Comparison of Radial Artery Occlusion Occurrence Between Compression Band Device and Manually Applied Gauze Compression After Transradial Coronary Procedure

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Abstract

INTRODUCTION: Hemostasis of the radial artery after transradial coronary procedure can be achieved either manually by means of a gauze or through a device compression band, and radial artery occlusion (RAO) is one of its common complications. The study sought to compare the occurrence of RAO between the two hemostasis methods being used after a transradial coronary procedure.

METHODS: This was a prospective, randomized, open-label, blinded endpoint study. A total of 137 patients undergoing a transradial coronary procedure were randomized equally using block randomization sampling technique. Radial artery patency was evaluated by color duplex ultrasonography within 24 to 72 hours after the procedure. The primary endpoint was early RAO. Secondary endpoints included complications such as access-site bleeding, pain, and hematoma.

RESULTS: Three (2.19%) early RAOs occurred: one (1.47%) in the band compression device group and two (2.9%) in the manual gauze compression group ($P = 1.000$). There were no significant differences between the two groups regarding access-site bleeding (type 1 bleeding, 3 [4.48%] vs 2 [2.90%]; $P = 0.678$), pain (median pain score of 0 [0–6] vs 0 [0–7]; $P = 0.742$), and hematoma (grade I: 3 [4.41%]vs 2 [2.9%]; grade II: 0 vs 2 [2.9%]; grade III: none, and grade IV: 0 vs 2 [2.9%]) ($P = 0.363$).

DISCUSSION: Compression band device and manually applied gauze compression have similar rates of early RAO, access-site bleeding, pain, and hematoma.

KEYWORDS: compression band device, hemostasis, manual gauze compression, radial artery occlusion

INTRODUCTION

Following the introduction of transradial coronary angiography by Campeau[1] in 1989, Kiemeneij et al[2] were the first to document coronary angioplasty and stenting via transradial approach (TRA) in 1993. Transradial catheterization for coronary angiography or coronary intervention is becoming increasingly popular, and its use has been expanding worldwide.[3] Transradial access has grown to become the default access site in the United Kingdom,[4–7] Europe, and Asia.[8] Transradial catheterization reduces the risk of vascular access complications and yields a good clinical outcome.[9,10] It was even associated with reduction in mortality in the setting of acute percutaneous coronary intervention as shown in the RIVAL (RadIal Vs femorAL access for coronary intervention) and RIFLE STEACS (Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome) studies.[11,12] It was also the preferred access of patients because of its convenience in terms of body pain, limitation of activities, and quality of life in 24 hours to a week after procedure.[13] However, TRA is not without challenges and complications. Transradial approach is technically more difficult with a longer learning curve and is associated with radial artery spasm and radial artery occlusion (RAO) particularly in females and elderly patients.[14,15]

One of the most common complication of TRA is RAO, which occurs in approximately 1% to 10% of cases.[16–19] Radial artery occlusion can be diagnosed through the use of color Doppler ultrasound, wherein absence of flow in the radial artery suggests occlusion.[20] In most cases, RAO occurs promptly after the procedure, and up to 50% of patients have spontaneous recanalization of the artery within 1 to 3 months.[20,21] Stella et al[17] found a 5.3% rate of RAO at the time of hospital discharge in a study of 563 patients who underwent transradial artery coronary angioplasty. The incidence of RAO, reported in a systematic review and meta-analysis that included 66 studies, was reported as 7.7% among those evaluated for RAO within 24 hours, 9.5% when evaluated more than 1 day but less than 1 week, and 5.56% for those evaluated more than 1 week.[22] In yet another study by Petroglou et al[23] comparing the occurrence of early RAO, 12% early RAO occurred in the manual group, whereas 8% occurred in the mechanical group. However, one practice survey showed that more than half of operators do not even assess radial artery patency before discharge.[24]

Patient's baseline characteristics (such as sex, age, and diabetes) and procedural characteristics (such as sheath size and its relation to radial artery diameter), as well as the utilization of specific pharmacological agents (such as anticoagulants and vasodilators), were identified by Avdikos et al[25] as factors predisposing to RAO. Other studies attempted to reduce RAO through different protocols of hemostasis, and results were variable, and many hemostasis devices and protocols were used.[26–29]

This study then had the general objective of comparing the two existing methods of hemostasis after a transradial procedure: the compression band device and manually applied gauze compression in terms of the incidence of early RAO. Specific objectives were to determine early RAO among all patients who underwent transradial procedures and to identify other complications such as pain, bleeding, or hematoma.

By comparing outcomes in terms of RAO and other associated complications between these two techniques, both with its pros and cons, we can recommend the more effective hemostasis method, with safer profile.

METHODS

This was conducted in compliance with the ethical principles set forth in the Declaration of Helsinki. Prior to the study initiation, the protocol was reviewed and approved by the Philippine Heart Center Institutional Ethics Review Board. Before a subject's participation, a written informed consent was obtained by the investigator from the patient.

This was a prospective, randomized, open-label, blinded endpoint study done at the our institution from June 14, 2021, to August 30, 2021. Baseline characteristics were initially taken such as age, gender, height, weight, body mass index, comorbidities (such as hypertension, diabetes, chronic kidney disease), and procedural-related characteristics (such as the type of procedure whether coronary angiogram or angioplasty, time of procedure, and use of medications intravascularly, dilators, and sheath size) were also noted prior to the procedure. Modified Allen test was done in all patients prior to enrollment. Consecutive patients who were admitted for a transradial coronary artery procedure were enrolled if they fulfill the following criteria: (1) 19 years or older; chronic kidney disease; (2) elective inpatient transradial coronary procedure either angiogram or angioplasty; and chronic kidney disease; (3) informed consent given by the patient. Patients were excluded to participate in the study if they have retained sheath for whatever reason, the radial artery was punctured without successful insertion of sheath and guide catheters and was shifted to another access site, the patients have more than one puncture on the same radial access site, they have known previous anatomic abnormality in the hand or hematologic problems, they failed the Allen test prior to the procedure, they have a previous ipsilateral transradial access, and if they are maintained on oral warfarin or novel anticoagulants. Block randomization sampling technique was used with a total of 14 blocks with 10 participants each who were randomly and equally assigned to either the band compression device using Terumo TR Band (Terumo Medical Corporation) group or the manual gauze compression group. Allocation concealment was ensured by use of sealed opaque envelopes containing the assigned compression technique from which the patients picked to determine their group. Details of the application and removal of the two methods of hemostasis mentioned are described in Appendix A.

The primary endpoint of the study was the incidence of early RAO. Radial artery occlusion was confirmed by the absence of anterograde flow in the radial artery while compressing the

ipsilateral ulnar artery using Philips Epiq 7 and Philips IU22 color Doppler ultrasound at the vascular laboratory. Color duplex ultrasound studies were performed in all patients within 24 to 72 hours following the procedure by a vascular technician who was blinded to the method of hemostasis applied. All images obtained from the study participants were stored in an external drive and were interpreted at once by the vascular consultant who was also blinded as to the method of hemostasis applied. Intraobserver variability in the interpretation of ultrasound result was prevented by letting the vascular consultant read 10 results again without knowing that these results were already read. Secondary endpoints included occurrence of access-site bleeding using the Bleeding Academic Research Consortium score, pain using a pain scale of 1 to 10, and hematoma, which was recorded via photographs and was interpreted by a dedicated invasive cardiology consultant who was also

blinded as to the hemostasis method used, by utilizing the Early Discharge After Transradial Stenting of Coronary Arteries Study hematoma scale.

A minimum of 136 patients were required for this study based on the RAO prevalence of 8% from the study by Petroglou et al[23] in 2018; 20% dropout rate, with 5% level of significance, and margin of error that equals half-width of confidence interval were computed using G*Power 3.1.9.2 (Heinrich Heine University, Dusseldorf, Germany) (Figure 1).[30]

Descriptive statistics was used to summarize the demographic and clinical characteristics of the patients. Frequency and proportion were used for categorical variables, median and interquartile range for non–normally distributed continuous variables, and mean and SD for normally distributed continuous

Figure 1. Study flow diagram.
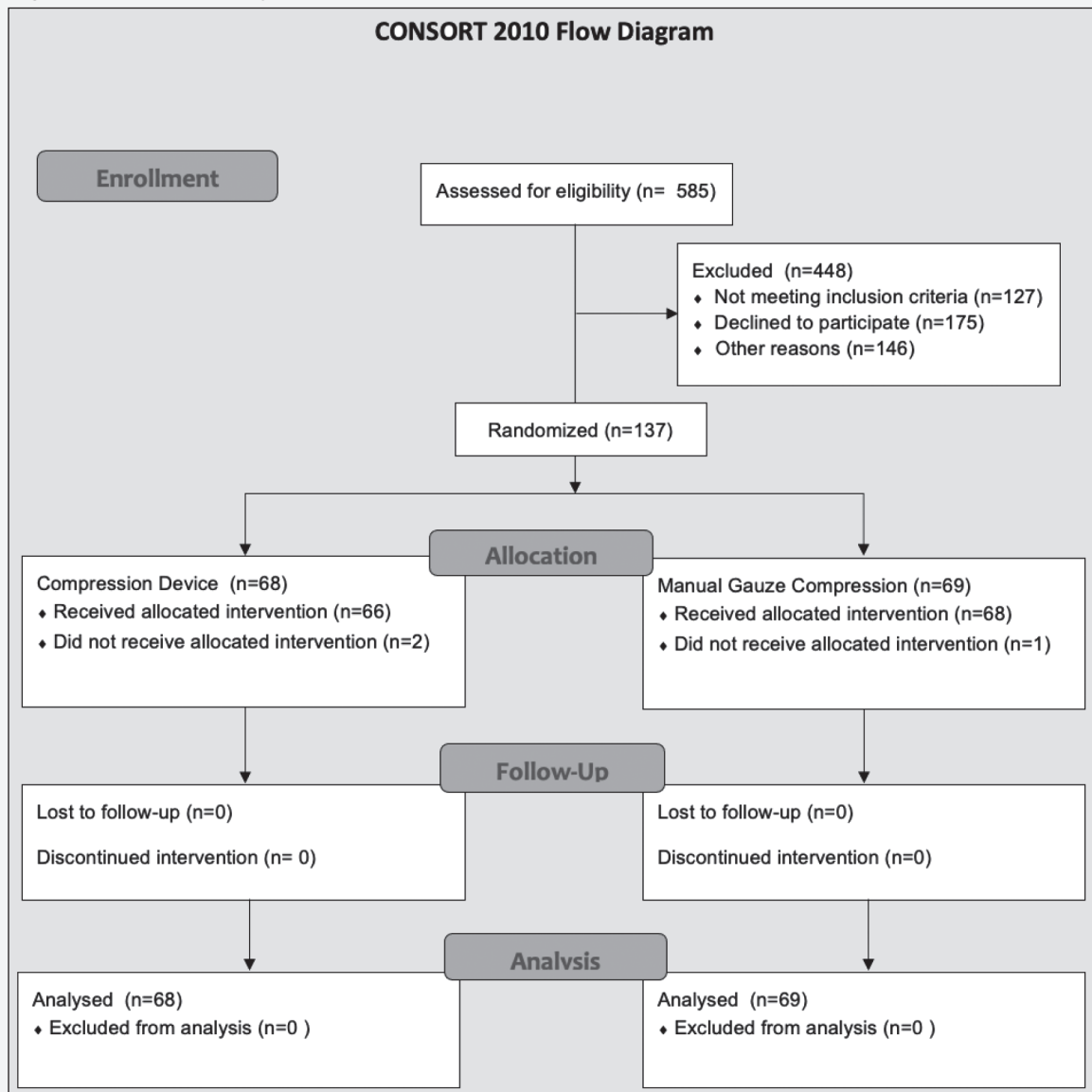
Table 1. Demographic and Clinical Profile of the Patients

	Total (n = 137)	Band Compression Device (n = 68)	Manual Gauze Compression (n = 69)	P
	Frequency (%), Mean ± SD, Median (Interquartile Range)			
Age, y	57.51 ± 10.34	57 ± 10.67	58.01 ± 10.06	0.568
Sex				1.000
Male	106 (77.37)	53 (77.94)	53 (76.81)	
Female	31 (22.63)	15 (22.06)	16 (23.19)	
Height, m	1.63 ± 0.07	1.63 ± 0.08	1.64 ± 0.07	0.771
Weight, kg	70.67 ± 14.24	71.27 ± 14.84	70.07 ± 13.70	0.624
BMI, kg/m²	26.32 ± 4.47	26.54 ± 4.3	26.09 ± 4.65	0.560
Comorbidities				
Hypertension	77 (56.2)	42 (61.76)	35 (50.72)	0.229
Diabetes mellitus	46 (33.58)	22 (32.35)	24 (34.78)	0.857
CKD	1 (0.73)	0	1 (1.45)	1.000
Type of procedure				0.717
CA	93 (67.88)	45 (66.18)	48 (69.57)	
PCI	44 (32.12)	23 (33.82)	21 (30.43)	
Duration of procedure*	20 (11 to 45)	21.5 (11 to 41.5)	20 (12 to 47)	0.745
Premedications				
NTG, µg	100 (0 to 500)	100 (100 to 500)	100 (100 to 400)	0.560
Verapamil, mg	0.5	—	0.5	—
Heparin, 1000 units	3 (3 to 5)	4 (3 to 5.25)	3 (3 to 5)	0.244
Sheath size				0.745
5F	9 (6.57)	5 (7.35)	4 (5.8)	
6F	128 (93.43)	63 (92.65)	65 (94.2)	
Length of compression				<0.001
<4 h	50 (36.5)	50 (73.53)	0	
4–6 h	16 (11.68)	16 (23.53)	0	
>6 h	71 (51.82)	2 (2.94)	69 (100)	

BMI=body mass index; CA=coronary angiogram; CKD=chronic kidney disease; DSU=double setup (coronary angiogram with PCI); F=French; NTG=nitroglycerin; PCI=percutaneous coronary intervention.
*From time of sheath insertion up to removal of coronary diagnostic or guide catheter.

variables. Independent-samples t test, Mann-Whitney U test, and Fisher exact/χ^2 test were used to determine the difference of mean, rank, and frequency, respectively, between patients with compression band device versus manual gauze compression. All statistical tests were two-tailed tests. Intention-to-treat approach was used wherein all participants who were randomized were included in the statistical analysis and analyzed according to the group they were originally assigned, regardless of what treatment they actually received. Shapiro-Wilk was used to test the normality of the continuous variables. There were no missing variables in the study. Null hypothesis was rejected at 0.05 α-level of significance. STATA 13.1 (StataCorp LLC, College Station, Texas) was used for data analysis..

RESULTS
A total of 137 patients were randomized, and the final analysis included 68 patients in the band compression group and 69 patients in the manual gauze compression group. Baseline demographics, medical history, treatment, and procedural characteristics were homogenous in both groups with the exception of length of compression, which was significantly shorter in the compression band device group (Table 1). The primary endpoint, occurrence of RAO 24 to 72 hours after the procedure, was similar (P = 1.000) between the band compression device group (n = 1 [1.47%]) and the manual gauze compression group (n = 2 [2.9%]). Compression band device and manual gauze compression showed no significant differences in the secondary endpoints as follows, respectively: access-site bleeding (type 1 bleeding, 3 [4.48%] vs 2 [2.90%]; P = 0.678), median pain score of 0 (0–6) versus 0 (0–7) (P = 0.742), and hematoma (grade I: 3 [4.41%] vs 2 [2.9%]; grade II: 0 vs 2 [2.9%]; grade III: none, and grade IV: 0 vs 2 [2.9%]) (P = 0.363) (Table 2). There were no crossovers or

Table 2. Outcomes of Patients Who Underwent Transradial Approach

	Total (n = 137)	Band Compression Device (n = 68)	Manual Gauze Compression (n = 69)	P
	Frequency (%), Median (Range)			
Primary Outcome				
No RAO Early RAO	134 (97.81) 3 (2.19)	67 (98.53) 1 (1.47)	67 (97.1) 2 (2.90)	1.000
Secondary Outcome				
Pain score	0 (0–7)	0 (0–6)	0 (0–7)	0.742
Type 1 bleeding	5 (3.68)	3 (4.48)	2 (2.90)	0.678
Hematoma None Grade I Grade II Grade III Grade IV	 128 (93.43) 5 (3.65) 2 (1.46) 0 2 (1.46)	 65 (95.59) 3 (4.41) 0 0 0	 63 (91.3) 2 (2.90) 2 (2.90 0 2 (2.90)	0.363

RAO=radial artery occlusion.

switching between the two methods of hemostasis during the conduct of this study.

DISCUSSION
Our study aimed to compare the occurrence of early RAO between compression band device and manual gauze compression after a transradial coronary procedure, as well as presence of access-site bleeding, pain, and hematoma. At our institution, manual gauze compression is currently part of the standard option for times when compression band device is not available or when patients are financially constrained.

To our knowledge, besides this present study, there is only one randomized controlled trial published, called the MEMORY trial, that similarly compared manual and mechanical hemostasis after transradial coronary angiography. And in the Philippines, thus far, this study is the first and only one randomized controlled trial to compare the safety and efficacy of these two methods of hemostasis.[23,26,30–33]

Results of the study showed that within 24 to 72 hours after the procedure, the occurrence of overall early RAO was 2.19%. Comparing the two methods of hemostasis, no significant difference was noted in the occurrence of early RAO between compression band device (1.47%) and manual gauze compression (2.9%). Moreover, incidence of access-site bleeding, pain, or hematoma was similar in both groups.

The primary endpoint, which is the occurrence of early RAO between the two methods of hemostasis, showed no significant difference, which is in line with the findings of Petroglou et al.[23] The overall early RAO, however, was low compared with previous studies mentioned.[1–7,22,24] This outcome may be affected by the smaller population of our study.

The secondary endpoints, which are the occurrence of access-site bleeding, pain, and hematoma between compression band device and manual gauze compression, also showed no significant differences and were also in keeping with the results of the MEMORY trial.[23]

Another finding in the study was that between the two methods of hemostasis, the length of compression was shorter in the compression band device compared with manual gauze compression, which contradicted the result of the MEMORY trial.[23] This can be explained by the differences in the manner of application and removal of manual gauze compression in our institution, which may vary in different catheter laboratories.

This study was done in a single center, limiting the number of study participants included. In addition, it was performed during the COVID-19 pandemic; hence, the results of the study included only early RAO because other findings that could be added such as late RAO and recanalization of those who had early RAO would require a patient to follow up, which may not be safe during this time. Lastly, only two methods of hemostasis were observed; other novel hemostasis techniques were not included because these are not available in our country.

Given the similar safety and efficacy profile between the two methods of hemostasis compared in this study, we can now recommend the use of manually applied gauze compression as an acceptable standard alternative of hemostasis after transradial coronary procedures.

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Appendix A. Step-by-Step Guide in the Application and Removal of Compression Band

I.   Manual Gauze Compression Using Cherry Band
   a.   Application
      The introducer sheath will be pulled out completely until some bleeding will be visible, to purge the prethrombotic and thrombotic material and establish radial artery flow as evidenced by mild bleeding at the site. Pressure over the puncture site using a manually applied rolled gauze with two layers (the first layer using one cherry, whereas the second layer using two cherries) will be held in place by 2-inch Leukoplast (3M) to achieve hemostasis. This will be performed by two operators.

   b.   Removal
      The top layer will be released after 4 hours, and the bottom layer will be removed after 6 hours. A light wound dressing will then be applied at the puncture site.

II. Device Compression Using TR Band
   a.   Application
      Upon completion of the procedure, withdraw the introducer sheath 2 to 3 cm. Apply the TR Band compression device by aligning the green marker, which is located on the center of the compression balloon 1 to 2 mm proximal to the puncture site, and fix the strap on the wrist with the adjustable fastener. The TR Band compression device should be fixed tight enough to prevent the band from spinning. This device must be positioned differently when used on the left or right wrist. When attaching the device, ensure that the Terumo logo on the support plate is closest to the patient's little finger. Slowly inject 15 to 18 mL of air while simultaneously removing the sheath. Air should be fully inserted when the sheath is completely removed with the goal for bleeding to cease when the sheath is completely removed. Begin titration of air to determine patent hemostasis by removing 1 mL per second while observing the access site for bleeding. When bleeding occurs, inject 1 to 2 mL of air until bleeding stops.

   b.   Removal
      Removal begins after 1 hour for patients who used heparin computed at 50 units/kg or less or after 2 hours for those who used greater than 50 units/kg. Remove 3 to 5 mL of air every 10 to 15 minutes. If bleeding occurs during removal, insert enough air to restore hemostasis. Wait for 15 to 30 minutes and then repeat the process of removing 3 to 5 mL of air every 10 to 15 minutes. Once air has been completely removed from the band, confirm that bleeding has stopped. Unfasten the adjusted band while stabilizing the access site with gentle pressure. Remove the band by lifting slowly toward the palm of the hand and then apply sterile dressing.