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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

Femoral compression device;
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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 thorough 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.

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.

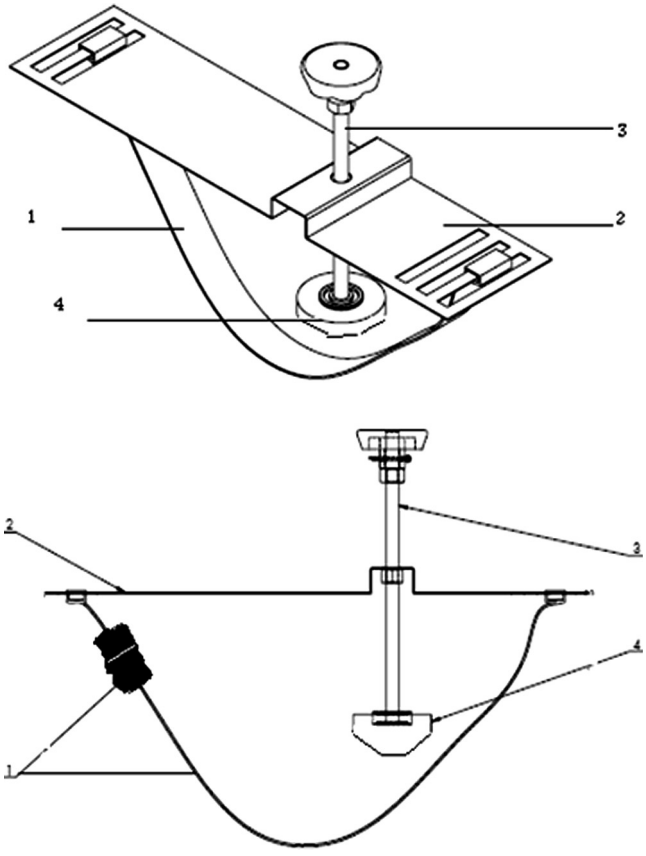

Figure 1 Device design. (1) Black fabric belt with a plastic fastener and an elongation kit. (2) Plexiglass arch. (3) Metallic screw. (4) Reusable pressure dome.