption reflects concerns of high cost and conflicting data regarding their safety.

Patients and methods: This was a prospective study. We enrolled 206 consecutive patients undergoing diagnostic coronary angiography From July, 2012 to April, 2013. They were divided into two groups: 100 patients used AFCD and 106 patients used MC for arterial hemostasis.

Results: Both groups were comparable regarding baseline characteristics. Concerning the primary effectiveness end point, there was no difference in the mean time-to-hemostasis with AFCD (12.5 ± 3 min) vs. MC (13 ± 2 min, $p = 0.4$). As regards safety, none of our research population experienced major adverse events. No complication was new or unanticipated, and the type of complication did not differ between the two groups. The incidence of vagal episodes were comparable between both groups (3 patients (3%) in AFCD vs. 2 patients in MC (1.8%); $p = 0.2$). The use of AFCD was associated with similar occurrence of minor complications, mainly ecchymosis and oozing, compared with MC (27% vs. 27.4%, $p = 0.8$). Large hematoma > 5 cm was noted only in 1 patients (1%) in the AFCD arm vs. 2 patients (1.8%) in the MC arm ($p = 0.8$).

Conclusion: Our results indicate that AFCD is a simple, safe and effective alternative to MC for hemostasis following diagnostic coronary angiography.

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1. Introduction

The femoral approach is commonly used to obtain arterial access in coronary angiography. Hemostasis is usually obtained by manual compression (MC) after sheath removal. Vascular access site complications result in significant morbidity after

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coronary interventional procedures, with incidence of 0.5–16.8% of cases.^{1–4} The rates of these complications depend on the operator's experience, the type of intervention attempted, the introducer size and primarily, on the duration of the MC.⁵

Even though femoral compression devices (FCD) are being introduced into the market since decades, they are not strongly implemented due to their higher cost without showing remarkable superiority in the safety or efficacy compared with the MC.⁶

At Assiut University Hospitals, we use only conventional MC to achieve hemostasis. Currently, with the increase in patient numbers done per day; finding an alternative to MC without increasing procedural complications or price is mandatory. For this reason, we collaborated with the Mechatronic Engineering Department, to develop a locally designed compression device.

At this early stage, we are reporting the safety and efficacy of this new assiut femoral compression device (AFCD) compared to conventional MC for femoral artery access site hemostasis after diagnostic coronary angiography.

2. Methods

2.1. Study design and patients selection

We performed a non-randomized, parallel assignment, prospective study at the catheterization laboratory of the Assiut University Hospitals. Patients between 18 and 85 years of age, scheduled to undergo a diagnostic coronary procedure via arterial puncture of common femoral artery were eligible for enrollment in the study. Patients were excluded from the study if they required Percutaneous Coronary Intervention (PCI) following coronary angiography, or if the patient has any mental illness, heart failure III/IV grades, or aged < 18 years.

2.2. Study groups and protocol

From July, 2012 to April, 2013, 206 consecutive patients that fulfilled the inclusion criteria were enrolled in this study. They were divided into two groups: 100 patients used AFCD and 106 patients used conventional MC for arterial hemostasis. The study protocol was reviewed and approved by the institutional review committee, and all patients granted their informed consent to be included in the study.

The demographic and clinical data were prospectively collected using a standardized "procedural datasheet" and the data were recorded on the day of the procedure, or at the time when the complications were noted.

All patients received a standard 2500 IU heparin in the sheath pre-procedural. The conventional compression therapy consisted of MC at the femoral access site immediately at the end of the diagnostic catheterization procedure for 10–15 min. Ambulation was normally initiated 4 h after complete hemostasis according to our local protocols.

All patients were scheduled to undergo a clinical assessment of the femoral access site the day after the procedure for any evidence of complications.

2.3. Device description

Assiut Femoral Compression Devices (AFCD) is a femoral compression system, made of plexiglass, consisting of an arch with

a reusable pressure dome connected with a metallic screw and a belt (Fig. 1). The pressure dome is situated over the vessel puncture site in the groin. The belt is placed around the patient and the dome applies a mechanical pressure over the vessel puncture site to induce hemostasis. The pressure of the dome is controlled by the assessment of distal pulse. The arch and the belt provide counter pressure for the dome. Sterile disposable gloves are positioned over the dome to prevent its contact with blood. The duration of compression should be 10–15 min with looking for dorsalis pedis pulsation and cyanosis of the limb. Instruction is to keep compression with no palpable dorsalis pedis pulsations for 2–5 min safely, then to release partly till the pulse is felt and to continue compression till 10–15 min is completed.

2.4. Study end points

2.4.1. The primary efficacy end point of the study was time-to-hemostasis (TTH), measured in minutes

Hemostasis was defined as no or minimal subcutaneous oozing and the absence of expanding or developing hematoma.⁷ TTH was measured from the time the introducer sheath was removed to the time hemostasis was achieved. The entry site was revised for signs of active bleeding (acknowledged as failure of closure strategy). In the case of failure, the compression was restored manually for additional 2–5 min and observed thereafter until bleeding stops.

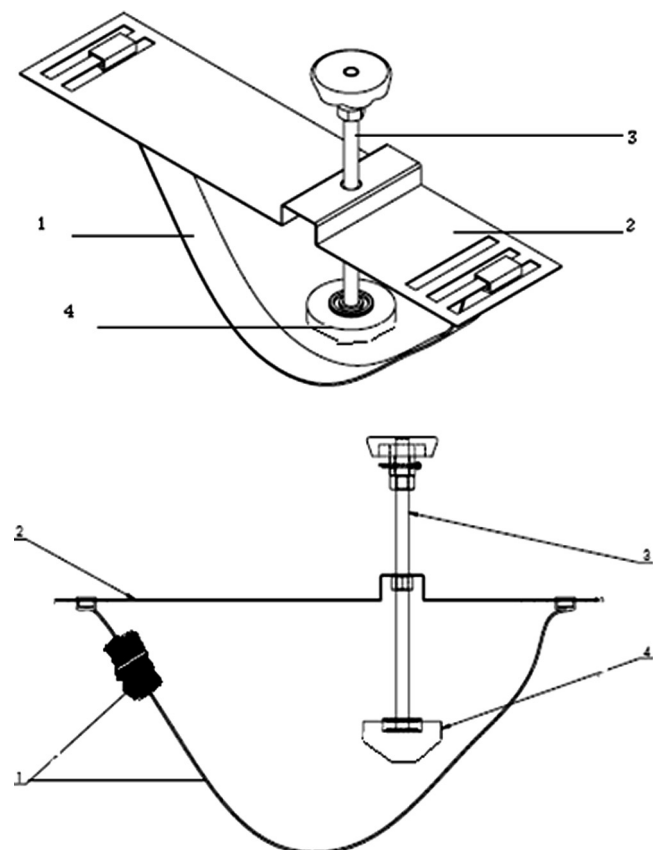


Figure 1 Device design. (1) Black fabric belt with a plastic fastener and an elongation kit. (2) Plexiglass arch. (3) Metallic screw. (4) Reusable pressure dome.

2.4.2. The secondary efficacy end point of the study was

1. **Device success:** This was defined as easy application of the device with good fixation and stability and achieving final hemostasis. Device stability was defined as absence of tilt and/or mobility after application of the device on top of the patient's 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".
2. **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.^{7,8}

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

2.4.3.1. 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.^{8,9}
2. **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).⁸
3. **Vasovagal manifestations** (sweating, bradycardia, nausea and vomiting) were recorded.

2.5. Sample size calculation

The study was designed to have an 80% power to detect a 2 min difference in time-to-hemostasis (TTH) with an overall type I error rate of 0.05 (two sided). Sample size calculated to be at least 99 patients in each arm. Mean TTH was estimated to be 15 min in the AFCD group and 13 min in the MC group with a common standard deviation (sigma) of 5 min.¹⁰

2.6. 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 the Kolmogorov-Smirnov test. Continuous and normally distributed data are presented as mean ± 1 standard deviation and were compared by two-tailed unpaired *t*-test. These comparisons were performed using the SPSS version

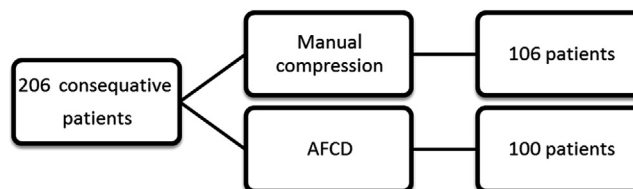


Figure 2 Flow of patients through the study. AFCD = asiut femoral compression device.

16.0 software package (SPSS Inc., Chicago, IL), and a *p* value of ≤ 0.05 was considered to be significant.

3. Results

3.1. Patients characteristics

The study population consists of 206 patients who underwent diagnostic coronary procedure via arterial puncture of the common femoral artery. These patients were divided into two groups: 100 patients used AFCD and 106 patients used MC for arterial hemostasis (Fig. 2). The baseline demographic and clinical characteristics of the two study groups are summarized in Table 1. The two groups were comparable with no significant differences in baseline characteristics.

Approximately three-quarters of patients in each group were men. The body mass index was > 30 kg/m² in 36% and 30% of patients in the AFCD and MC groups, respectively (*p* = NS).

3.2. Analysis of efficacy

Concerning the primary effectiveness end point, the mean TTH was 12.5 ± 3 min in the AFCD group vs. 13 ± 2 min in the MC group, with no significant difference between the two groups (*p* = 0.4) (Fig. 3).

The procedure success was observed in 95 patients of the AFCD group and all patients of the MC group. None of our research population experienced a MAE.

The device success was observed in 90 patients of the AFCD group. Ten patients experienced device failure (Fig. 4). Five of them had a difficult application process but ultimately good hemostasis. The remaining 5 patients crossed over to MC without further vascular complication because of a device failure. In one patient, inadequate hemostasis was associated with a device malfunction in the form of sudden break of the belt fastener due to marked stretch of the belt around an overweight patient. The remaining four cases were associated with in-appropriate positioning of the belt under the patient that resulted in instability of the dome with tilting of the AFCD and ineffective compression.

3.3. Regarding safety

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

Some secondary adverse events occurred in each study group, without statistically significant differences among the

Table 1 Baseline characteristics of the study population.

Variable	MC (N = 106)	AFCD (N = 100)	P
Age (years)	55 ± 16	52 ± 10	NS
Male gender n (%)	75 (70.7%)	76 (76%)	NS
Smoking n (%)	31 (29.2%)	37 (37%)	NS
Hypertension n (%)	46 (43.4%)	51 (51%)	NS
IHD n (%)	70 (66%)	60 (60%)	NS
Dyslipidemia n (%)	30 (28.3%)	31 (31%)	NS
Diabetes mellitus n (%)	34 (32%)	35 (35%)	NS
Body mass index n (%)			
From 18.5 to 25 kg/m ²	37 (35%)	31 (31%)	NS
From 25 to 30 kg/m ²	37 (35%)	33 (33%)	
> 30 kg/m ²	32 (30%)	36 (36%)	
Previous femoral puncture	8 (7.5%)	6 (6%)	NS
INR impaired n (%)	2(1.8%)	4(4%)	NS
Warfarin before hospital admission	5 (4.7%)	4 (4%)	NS
Chronic aspirin therapy	90 (84.9%)	96 (96%)	NS
Chronic clopidogrel therapy	33 (31.1%)	30 (30%)	NS

Data are presented as mean ± standard deviation, number (%) of patients. MC = manual compression; AFCD = assit femoral compression device; IHD = ischemic heart disease; NS = not significant.

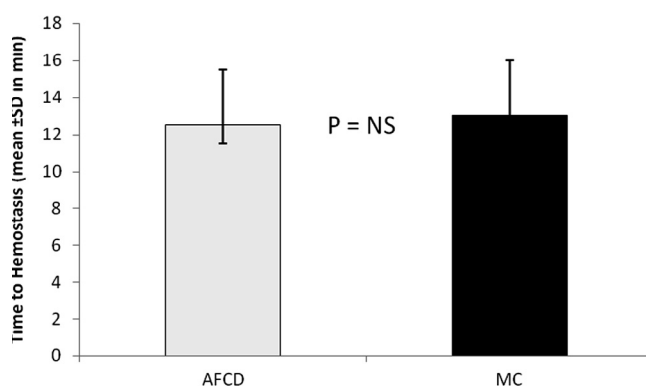


Figure 3 Primary effectiveness endpoint: time-to-hemostasis in the AFCD group compared to those with MC. Time-to-hemostasis showed no significant difference between the two groups ($p = NS$). MC = manual compression; AFCD = assit femoral compression device.

groups (Fig. 5). The overall incidence of minor complications was 27.4% (29 patients) in the MC group and 27% (26 patients) in the AFCD group with no statistically significant

difference between them (Table 2). These minor complications were mainly ecchymosis and oozing in both groups. Large hematoma > 5 cm was noted in 2 pts. (1.8%) in MC arm vs. 1 pt. (1%) in AFCD arm ($p = 0.8$).

3.4. Regarding pain

The median and mean scores of pain assessment scale for each group is presented in Table 2. Patients did not report a significant difference in the pain score in the AFCD group compared with MC group ($p = NS$). None of the closure procedures using AFCD was aborted because of pain at the access site. The incidence of vagal episodes was comparable between both groups (2 pts. in MC (1.8%) and 3 pts. (3%) in AFCD; $p = 0.2$) (Table 2).

4. Discussion

In this prospective study of a new locally developed femoral compression device, we could demonstrate a high procedural success rate, with no significant difference in the mean time-to-hemostasis, nor complication rate compared to MC.

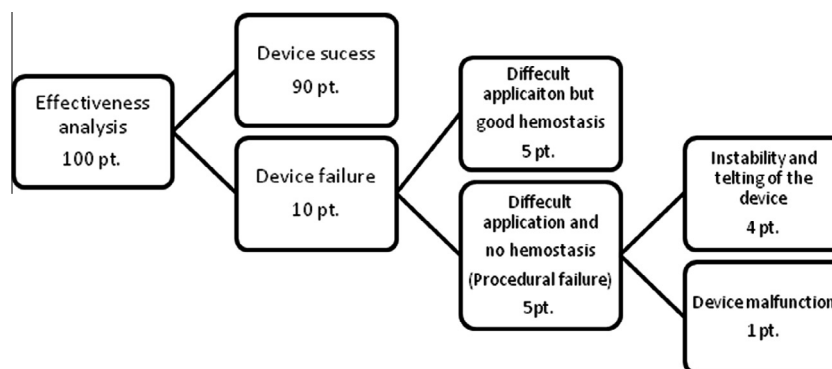


Figure 4 Secondary effectiveness endpoints: device success and failure flow chart. Pt. = patients.

None of our study population reported any MAE, confirming that AFCD is a simple, safe and effective alternative to MC for hemostasis following diagnostic coronary angiography.

Few large studies have compared vascular access strategies in patients undergoing elective coronary procedures.^{6,11,12} Several devices have been developed to aid in the closure of the femoral arteriotomy, including, extravascular plug devices (VasoSeal, AngioSeal, ExoSeal),^{7,13} percutaneous suture closure devices (Perclose, StarClose),¹⁴ and mechanical compression devices.^{15–19} 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). The C-clamp compression device was first introduced in 1974 and functions much like a C-clamp used in carpentry.^{15–19} The

pneumatic FemoStop device consists of a belt positioned under the patient's hips that holds a plastic arch bar over the groin. On one side of the bar, there is a clear soft dome that can be inflated using a hand-held manometer. Compression to the femoral artery site occurs via the pressure exerted by the inflated dome.^{15–17,19} 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.^{15,19} Our AFCD total cost is around 15 \$ once.

The C-clamp and Femostop devices were compared to MC in a number of studies,^{15–17,19} which generally reported equal efficacy with no significant differences regarding femoral vascular complication rates.

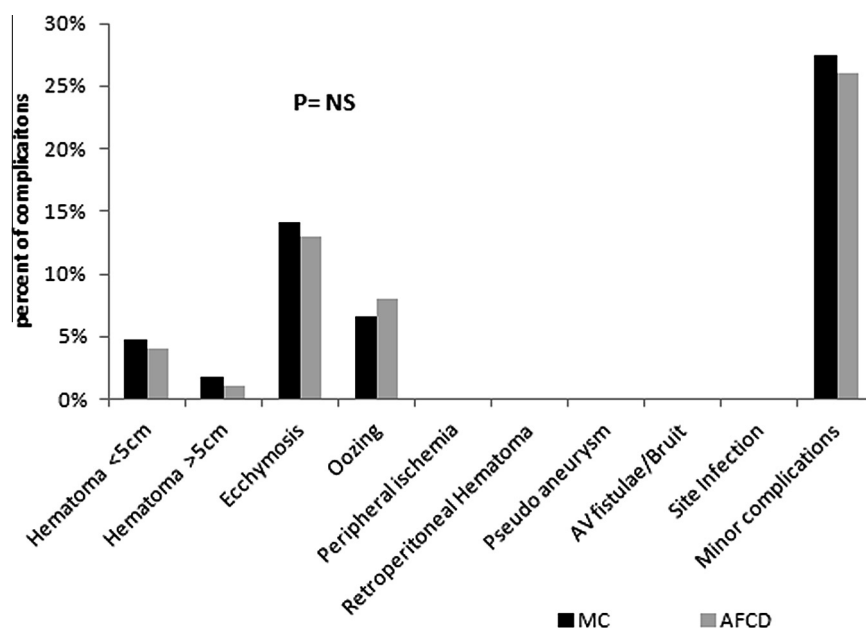


Figure 5 Percent of complications in the study group. MC = manual compression; AFCD = assist femoral compression device.

Table 2 Effectiveness and safety results in the study groups.

Parameter	MC (<i>N</i> = 106)	AFCD (<i>N</i> = 100)	<i>P</i>
Time-to-hemostasis (min ± SD)	13 ± 2	12.5 ± 3	NS
Pain grade (median (mean ± SD))	2 (2.57 ± 0.6)	2 (2.56 ± 0.83)	NS
Vagal episodes	2 (1.8%)	3 (3%)	NS
Hematoma < 5 cm	5 (4.7%)	4 (4%)	NS
Hematoma > 5 cm	2 (1.8%)	1 (1%)	NS
Ecchymosis	15 (14.1%)	13 (13%)	NS
Oozing	7 (6.6%)	8 (8%)	NS
Peripheral ischemia	0	0	
Retroperitoneal hematoma	0	0	
Pseudo aneurysm	0	0	
AV fistulae/bruit	0	0	
Site infection	0	0	
Minor complications	29 (27.4%)	26 (26%)	NS
Major adverse events	0	0	–

Data are presented as mean ± standard deviation, number (%) of patients or median. MC = manual compression; AFCD = assist femoral compression device; AV = arterio-venous; NS = not significant.

Regarding AFCD efficacy and its ability to obtain full hemostasis, our study showed equal efficacy that is presented as equivalent mean TTH between AFCD and MC (12.5 ± 3 vs. 13 ± 2 min), in accordance with Lehmann et al.²⁰ who demonstrated that TTH was 13.9 ± 3.5 min for MC and 14.5 ± 4.5 min for C-clamp and 15.6 ± 4.81 min for Femostop device. Also Bogart¹⁹ demonstrated that mean TTH was 22 min for MC and 31 min for mechanical device compression. On the other hand, Walker et al.¹⁵ showed that TTH was much shorter in the MC group (12.9 min) than the Femostop group (35.2 min). This can be explained by the difference in the study design, where Femostop application protocol was extended for 30 min.

Device failure rate in our study was 10%, which was in agreement with Femostop device failure rate.^{15,21} Bogart¹⁹ reported that 13% of cases with compressor device was 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 AFCD groups compared with the MC group. This was in agreement with Benson et al.²² 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.¹⁵ showed that there was more discomfort with the Femostop device than with the MC as the device application was for 1 hour in all coronary angiography patients compared to 12 min for MC. Also, Lehmann et al.²⁰ 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. Sridher et al. showed a lower complication rate in the Femostop device group compared with MC group.²² Also Beres et al.¹⁵ agreed with this finding. On the other hand, Lehmann et al.²⁰ concluded that the use of the Femostop device leads to longer compression times, greater discomfort, more bleeding, and larger hematomas.

In our study, no complication was new or unanticipated. Neither the type nor the incidence of complication differs between the two groups. None of our study population reported any MAE. The incidence of hematoma was 5% in AFCD group vs. 6.5% in the MC group in accordance with Lehmann et al.²⁰ 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 the MC group (9.1%). On the other hand, Norderhaug et al.¹⁵ showed that the prevalence of hematoma was less in the Femostop group 7% vs. 11% in the MC group. Also, Semler¹⁷ reported that the incidence of hematoma was 2% using the Compressor compared with 6% for MC.

Our study represents a similar incidence of ecchymosis between MC (14%) and AFCD (13%) in accordance with Lehmann et al.²⁰ 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 study signify oozing frequency to be statistically similar between MC (6.6%) and AFCD (8%) in accordance with Lehmann et al.²⁰ 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.²² 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 study had several limitations; the application of AFCD was not randomly assigned between the study groups; however the results regarding efficacy and complications were reported prospectively by the resident doing the compression using a standardized “procedural datasheet”. The nature of the study precluded blinding of treatment strategy for either patient or treating physician, though most outcomes were evaluated without knowledge of the assigned technique. Furthermore, cost-effectiveness has not been examined in this study, however, it is well known that the locally developed device costs much less than any commercially available one. Finally, improvement of device belt with removal of the fastener clip is a point for improvement in the device for further applications.

5. Conclusions

Our results indicate that AFCD is a simple, safe and effective alternative to MC for hemostasis following diagnostic coronary angiography.

Future prospective

Next step is to use AFCD in more complicated patients undergoing PCI. Aim is to reduce time of post-procedural recumbence from 12–14 h. with MC to 4–6 h. with the AFCD. This will reduce expenses of the procedure and reduce hospital stay.

Conflict of interest

We have no conflict of interest to declare.

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