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ORIGINAL ARTICLE

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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KEYWORDS

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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.

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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.

1. Introduction

Percutaneous coronary intervention (PCI) is inevitably associated with the risk of access site complications as high as 16%,[1–4] 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,[5] 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 trans-femoral 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.[6] 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.[7]

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.[7]

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.[8,9] 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 discursion. 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