CLINICAL STUDY

A comparative study of TR Band and a new hemostatic compression device after transradial coronary catheterization

Yong Wang [#], Jing Tang [#], Jingwei Ni, Xin Chen, Ruiyan Zhang *

Abstract

Objective: Transradial coronary catheterization has proved to be safe and effective in clinical practice. Various hemostatic compressive devices have been used in subsequent procedures. The objective of this study was to compare the efficacy and safety of a new hemostatic compression device and the widely used TR Band.

Methods: A total of 118 patients were divided randomly into two groups: TR Band and the new hemostatic compression device. Efficacy of hemostasis, patient comfort, local vascular dysfunction, and radial artery occlusion (RAO) were evaluated and compared between groups.

Results: Occurrence of errhysis or hematoma did not significantly differ between groups (13.6% vs. 11.9%, P = 0.782). Fewer patients had moderate to severe pain or moderate to severe numbness in the new hemostatic compression device group (1.7% vs. 22.0%; 1.7% vs. 18.6%, respectively). Pulse loss between distal artery and device was lower in the new hemostatic compression device group (5.1% vs. 22.0%, P = 0.007), and fewer patients experienced obstruction of venous reflux compared with the TR Band group (6.8% vs. 25.4%, P = 0.006). Combined incidence of RAO at discharge was 7.6%, and was lower in the new hemostatic compression device group (1.7% vs. 13.6%, P = 0.015). In contrast to the TR Band, application of the new hemostatic compression device was independently associated with lower incidence of RAO at discharge (odds ratio: 0.062, 95% confidence interval: 0.006–0.675, P = 0.022).

Conclusions: Both the new hemostatic compression device and the TR Band can efficiently achieve hemostasis following transradial coronary catheterization. However, fewer patients felt discomfort with application of the new hemostatic compression device. Pulse loss in the artery distal to the compression device, obstruction of venous reflux, and RAO occurred significantly less often with application of the new device.

Keywords: transradial coronary catheterization; hemostatic compression device; radial artery occlusion

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INTRODUCTION

The traditional site of vascular access for coronary angiography or angioplasty has been through the femoral artery, and the vast majority of coronary procedures were performed this way previously (1,2). However, this can also potentially cause vascular complications, such as pseudoaneurysm, arteriovenous fistula, and most seriously, retroperitoneal bleeding (3). In 1989, Campeau (4) introduced transradial access (TRA) for performing coronary angiography, and in 1993, Kiemeneij and Laarman (5,6) reported his experience with coronary angioplasty through the radial route. The transradial route is increasingly popular, with the primary advantages of allowing earlier mobilization of patients post procedure and significantly less vascular complications compared with transfemoral access (7,8).

As the arterial sheath can be removed immediately after the procedure, with mechanical compression applied over the puncture site of the radial artery, early hemostasis can be achieved. This allows early mobilization and discharge from hospital (9). Several types of hemostatic compression devices have been used, and proved effective and safe. The TR Band is produced by Terumo in Japan, and is now commonly used in China to assist in hemostasis of the radial artery after a transradial procedure. By injecting a certain volume of air into the transparent balloon in the TR Band, the radial artery is compressed and hemostasis is achieved (10,11). However, because the wrist size of patients varies, the fixed volume of air may produce differing pressures on wrists, resulting in unstable efficacy of compression. A newly designed radial compression device that injects air to the balloon with a particular pressure may supply stable and appropriate compression, and seems to be promising in clinical practice. The objective of our study was to compare the effect of this new hemostatic compression device with the TR Band on efficacy of hemostasis, patient comfort, local vascular dysfunction, and radial artery occlusion.

MATERIALS AND METHODS

Study subjects

The enrolled patients were hospitalized at the cardiology department in Shanghai Rui Jin Hospital during June and July 2018. Patients with suspected or established stable coronary artery disease were considered for coronary angiography and intervention through the transradial route. Exclusion criteria included acute infectious disease, acute myocardial infarction, uremia, mental disorder, thrombocytopenia, hemorrhagic disease, forearm arteriovenous fistula, or history of previous ipsilateral transradial procedure. Each patient received an Allen's test, but was not excluded on the basis of an unfavorable result. The study complied with the Declaration of Helsinki and was approved by the ethics committee of Shanghai Jiao Tong University. Informed consent was obtained from the patients prior to enrollment.

Study design

For this prospective randomized study the patients were divided randomly into two groups according to radial compression device before procedure: a TR Band group (Terumo, Japan) and a group receiving the new hemostatic compression device. Randomization was performed using computer-generated random numbers. All procedures were performed by the same two interventional cardiologists at a single cardiac catheterization laboratory under similar operating conditions. Radial hemostatic compression devices were applied following coronary catheterization. During and following the hemostatic compression, the outcomes were recorded.

Study outcome

The outcome evaluation included efficacy of hemostasis, patient comfort, local vascular dysfunction, and radial artery occlusion (RAO). Efficacy of hemostasis was assessed by whether patients had errhysis or hematoma during and following the hemostatic compression. Patient comfort was evaluated by whether the patients had pain or a feeling of numbness around the puncture site during hemostatic compression. Pain levels were graded as no pain, mild pain, or moderate to severe pain. Feeling of numbness was graded as no numbness, mild numbness, or moderate to severe numbness. Local vascular dysfunction was judged by pulse loss in the distal artery to the hemostatic compression device or obstruction of venous reflux during hemostatic compression. RAO at discharge was confirmed by the absence of palpable radial artery pulsation and one of the following two verification tests: abnormal reverse Allen's test or absent Doppler flow signal on hand-held Doppler.

Clinical data collection

Clinical characteristics were obtained by hospital chart review and patient interview. Body mass index (BMI) was calculated as body weight in kilograms divided by body height in meters squared (kg/m^2). Current smoking was defined as smoking currently and smoking more than one cigarette daily for at least one year continuously. Patients with total cholesterol ≥ 5.7 mmol/L, or low-density lipoprotein cholesterol ≥ 3.6 mmol/L, or triglyceride ≥ 1.7 mmol/L, or receiving treatment with antihyperlipidemic agents due to hyperlipidemia were considered as having a history of lipid disorder. Hypertension was diagnosed as systolic blood pressure (SBP) ≥ 140 mmHg, or diastolic blood pressure (DBP) ≥ 90 mmHg, or when patients were being actively treated with anti-hypertension drugs. Diabetes mellitus was diagnosed by a fasting plasma glucose test showing ≥ 7.0 mmol/L, or by a random plasma glucose test showing ≥ 11.1 mmol/L, or when patients were actively receiving therapy using insulin or oral medications for diabetes.

Procedures

The radial artery was punctured with a 21-gauge arterial needle before transradial coronary catheterization was performed. The needle was then withdrawn and a 6F introducer sheath inserted through the guidewire. All introducer sheath kits used were from the same manufacturer (Terumo, Japan). The remaining procedures were performed according to the operator's preference. All patients received intravenous heparin after sheath insertion, using 70 U/kg for diagnostic procedures. Additional heparin was given for percutaneous coronary intervention (PCI) if needed.

Hemostatic device application

The introducer sheath was removed when the procedure was finished, and hemostasis compression was simultaneously applied using either TR Band (Figure 1A) or the new hemostatic compression device (Figure 1B), according to randomization. The TR Band was applied according to the manufacturer's instructions. A volume of 14–16 mL of air was injected slowly to the balloon according to the patient's wrist size, while simultaneously removing the sheath. When the air was fully inserted, the sheath was completely removed. Reduction in compressive pressure was started 4 hours after the procedure; thereafter operators removed 2 mL air every 2 hours until hemostasis was achieved, and the device was then removed. Similarly, the new hemostatic compression device (Shanghai KDL medical instrument company, China) was used according to the manufacturer's instructions. Air was injected slowly to the balloon until a pressure of 250 mmHg was achieved, guided by a pressure indicator. When the air was fully inserted, the sheath was removed. Reduction in compressive pressure was started 4 hours after the procedure. Operators subsequently removed 1 mL of air every 2 hours until hemostasis was achieved, and the device was then removed.

Before clinical application of the new hemostatic compression device, a series of experiments was performed to test the efficacy of hemostatic compression. From injection of air into the balloon in the band, air pressure in the balloon was produced

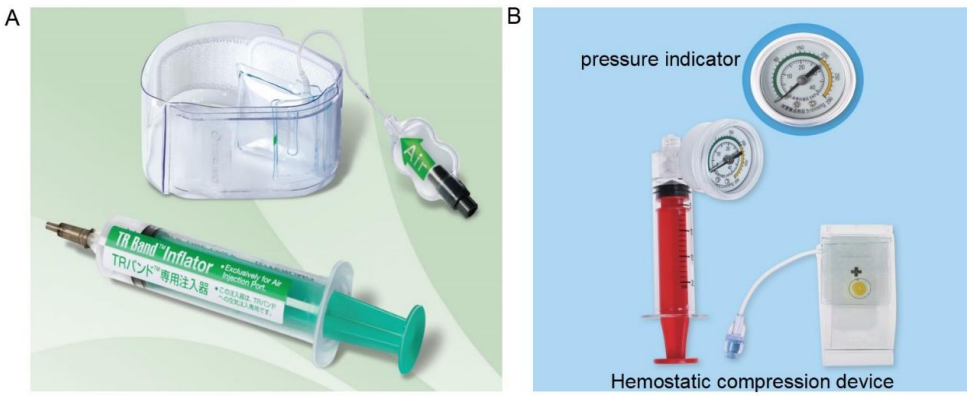

Figure 1. (A) TR Band. The band and injector are included. (B) New hemostatic compression device. The injector, pressure indicator, and band are included.

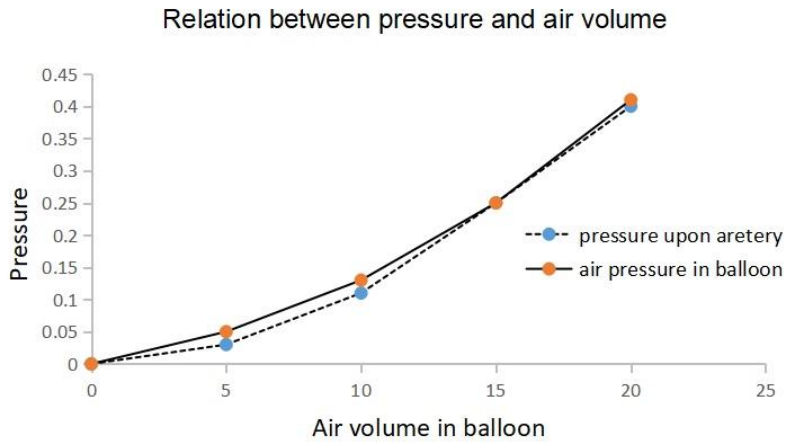

Figure 2. Air pressure in balloon and actual pressure on artery according to balloon air volume.

followed by pressure on the artery. To study air pressure changes in the balloon and actual pressure on the artery following the use of different air volumes in the balloon, an experiment was conducted, with results data shown in Figure 2. An understanding of the relationships between balloon air volume, balloon air pressure, and actual pressure on the artery assisted in the design of the pressure indicator and the new hemostatic compression device.

Statistical analysis

Data were analyzed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA) software. Continuous variables with a normal distribution were expressed as mean ± standard deviation, and variables with a skewed distribution were reported as median (interquartile range). Categorical variables were expressed as frequency and percentage. The chi-square test was used to compare categorical variables between several groups. The independent-sample *t* test or Mann-Whitney U test were used to compare continuous variables with normal or skewed distribution between two groups, respectively. Multiple logistic regression analysis was used to assess the independence of the association between risk factors and RAO. The odds ratio (OR) and 95% confidence interval (CI) were calculated. Two-sided $P < 0.05$ was considered significant.

RESULTS

Baseline Characteristics

A total of 133 consecutive hospitalized patients were screened and 118 patients were finally included in the study. Fifteen patients were excluded because they had undergone a previous ipsilateral transradial procedure. The average age was 64.5 ± 10.4 years. Seventy-nine patients (66.9%) were male. The demographic and clinical features of the patients, according to radial compression device, are shown in Table 1. The data suggested that patient age, gender, height, weight, body mass index, blood pressure, heparin dosage, hypertension, prevalence of diabetes mellitus and lipid disorders, current smoking status, and prevalence of PCI were similar in both groups. PCI prevalence was 39.0% (46 patients) and the other 72 patients received only coronary angiography.

Efficacy of hemostasis

The total proportion of patients developing errhysis or hematoma during and following hemostatic compression was 12.7% (Table 2), and was not significantly different between the two groups (13.6% vs. 11.9%, P = 0.782).

Patient comfort during hemostatic compression

Pain levels differed significantly between the two groups (Figure 3; P = 0.003), with more patients in the new hemostatic compression device group experiencing no pain than in the TR Band group (40.7% vs. 33.9%). Less participants in the new hemostatic compression device group experienced moderate to severe pain than in the TR Band group (1.7% vs. 22.0%).

Table 1 Clinical characteristics of study patients according to hemostatic compression device

Variable*	All (n=118)	TR Band (n=59)	New hemostatic compression device (n=59)	*P* value
Age (years)	64.5±10.4	64.5±9.73	64.5±11.1	0.965
Men (n, %)	79 (66.9%)	40 (67.8%)	39 (66.1%)	0.845
Height (m)	1.66±10.2	1.68±7.92	1.65±11.9	0.162
Weight (kg)	69.5±12.2	71.5±12.0	67.6±12.3	0.091
BMI (kg/m^2)	25.3±5.09	25.5±3.98	25.1±6.03	0.727
Heparin dose (U)	3000 (3000–7000)	5000 (3000–7000)	3000 (3000–7000)	0.150
Systolic BP (mmHg)	131.6±23.1	133.8±23.8	129.4±22.5	0.310
Diastolic BP (mmHg)	75.2±9.46	75.7±9.82	74.8±9.15	0.608
Current smoking (n, %)	10 (8.5%)	5 (8.5%)	5(8.5%)	1.000
Diabetes mellitus (n, %)	34(29.1%)	19(32.2%)	15 (25.9%)	0.450
Hypertension (n, %)	79 (66.9%)	44 (74.6%)	35 (59.3%)	0.078
Lipid disorders (n, %)	43 (36.4%)	21 (35.6%)	22 (37.3%)	0.848
PCI (n, %)	46 (39.0%)	25 (42.4%)	21 (35.6%)	0.450

BMI: body mass index; BP: blood pressure; PCI: percutaneous transluminal coronary intervention.
*Values are mean ± standard deviation, median (interquartile range), or n (%).

Table 2 Local vascular outcome during and following the application of hemostatic compression devices

Variable	All (n=118)	TR Band (n=59)	New hemostatic compression device (n=59)	*P* value
Errhysis or hematoma (n, %)	15 (12.7%)	8 (13.6%)	7 (11.9%)	0.782
Loss of pulse in artery distal to hemostatic compression device (n, %)	16 (13.6%)	13 (22.0%)	3 (5.1%)	0.007
Obstruction of venous reflux (n, %)	19 (16.1%)	15 (25.4%)	4 (6.8%)	0.006
RAO at discharge (n, %)	9 (7.6%)	8 (13.6%)	1 (1.7%)	0.015

RAO: Radial artery occlusion.

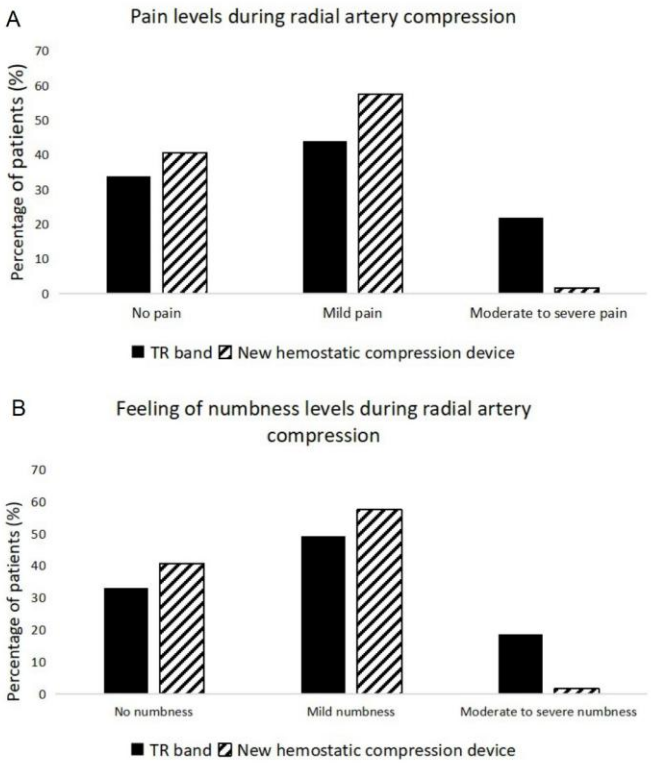

Figure 3. Patient discomfort during application of the hemostatic compression devices. A: Comparison of pain levels in patients with the new hemostatic compression device and the TR Band (P = 0.003). B: Comparison of feeling of numbness in patients with new hemostatic compression device applied and those with the TR Band (P = 0.010).

Table 3 Clinical characteristics of study patients with or without RAO at discharge

Variable	All (n=118)	With RAO (n=9)	Without RAO (n=109)	*P* value
Age (years)	64.5±10.4	64.4±7.32	64.5±10.6	0.987
Men (n, %)	79 (66.9%)	6 (66.7%)	73 (67.0%)	0.985
Height (m)	1.66±10.2	1.68±8.25	1.66±10.3	0.571
Weight (kg)	69.5±12.2	72.9±15.2	69.3±12.0	0.395
BMI (kg/m2)	25.3±5.09	25.2±5.07	25.9±5.65	0.719
Heparin dosage (U)	3000 (3000–7000)	3000 (3000–3000)	5000 (3000–7000)	0.014
Systolic BP (mmHg)	131.6±23.1	128.2±20.1	131.9±23.4	0.650
Diastolic BP (mmHg)	75.2±9.46	77.7±12.2	75.0±9.23	0.420
Current smoking (n, %)	10 (8.5%)	0 (0.0%)	10 (9.2%)	0.342
Diabetes mellitus (n, %)	34 (29.1%)	5 (55.6%)	29 (26.9%)	0.068
Hypertension (n, %)	79 (66.9%)	8 (88.9%)	71 (65.1%)	0.145
Lipid disorders (n, %)	43 (36.4%)	4 (44.4%)	39 (35.8%)	0.604
PCI (n, %)	46 (39.0%)	1 (11.1%)	45 (41.3%)	0.074
New hemostatic compression device (n, %)	59 (50.0%)	1 (11.1%)	58 (53.2%)	0.015

RAO: Radial artery occlusion; BMI: body mass index; BP: blood pressure; PCI: percutaneous transluminal coronary intervention.
Values are mean ± standard deviation, median (interquartile range), or n (%).

Numbness level during radial artery compression was significantly different between groups (Figure 3; P = 0.010). More patients experienced no numbness in the new hemostatic compression device group compared with the TR Band group (40.7% vs. 32.2%). Moderate to severe numbness was reported less often in the new hemostatic compression device group than in the TR Band group (1.7% vs. 18.6%).

Local vascular dysfunction during hemostatic compression

The proportion of patients experiencing pulse loss in the artery distal to the new hemostatic compression device was 13.6% (Table 2). There were fewer patients in the new hemostatic compression device group experienced pulse loss than in the TR Band group (5.1% vs. 22.0%, P = 0.007).

Obstruction of venous reflux was experienced by a total proportion of 16.1% of the patients. Significantly fewer patients in the new hemostatic compression device group experienced obstruction of venous reflux than in the TR Band group (6.8% vs. 25.4%, P = 0.006).

Incidence of radial artery occlusion at discharge

RAO at discharge was experienced by 7.6% of the patient total (Table 2), with fewer patients in the new hemostatic compression device group experiencing RAO than in the TR Band group (1.7% vs. 13.6%, P=0.015).

Clinical characteristics associated with RAO at discharge

Age, gender, height, weight, BMI, blood pressure, hypertension, lipid disorders, and current smoking prevalence were similar in patients with and without RAO (Table 3). Patients with RAO at discharge received less heparin during percutaneous coronary catheterization compared with those without RAO at discharge (P = 0.014), and fewer patients receiving the new hemostatic compression device following percutaneous coronary catheterization experienced RAO (11.1% vs. 53.6%, P = 0.015). Diabetes mellitus prevalence and prevalence of patients receiving PCI was higher in patients with RAO at discharge, although the difference was not significant (P = 0.068, and P = 0.074 respectively).

Multiple regression analysis was used to confirm the independent risk factors associated with RAO at discharge. Basic demographic data such as age and gender were entered into the logistic regression equation. At the same time, discrepant risk factors (P < 0.10) between two groups were screened using univariate analysis and also entered into the multiple regression analysis. Lower heparin dosage (OR: 0.998, 95% CI: 0.996–1.000, P = 0.034) and diabetes mellitus (OR: 7.122, 95% CI: 1.225–41.411, P = 0.029) were independently associated with RAO at discharge (Table 4). However, application of the new hemostatic compression device was independently associated with low incidence of RAO at discharge (OR: 0.062, 95% CI: 0.006–0.675, P = 0.022).

Table 4 Independent risk factors associated with RAO at discharge

Variable	OR*	95% CI	*P* value
Age (per year)	0.981	0.887–1.084	0.702
Men (1=no, 2=yes)	1.055	0.182–6.105	0.953
Heparin dosage (per U)	0.998	0.996–1.000	0.034
Diabetes mellitus (1=no, 2=yes)	7.122	1.225–41.411	0.029
PCI (1=no, 2=yes)	36.632	0.425–3154.345	0.113
New hemostatic compression device (1=no, 2=yes)	0.062	0.006–0.675	0.022

CI: confidence interval. PCI: percutaneous transluminal coronary intervention.
*Multiple logistic regression analysis was used to calculate the odds ratio (OR) of various risk factors associated with RAO (radial artery occlusion).

DISCUSSION

Various types of radial hemostatic compression device have been used following percutaneous coronary catheterization and have proved effective, safe, and well tolerated. Previous studies have compared efficacy of hemostasis, patient comfort, and local vascular complications among hemostatic compression device types (9-11). Through its transparent structure designed for visual control and selective compression of the radial artery to allow blood return and preserve patency, the TR Band assists in maintaining radial artery patency at the time of hemostasis in order to prevent future RAO and canoften produce optimal patient comfort (10,11). A previous comparative study indicated that the TR Band performs well compared with other hemostatic compression devices (10). A new type of radial compression device designed to inject air at a particular pressure has been produced, with the intention of providing stable and appropriate compression on the puncture site. To our knowledge, this is the first randomized trial evaluating the efficacy and tolerance of this new radial compression device by comparing it with the commonly used TR Band.

Many studies have proved that the TR Band can efficiently assist in achieving hemostasis. The incidence of bleeding, including errhysis or hematoma, during application of TR Band radial compression was 14.2%–26.3% in previous studies (10,12,13). Our study indicated that 13.6% of patients developed errhysis or hematoma with application of the TR Band; a similar proportion of patients were detected with errhysis or hematoma (11.9%) following application of the new hemostatic compression device. Our study data suggested that both of these hemostatic compression devices were effective in achieving hemostasis.

In our study, the new hemostatic compression device supplied excellent patient comfort, with more patients experiencing no pain or feelings of numbness in the new hemostatic compression device group, compared with the TR Band. Improvements to patient comfort such as this are beneficial in alleviating suffering. Although in the application of the TR Band 14–16 mL of air is injected into the balloon according to the size of the patient's wrist, the pressure on the puncture site fluctuates, varying widely among patients. Thus, the band may be tight in some patients and loose on others. This instability condition may cause patient discomfort. However, with the new hemostatic compression device, a specific pressure of air is injected into the balloon for a precise fit and optimal patient comfort.

Pulse loss in the artery distal to the hemostatic compression device and obstruction of venous reflux was significantly lower with the new device. A volume of air that is virtually fixed is injected into the balloon when applying the TR Band, and thus the band may be very tight if the band is tied too tightly or the patient's wrist is big. As a result, too much compression on the radial artery may cause loss of arterial pulse distal to the hemostatic compression device. Simultaneous obstruction of venous reflux also tended to occur. Too much compression on the artery and vein may cause patient discomfort and increase the risk of local vascular complications (14).

RAO is one of the few postprocedural complications of TRA for diagnostic and interventional procedures. Previous studies have reported RAO rates ranging from 3% to 12% (7,12,15). Data in our study suggested that a lower heparin dose and diabetes mellitus were independently associated with RAO at discharge. These results were consistent with the results of a previous study, which also demonstrated that diabetes mellitus was independently associated with RAO (16). Several studies have shown that heparin use helps to reduce the occurrence of RAO (10,14,16). Heparinization, when safe, is important and probably aids recanalization after an

occlusive hold, by making the local environment less thrombotic.

In our study, in contrast to the TR Band, the application of the new hemostatic compression device was independently associated with lower incidence of RAO at discharge, with adjustment for potential confounders. Excessive compression on the radial artery tended to be avoided because a fixed pressure, but not fixed volume, of air was injected into the balloon when the device was applied. In fact, a previous study proved that use of pneumatic compression guided by mean blood pressure can significantly lower the incidence of RAO (12). The related mechanism is similar.

In summary, both the new hemostatic compression device and the TR Band can efficiently achieve hemostasis following transradial coronary catheterization. However, fewer patients felt discomfort with application of the new hemostatic compression device. Pulse loss in the artery distal to the compression device, obstruction of venous reflux, and RAO were significantly lower with the new device.

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