Manual versus mechanical compression hemostasis approach after coronary angiography via snuffbox access

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Abstract

Objective: Distal radial artery access or trans-snuffbox access (TSA) is a novel, safe, and feasible technique for coronary artery interventions wherein its vascular hemostasis is still concerned. So, this study aimed to compare two homeostasis methods comprising manual and mechanical compression approaches in patients undergoing coronary angiography (CAG) via TSA.

Methods: In a prospective nonrandomized clinical trial, a total of 80 patients undergoing diagnostic CAG by TSA were divided into two equal groups: manual compression and mechanical compression (using radial TR band), the main end point of which was primary hemostasis time. Other variables were patient satisfaction, puncture site pain severity, hospitalization time, and local neurovascular complication during the 30-day follow-up.

Results: The mean age of the patients was 57.1±8.0 years, with 40 of them (54.1%) being male. The primary hemostasis time was significantly shorter in the manual compression approach [15.0±5.9 minutes with median 15 (9–20)] than in the TR band group [25.7±4.9 minutes with median 25 (20–30)] (p<0.001). No significant difference was noted in the patient's satisfaction and puncture site pain severity as well as hospitalization time between the two methods (p>0.050). The neurovascular complication, including hematoma, numbness, and dRA occlusion, rates had also no significant difference between the two groups (p>0.050).

Conclusion: The manual compression approach on the puncture site reduces hemostasis time in patients undergoing CAG via TSA when compared with the mechanical compression method.

Keywords: distal radial artery, snuffbox, hemostasis

Introduction

Today, upper extremity accesses including radial and even ulnar arteries have been introduced as preferred methods for coronary catheterization as far as transradial access (TRA), which has been confirmed as the default approach for coronary interventions especially for acute coronary syndrome (ACS) patients (1-4). TRA has faster hemostasis, earlier patient ambulation, higher patient satisfaction, lower rate of access site complications, and shortened hospital stay in comparison to femoral artery access (5, 6). With the advent of the TRA in recent years, the term distal radial artery (dRA) access to reduce complications such as radial artery occlusion (RAO), pseudoaneurysm, and arteriovenous fistula has been introduced (7-10), which has

some advantages compared to TRA, including early hemostasis due to carpal bones and smaller diameter and lesser likelihood of RAO and compartment syndrome, crossover to TRA in times of failure, and possibility of forearm splint, bangle, or ulcer in patients (11-13). As noted, one of the advantages of TSA was faster puncture site hemostasis than TRA; but despite numerous studies and methods in this area, there is still no unanimous agreement as to the best hemostasis approach. These studied methods were manual compression, compression bandage, mechanical compression with radial TR band, combination of both manual and mechanical methods, and even specialized dRA TR band (14-18).

Since the timing and success rate of TR band hemostasis approaches are not the same in all individuals, and there is a lack of general consensus on preferred hemostatic methods,

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HIGHLIGHTS

- The preferred homeostasis method for coronary angiography through snuff-box access is still concerned.
- The hemostasis time was shorter in manual comparison approach compared to mechanical compression by TR band.
- There was no significant difference in patient's satisfaction, puncture site pain severity and complications between the manual and mechanical methods.

we conducted this clinical trial study with the aim of comparing and describing our center experiences in TSA hemostasis approaches including manual local compression versus mechanical compression with the TR band device.

Methods

Study participants and design

The current study is a prospective nonrandomized clinical trial that was conducted on 80 patients admitted to Shahid Chamran Heart Center, Isfahan, Iran, from July 2018 to January 2020. The target population of the study was patients undergoing elective diagnostic coronary angiography (CAG) via TSA approach. Exclusion criteria were the need for angioplasty, unstable hemodynamics, acute myocardial infarction or ACS, severe renal failure (GFR <30), Reynaud disease, carpal tunnel syndrome, coagulation disorders or the use of any anticoagulant medications, sensory and motor deficits in the hands' nerves, and fracture of the wrist bones. The

procedure was performed after obtaining a signed written consent form from each participant. Eligible patients were divided into two equal groups. The first group used TR band device on the puncture site, while the second group used manual compression to achieve hemostasis. This study was also approved by the Research Ethics Committees in the School of Medicine - Isfahan University of Medical Sciences, Isfahan, Iran (IR.MUI.MED.REC.1398.658). It was also registered in the Iranian Registry of Clinical Trials (http://www.irct.ir) with IRCT number IRCT20181228042155N2.

Procedure

Based on center experience, our success rate on puncture, guidewire, and sheath insertion is about 90%–95% (12). After the preparation of the puncture site, 2–2.5 ml of 2% lidocaine was injected subcutaneously in the anatomic snuffbox. Intravenous midazolam (1–2 mg) plus 0.4 mg sublingual trinitroglycerin was administered to decrease arterial spasm and patient anxiety. The dRA was punctured using a 21-gauge arterial needle, and then a 5 or 6F radial hydrophilic sheath (Prelude Ease, Merit Medical) was inserted through the 0.018 guidewire. Spasmolytic cocktail consisted of 200–250 micrograms of nitrate, and 2.5 mg verapamil was injected through the sheath. Unfractionated heparin (2500–5000 IU) was used as an anticoagulant in all patients (Fig. 1a, 1b), who were punctured from the right hand. All procedures were done by the same two interventional cardiologists.

Hemostasis methods

In manual compression approach, the sheath was pulled out gently, and after blood oozing, hemostasis was obtained by local hand compression for 5–15 minutes (for primary hemostasis). Once the primary hemostasis is fully established, a pressure
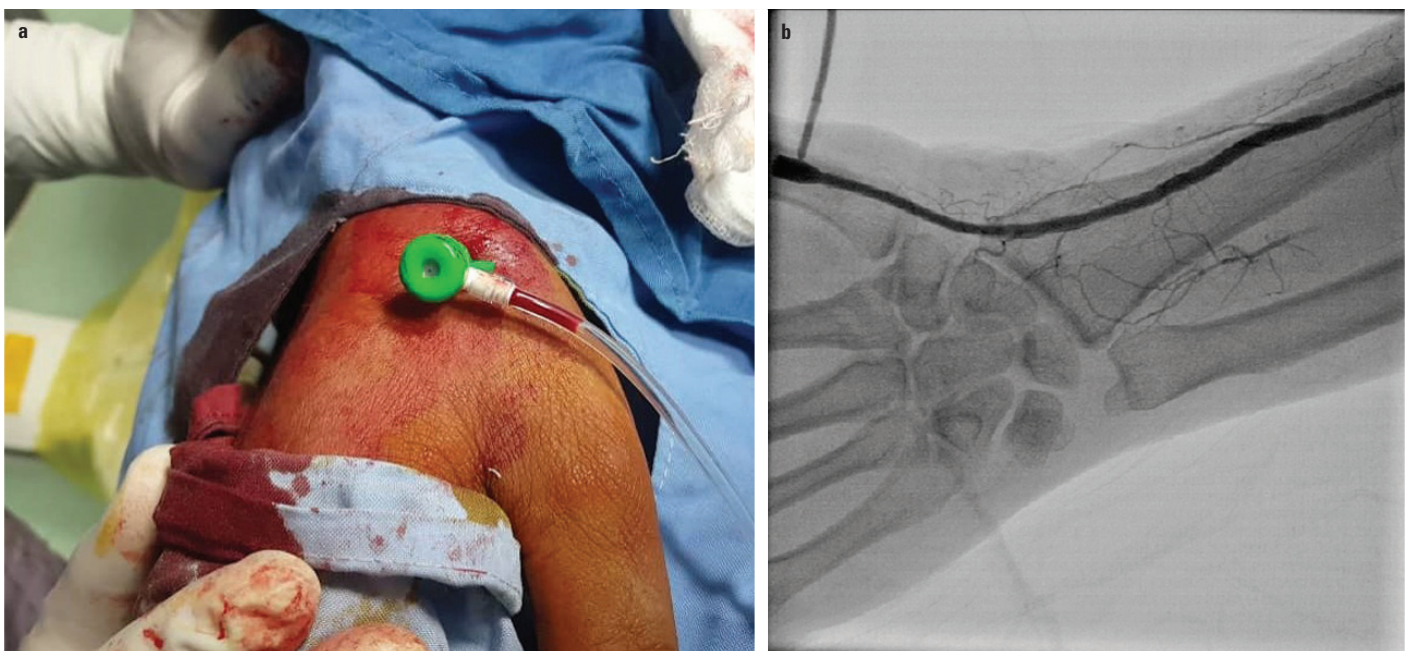

Figure 1. Cannulation of the distal radial artery (snuffbox) (a), and angiographic depiction of trans-snuffbox access (b).

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Figure 2. Hemostasis methods in trans-snuffbox access: manual compression (a, b) and mechanical compression by TR band (c).

bandage pack on the puncture site was placed, which remained for 1–2 hours (Fig. 2a, 2b). In mechanical compression approach a TR band device (manufactured by Lepu Medical Technology Co. Beijing, China) was applied, which was filled with 10–15 cc of air on the balloon, concurrently removing the sheath. Then, the bladder was decompressed to reduce the compression pressure until blood oozed, ensuring radial artery blood flow (patency), and again the device was reinflated with 1–2 cc of air to allow homeostasis. Every after 20 minutes and every 5–10-minute intervals, the wrist bracelet air was reduced to evaluate primary hemostasis. When the primary hemostasis was achieved, the TR band was inflated again with at least 10 cc of air and reduced gradually, 2 cc every 10 minutes (Fig. 2c).

Variables

Baseline characteristics including age, gender, body mass index (BMI), body surface area (BSA), dyslipidemia, diabetes mellitus, hypertension, current smoking, and a family history of coronary artery disease (CAD) (for males age ≤55 and females age ≤65 years) were recorded in the checklist. Prior to angiography, hemoglobin (mg/dL) and creatinine (mg/dL) levels and platelet count (10^3/μL) were also examined. Procedural data such as number of needle attempts, sheath size, contrast volume, procedure time, heparin dose, and antiplatelet medication consumptions were also recorded.

The primary hemostasis time in each group was the main endpoint. Primary hemostasis is defined as the first step in the hemostasis process that stops bleeding clinically, which refers to platelet aggregation and platelet plug formation. It was chosen instead of complete homeostasis because of reduced homeostasis time, bias, and variation, which was seen especially in the TR band approach. Local neurovascular complications, such as hematoma, RAO, and hand paresthesia or numbness, hospitalization time, puncture site pain severity, and patient satisfaction were other endpoints. The Early Discharged After Transradial Stenting of the Coronary Arteries (EASY) study scale was used to evaluate the

hematoma in which patients were divided into five grades: grade 1, <5 cm local hematoma; grade 2, between 5 and 10 cm hematoma with muscular infiltration; grade 3, hematoma expanded to below the elbow; grade 4, hematoma expanded to above the elbow; and grade 5, presented with compartment syndrome (19). RAO was examined by touching the radial artery pulse, and in case of unpalpable pulse, arterial Doppler ultrasound was performed. Paresthesia or numbness was examined by using of an insulin needle tip in terminal branches of the radial nerve, which appeared in the first to third fingers. Puncture site pain severity was assessed using a 10 cm visual analog scale, where 0 represents no pain and 10 most unbearable pain (20). Patients' satisfaction was assessed by asking a quantitative question, scaled from 0 to 10, with 0 being completely dissatisfied and 10 being completely satisfied. All the patients were followed up in the post-procedure period with the following interval: immediately after angiography, 1 and 4 hours, and 7 and 30 days later.

Statistical analysis

The obtained data were finally entered into SPSS-23 software (SPSS, Inc., Chicago, IL, USA). Continuous data are presented as mean±SD, while categorical data are presented as number (percent). Chi-square or Fisher's exact test (if needed) was used for categorical data. Kolmogorov-Smirnov was used to test normality assumption, and based on the result of this test, either independent t-test or Mann–Whitney U test was used for continuous and categorical variables, respectively. Linear regression was used to evaluate the effect of confounding variables on hemostasis time. A two-tailed p-value<0.05 was considered statistically significant.

Results

A total of 80 patients with successful dRA puncture were screened, but 6 of them were excluded because of missed fol-

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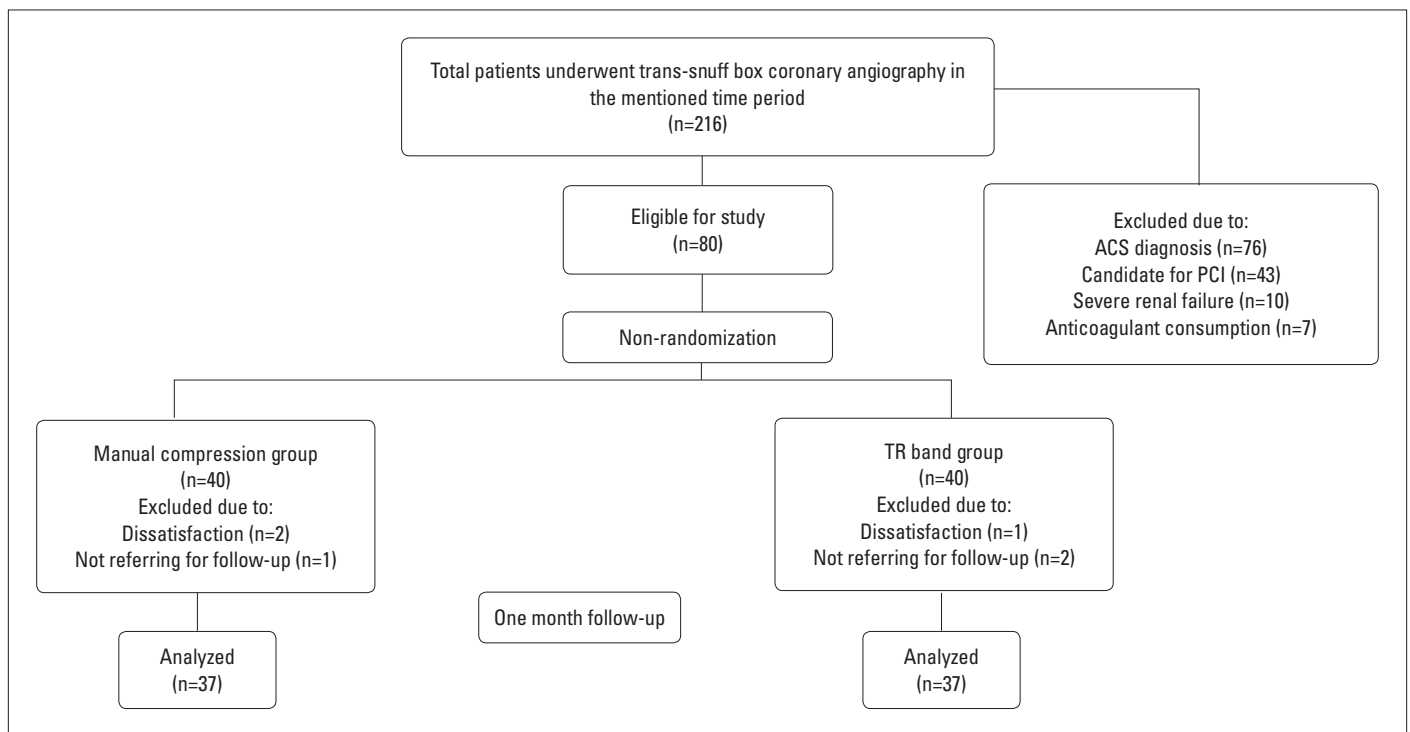DOI:10.14744/AnatolJCardiol.2020.99672

Figure 3. Study flow diagram.

low-up and dissatisfaction. The final analysis included 37 subjects in each group (Fig. 3). The mean age of the patients was 57.1±8.0 years, ranging from 43 to 73 years. Forty patients (54.1%) were male. Table 1 shows the distribution of demographic and clinical variables in the two study groups, with no significant difference between them in terms of age and sex distribution, BMI, BSA, and hemoglobin and creatinine levels, as well as platelet count (p>0.050). Also, no significant difference was noted between the two groups for CAD risk factors. Two groups had no significant difference for procedural data including number of puncture attempts, sheath size, contrast volume, procedure time, and heparin dose (Table 1). The most common antiplatelet drug used was aspirin with 25 (67.5%) and 24 cases (64.9%) in manual and mechanical groups, respectively, and also, no significant difference was noted between the two groups for the type of antiplatelet medications (p>0.050). The mean time of discharge was 9.1±5.1 and 8.6±3.5 hours in manual and mechanical compression approaches, respectively (p=0.665).

The primary hemostasis time was significantly shorter in manual compression approach (15.0±5.9 minutes) than in the TR band group (25.7±4.9 minutes) (p<0.001). The median time was 15 (9–20) and 25 (20–30) minutes for manual and mechanical approaches, respectively. Linear regression test was performed to see the correlation between the hemostasis time (as a dependent factor) and basic clinical/laboratory variables and procedural data. Diabetes mellitus, hypertension, smoking status, BMI, platelet count, and creatinine level were considered independent clinical/laboratory variables. Procedural data were puncture attempt number, sheath size, procedure time, heparin dose, and antiplatelet consumption.

In all the analyzed models, a significant p-value was reported, which indicates the effect of the mentioned factors on the homeostasis time in studied groups (Table 2).

The median score of patient satisfaction was 8 (7.5–9) and 9 (8–9) in manual and mechanical compression methods, respectively, with a nonsignificant statistical difference (p=0.139). The mean of the puncture site pain severity scale had no significant difference among the groups (p>0.050) (Table 3). In terms of complications, four patients (5.4%) had local transient paresthesia, three of whom were from the manual compression group and one from the TR band group (8.1% vs. 2.7%) (p=0.622). Seven (9.5%) hematoma cases were noted, five of which occurred in the manual approach group and two in the mechanical approach group (13.5% vs. 5.4%) (p=0.431). Four patients (5.4%) had grade 1 hematoma (two patients in each group), while three had (4.1%) grade 2, only in the manual compression group (p=0.331) (Table 3). All hematomas were resolved in 30 days with no further therapy required. Snuffbox artery occlusion with impalpable pulse was detected in one case per group (2.7% for each group), which was confirmed by Doppler sonography. They were asymptomatic until the follow-up period. In general, no significant difference was noted between the two groups in post-procedural complications (p>0.050).

Discussion

Coronary artery catheterization through the dRA (or TSA) is one of the methods considered in recent years; and more stud-

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Table 1. Demographic, clinical, and procedural data

Variables	Hemostasis method		P-value
	Manual compression (n=37)	Mechanical compression (n=37)	
Age (years), mean±SD	57.2±8.4	57±7.7	0.913
Gender (Male/Female), n	20/17	20/17	>0.999
BMI (kg/m²), mean±SD	25.2±4.4	26.8±5.0	0.165
BSA (m²), mean±SD	1.6±0.2	1.7±0.2	0.161
Hyperlipidemia, n (%)	15 (40.5)	11 (29.7)	0.332
Diabetes, n (%)	17 (45.9)	16 (43.2)	0.821
Hypertension, n (%)	20 (54.1)	19 (51.4)	0.823
Current smoking, n (%)	13 (35.1)	6 (16.2)	0.068
Family history of CAD, n (%)	6 (16.2)	11 (29.7)	0.175
Platelet count (10³/µL), mean±SD	222.4±100.2	235.3±95.3	0.261
Hemoglobin level (g/dL), mean±SD	13.5±2.9	13.5±1.4	0.946
Creatinine level (mg/dL), mean±SD	1.0±1.8	1.1±0.2	0.267
Number of punctures			
1 attempt n (%)	24 (64.9)	21 (56.8)	0.481
≥2 attempt n (%)	13 (35.1)	16 (43.2)	
Sheet size			
5 French n (%)	20 (54.1)	20 (54.1)	>0.999
6 French n (%)	17 (45.9)	17 (45.9)	
Contrast volume (mL), mean±SD	97.6±6.3	98.0±5.0	0.775
Procedure time (minute), mean±SD	20.5±6.2	19.2±5.8	0.341
Heparin dose (IU), mean±SD	3851.3±1263.0	4256.7±1158.4	0.155
Antiplatelet consumption			
Total consumption, n (%)	25 (67.5)	26 (70.3)	0.897
Aspirin, n (%)	25 (67.5)	24 (64.9)	0.621
Clopidogrel, n (%)	8 (21.6)	12 (32.4)	0.298
Ticagrelor, n (%)	1 (2.7)	0 (0)	0.491
Prasugrel, n (%)	0 (0)	0 (0)	>0.999
DAPT, n (%)	9 (24.3)	10 (27)	0.791

BMI - body mass index; BSA - body surface area; CAD - coronary artery disease; DAPT - dual antiplatelet therapy

Table 2. Linear regression analysis in crude and adjusted models for hemostasis time

Analysis models	Unstandardized coefficients		P-value
	Beta	Standard error	
Crude model	10.67	1.27	<0.001
Model 1	10.68	1.28	<0.001
Model 2	10.07	1.33	<0.001
Model 3	10.51	1.28	<0.001

Model 1: adjusted with age and sex. Model 2: adjusted with age, sex, and clinical and laboratory findings (diabetes mellitus, hypertension, smoking status, BMI, platelet count, and creatinine level). Model 3: adjusted with age, sex, and procedure characteristics (puncture attempts, sheath size, procedure time, heparin dose, and antiplatelet consumption)

ies have shown that TSA CAG is possible with less post-procedural complications and shorter hemostasis and hospitalization time (12-17). However, as mentioned above, no appropriate hemostatic method for the dRA approach has been established yet. In this clinical trial, we compared manual compression and mechanical compression (by using of TR band) hemostasis methods in patients who underwent CAG via TSA. In our experience, primary hemostasis time was significantly shorter in the manual approach than in the mechanical method. In a clinical study, Ziakas et al. (21) used manual compression method (64% of patients) and device-based methods including air bracelet (TR band) (14% of patients) and plastic strip (22% of patients) for TSA hemostasis. The mean of the hemostasis time in manual approach was about 11 minutes, while in device-based methods, it was 198 minutes (21). In contrast to our study, they used total

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Table 3. Endpoint data

Variables	Hemostasis method		P-value
	Manual compression (n=37)	Mechanical compression (n=37)	
Hemostasis time (minute), mean±SD	15.0±5.9	25.7±4.9	<0.001
Satisfaction, median (25%–75% percentile)	8 (7.5-9)	9 (8-9)	0.139
Pain assessment (VAS), mean±SD			
Just after the procedure	3.0±1.6	2.8±1.1	0.631
1 hour later	1.6±1.3	1.4±0.8	0.532
4 hours later	0.8±0.1	0.9±0.7	0.581
24 hours later	0.5±0.8	0.5±0.5	0.748
7 days later	0	0	>0.999
1 month later	0	0	>0.999
Hematoma, n (%)	5 (13.5)	2 (5.4)	0.431
Numbness, n (%)	3 (8.1)	1 (2.7)	0.622
dRA occlusion, n (%)	1 (2.7)	1 (2.7)	>0.999
Hospitalization time (hour), mean±SD	9.1±5.1	8.6±3.5	0.665

VAS - visual analog scale; dRA - distal radial artery

hemostasis time, not primary hemostasis duration. It is also to be noted that our patients have underwent only diagnostic angiography with lower doses of heparin. The TR band is designed to assist in radial artery hemostasis, and its use in snuffbox anatomy is accompanied by limitations such as instability and patient dissatisfaction. Therefore, some clinicians believe that it should be modified (22) or the new special device for snuffbox anatomy named the PreludeSYNC DISTAL should be used (18). Another commonly used method for TSA hemostasis is elastic band with compacted bandages or the latter alone. Approximately half of the published studies are applied in this method. In this appropriate technique, primary hemostasis is obtained by manual compression, and then the puncture site is covered with an elastic bandage with gauze for 2–3 hours (16, 23). However, this approach does not always require achieving primary hemostasis. Bandage alone without the need for manual compression could be effective (24). Patients' satisfaction and puncture site pain severity were not investigated in other studies. In our study, no significant difference was noted between the two methods.

One of the important aspects of choosing a suitable homeostasis method is its ability to reduce neurovascular complications. In theory, dRA occlusion rate at the access site is considered to be higher than in the traditional radial access site, because of its smaller diameter; but, fortunately, previous studies have shown that the dRA occlusion rate is very low, even in comparison to the usual transradial accesses (18, 21, 25). In this study, one asymptomatic case of dRA occlusion was seen in each group (2.7% for each method). In cases of dRA occlusion, hand ischemia is rare, because of the anterograde flow of superficial palmar artery, ulnar side compensatory blood flow, and multiple collateral vessels communicating between the superfi¬cial and deep palmar arches.

A relatively higher hematoma rate was noted in our study (9.5%) than in most studies (less than 5%) (18, 22, 25) but lesser than in Ziakas et al.'s (21) study (15.9%); however, the hematomas were mildly self-limiting in the follow-up period. Most hematoma cases were in the manual compression group, which could indicate ineffective and inappropriate bandage after primary homeostasis.

Study limitations

This study has some limitations. First, the number of studied cases was rather low, and the follow-up time was short. A single-center study design was also utilized. Second, hemostasis in patients requiring coronary angioplasty was not considered. Third, ultrasound was not used for accurate puncture site and post-procedure follow-up. Fourth, our experience was limited to two approaches, and other methods like elastic bandage were not used. A randomized clinical trial design is therefore recommended for future studies.

Conclusion

The results of our study showed that the use of manual compression approach in patients undergoing CAG by snuffbox method is safe and feasible and reduces hemostasis time when compared with mechanical compression approach.

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