Cardiovascular Revascularization Medicine xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

# Comparison of manual compression and vascular hemostasis devices after coronary angiography or percutaneous coronary intervention through femoral artery access: A meta-analysis of randomized controlled trials☆,☆☆

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ARTICLE INFO

*Article history:*
Received 25 May 2017
Received in revised form 11 August 2017
Accepted 15 August 2017
Available online xxxx

*Keywords:*
Manual compression
Vascular hemostasis device
Time-to-hemostasis
Time-to-ambulation

ABSTRACT

*Objectives:* To compare the efficacy and safety of manual compression (MC) with vascular hemostasis devices (VHD) in patients undergoing coronary angiography (CA) or percutaneous coronary intervention (PCI) through femoral artery access.
*Introduction:* The use of femoral artery access for coronary procedures may result in access-related complications, prolonged immobility and discomfort for the patients. MC results in longer time-to-hemostasis (TTH) and time-to-ambulation (TTA) compared to VHDs but its role in access-related complications remains unclear in patients undergoing coronary procedures.
*Methods:* We searched MEDLINE, EMBASE, Cochrane CENTRAL and relevant references for English language randomized controlled trials (RCT) from inception through September 30, 2016. We performed the meta-analysis using random effects model. The outcomes were time-to-hemostasis, time-to-ambulation, major bleeding, large hematoma >5 cm, pseudoaneurysm and other adverse events.
*Results:* The electronic database search resulted in a total of 44 RCTs with a total of 18,802 patients for analysis. MC, compared to VHD resulted in longer TTH [mean difference (MD): 11.21 min; 95% confidence interval (CI) 8.13–14.29; $P < 0.00001$] and TTA [standardized mean difference: 1.2 (0.79–1.62); $P < 0.00001$] along with excess risk of hematoma >5 cm formation [risk ratio (RR): 1.38 (1.15–1.67); $P = 0.0008$]. MC resulted in similar risk of major bleeding [1.01 (0.64–1.60); $P = 0.95$] pseudoaneurysm [0.99 (0.75–1.29); $P = 0.92$], infections [0.52 (0.25–1.10); $P = 0.09$], need of surgery [0.60 (0.29–1.22); $P = 0.16$), AV fistula [0.93 (0.68–1.27); $P = 0.63$] and ipsilateral leg ischemia [0.95 (0.57–1.60); $P = 0.86$] compared to VHD.
*Conclusion:* Manual compression increase time-to-hemostasis, time-to-ambulation and risk of hematoma formation compared vascular hemostasis devices.



## 1. Introduction

Femoral artery remains the most widely used access site for coronary angiography (CA) and percutaneous coronary intervention (PCI) in the United States despite the increasing popularity of radial artery access [1]. Femoral artery puncture results in significant risks of access-site complications including hematoma, bleeding, infection and vascular complications [2]. In addition, it requires bedrest after the completion of the procedure that may result in increased discomfort and immobility to the patient. Manual compression (MC) is a standard hemostasis procedure that requires prolonged compression of the

*Abbreviations:* ACC/AHA, American College of Cardiology/American Heart Association; CA, Coronary angiography; CI, Confidence interval; MC, Manual compression; MD, Mean difference; PCI, Percutaneous Coronary Intervention; RCT, Randomized controlled trial; RR, Risk ratio; SMD, Standardized Mean Difference; VHD, Vascular Hemostasis Device.

☆ Conflict of Interest Disclosures: All authors have nothing to disclose.

☆☆ Funding/Support: There was no external funding for this study.

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http://dx.doi.org/10.1016/j.carrev.2017.08.009
1553-8389/

arterial puncture site to reduce access-related complications. Although several types vascular hemostatic devices (VHD) have been designed and used clinically to reduce the duration of bed rest, and improve patient's mobility and comfort, their role in reduction of access-related complications remains unclear and controversial [3–5]. AHA/AHA Scientific statements give class IIa indication for the vascular closure devices for the purpose of achieving faster hemostasis and earlier ambulation cautioning against its routine use for the purpose of decreasing vascular complications including bleeding [6,7].

Several randomized trials have been performed to assess the safety and efficacy of MC and VHDs with conflicting results [3,8]. Two large studies by Schulz-Schupke et al. [3] and Holm et al. [9] showed increased risks of large hematoma with the use of MC compared to VHDs, whereas the studies by Wong et al. [8] and Yeni et al. [10] showed similar risks of hematoma formation. Access-related complications have shown to increase morbidity and mortality with a recent study showing reduced 30-day mortality with the use of vascular closure devices compared manual compression [11]. In this context, to compare the safety and efficacy of manual compression with VHDs as a group with emphasis on access-related complications, we designed this systematic review and meta-analysis of randomized controlled trials.

## 2. Methods and materials

### 2.1. Data sources and search strategy

The meta-analysis was performed with a study protocol written in accordance with Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [12]. We searched MEDLINE, EMBASE and Cochrane CENTRAL Register of Clinical Trials for English language publications from inception through September 30, 2016. The search terms were “vascular closure device” or “vascular hemostasis device” or “arteriotomy closure device” or “manual compression” with restriction to randomized study designs. Database search was independently performed by two researchers (K.D. and J.R.) and disagreement was resolved by consensus. A manual search was performed for all relevant references including published reviews and meta-analyses. The flow diagram for study selection is shown in Fig. 1.

### 2.2. Study inclusion and exclusion criteria

Randomized controlled trials that compared MC with various VHD in adults (≥18 years of age) undergoing either CA or PCI were included in the analysis. For inclusion in the meta-analysis, the studies had to provide complete data for at least one of the outcomes of interest. The studies, which were non-randomized or involved pediatric patients and procedures other than CA or PCI, were excluded.

### 2.3. Data extraction

Data were extracted by two groups (K.D./S.S. and J.R/R.S.) in duplicate using standardized data extraction tables. The parameters included were study and patient characteristics, type of coronary procedures or VHD used and safety and efficacy outcomes.

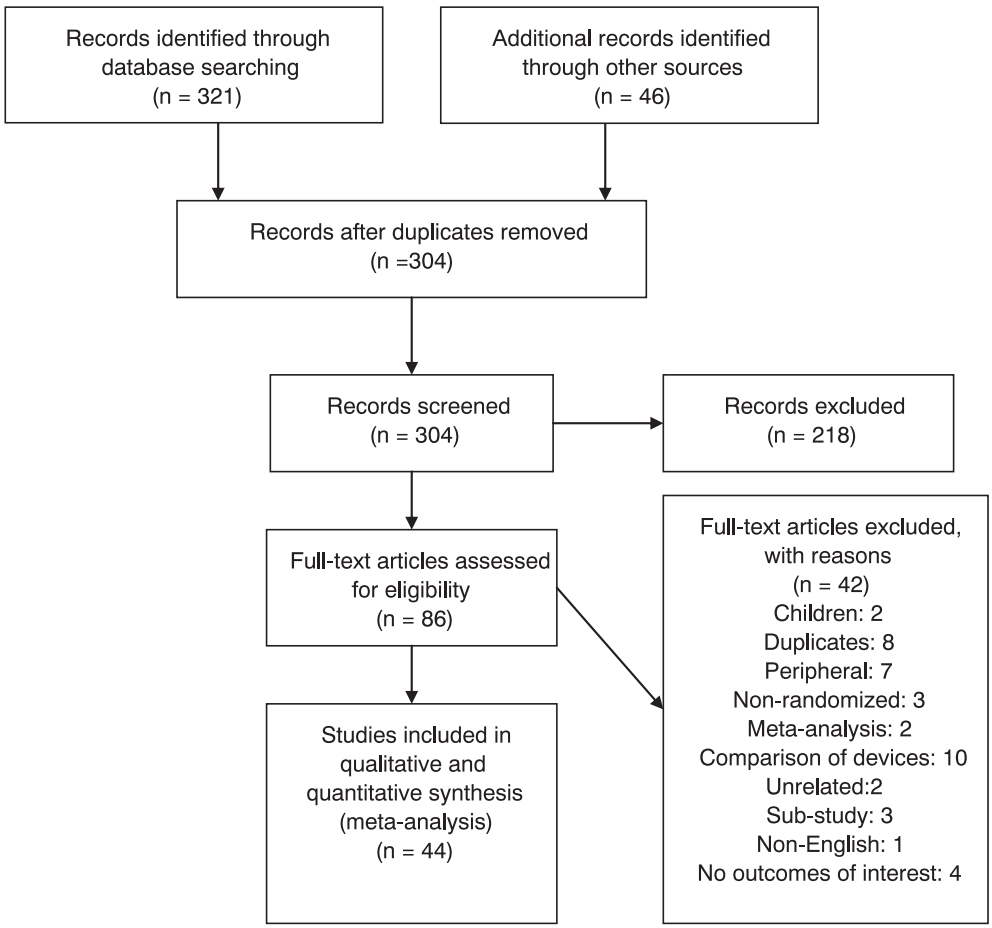


**Fig. 1.** Flow diagram for study selection.

Please cite this article as: Dahal K, et al, Comparison of manual compression and vascular hemostasis devices after coronary angiography or percutaneous coronary intervention ..., Cardiovasc Revasc Med (2017), http://dx.doi.org/10.1016/j.carrev.2017.08.009