A comparative study of Terumo radial Band® and PreludeSYNC hemostasis compression device after transradial coronary catheterization

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Abstract

Objective: Novel hemostasis strategies, including PreludeSYNC DISTAL, Merit Medical Systems, Inc. South Jordan, UT, USA (PSD) radial compression device for distal radial artery (DRA) access, have been described for radial access protocols. This study aimed to compare the safety profile of PSD and Terumo radial (TR) Band®.

Methods: This prospective interventional study was conducted on patients who underwent coronary interventions via either the DRA or forearm radial artery (FRA). Patients with an arterial diameter of <2 mm, requiring dialysis, with unstable acute coronary syndrome, failed radial cannulation, and sheath insertion were excluded. PSD and TR Band® were used for hemostasis after DRA and FRA access, respectively. The time to hemostasis and complications, including minor/major hematoma, radial artery occlusion (RAO), and neurological symptoms (after 20 days) were recorded. The mean and standard deviation were calculated for age and hemostasis duration. Frequency and percentages were calculated for categorical variables. Independent t-test and Chi-squared test were performed to determine the significance of the differences between the two groups. A p-value of <0.05 was significant.

Results: Of 139 participants, TR Band® and PSD were used in 76 and 63 patients, respectively. The mean age of the participants was 58.70±10.00 years, and the majority of the patients were men (67.60%). The hemostasis time of both devices was similar (p>0.490). Compared with PSD, TR Band® had more complications (52.63% vs. 23.81%; p=0.020), particularly RAO [odds ratio (OR), 3.17; p=0.018] and neurological problems (OR, 5.33; p=0.005).

Conclusions: Although, PSD seems safer in patients with coronary interventions, the device should further be explored in crossover trials for the two access types to determine the overall safety profile.

Key words: TR Band®, PreludeSYNC, radial artery compression device, radial artery occlusion

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Introduction

The use of radial first strategy as the norm for coronary angiography and percutaneous coronary intervention (PCI) has significantly increased in the last decade (1, 2). Its use currently exceeds >70% of the arterial access during coronary procedures (3). Before the advent of coronary catheterization, the transfemoral approach was the main access site. However, many studies have indicated that the transradial approach is beneficial in terms of complications, patient comfort, hospital stay, and prognosis (4, 5). The major disadvantage with this access is radial artery occlusion (RAO), which can occur with or without symptoms. Its incidence was reported to be 0.8% to 30% (6). Factors, such as long hemostasis time and sheath size, are responsible for RAO (7). Using a smaller sheath size and a device that shortens the hemostasis time can effectively prevent RAO (8, 9).

Within radial access protocols, various hemostasis strategies have been described using a variety of focused band-type compression devices and inflatable balloon-type compression plates over the radial artery puncture sites. Recently, a new approach of balloon inflation at the anatomical snuffbox has been made available for radial artery hemostasis. The Prelude-

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HIGHLIGHTS

- This study highlights one of the novel strategies of distal radial artery access using a relatively new device, the PreludeSYNC DISTAL radial device.
- There is a comparison of the two access sites with two different radial compresson devices (the PreludeSYNC DISTAL and TR Band®).
- PreludeSYNC DISTAL radial compression device is not only safe but appears to be superior in terms of complicaitons and patietn safety.

SYNC DISTAL radial compression device (PSD; Merit Medical Systems, Inc., South Jordan, UT, USA) was developed exclusively for the distal radial artery (DRA) approach. The device has been in use since February 2019 in the United States and Japan. It is a disposable hemostatic device used to compress the DRA site with an inflatable balloon like the Terumo radial (TR) Band® radial compression device. Effectiveness in terms of complications and hemostasis time has not been well established between the two devices.

In this study, the outcome of the PSD was compared with the TR Band® Radial compression device (Terumo Medical Corporation, Somerset, NJ, USA) for associated complications of the radial artery approach prospectively. To the best of our knowledge, this is the first study to compare these two hemostatic devices in terms of safety profile after coronary catheterization procedures.

Methods

This was a prospective observational study conducted at our institute. All patients provided informed written consent, and Institutional Ethical Board approval was granted before data collection. Patients who underwent coronary angiography or angioplasty via DRA or the conventional approach of the forearm radial artery (FRA) for the first time were enrolled for 6 months between January 2020 and June 2020. Routine indication was applied for all the procedures according to institutional guidelines. The arterial diameter of the DRA and FRA was measured using vascular ultrasound. Patients with an arterial diameter of <2 mm were excluded. Those requiring dialysis and with acute coronary syndrome leading to emergency PCI, failed radial cannulation, or sheath insertion were excluded.

After administration of local anesthesia, a disposable needle was used to puncture the radial artery by using the Seldinger technique at the anatomical snuffbox. The hydrophilic wire and sheath were inserted carefully over the wire into the artery. A 5-Fr and 6-Fr sheaths (Radifocus® Introducer II Transradial Kit Introducer Sheath, Terumo Europe NV) were used for angiography and PCI/angiography, respectively. FRA was cannulated on the same principle as mentioned above. Unfractionated heparin was administered through the intravenous cannula. A standard dose of 5000 and 10,000 units was used for angiography and PCI, respectively. An additional 2000 units was administered hourly during PCI. Activated clotting time (ACT) was measured at sheath removal. The authors did not perform any procedure to eliminate bias.

PSD was used for hemostasis after coronary intervention in the DRA access and the TR Band® after the FRA access. A set protocol was applied for both procedures to eliminate any negligence, and the staff was trained for 1 week on simulated patients. After cleaning the site with alcohol, PSD/TR Band® was applied to the puncture site, and the sheath was withdrawn at approximately 1 inch (2.54 cm). The balloon was inflated using a syringe based on the position of the anatomical snuffbox, and the band was wrapped between the forefinger and thumb. For the TR Band®, the sheath was removed from the FRA after inflation of 14–16 ml of air. After the sheath was fully removed, the inflated air volume was adjusted accordingly. PSD and TR Band® were removed after complete hemostasis was achieved. Time to hemostasis was recorded for each procedure.

Radial pulsation and noted complications were recorded after 1 day and 20 days after the procedure. At the 20-day follow-up, the patency of the radial artery was confirmed using vascular ultrasound. Time to hemostasis was defined as the period from sheath removal to PSD removal. A minor hematoma was defined as <2 cm without symptoms, and a major hematoma was defined as >2 cm with symptoms. RAO or the presence of an aneurysm or pseudoaneurysm was seen on ultrasound. Any neurological sequelae were defined as numbness or paresthesia on the hand or arm during radial artery compression after 1 day and at 20 days follow-up. Neurological dysfunction was assessed at the time of compression device in place, at device removal, and after 20 days follow-up. Any sensory and motor symptom, including paresthesia, numbness, and weakness of loss of power, was noted.

Statistical analysis was performed using Statistical Package for Social Sciences version 26 (IBM Corp., Armonk, NY, USA) software. Continuous variables were expressed as mean ± standard deviation. Kolmogorov–Smirnov and Shapiro–Wilk tests were applied for continuous variables to determine their distribution, and Mann–Whitney U test was used to test non-normally distributed continuous variables between the two groups [age, body mass index (BMI), ACT, and hemostasis time]. Frequency and percentages were calculated for categorical variables. Chi-squared test was used to compare categorical variables between the two groups. Odds ratio (OR) and 95% confidence interval were calculated for complications between the two groups. Two-sided $p<0.05$ was considered significant.

Results

This observational study included 139 patients. Table 1 shows the background characteristics and coronary catheterization procedures. The mean age was 58.7±10 years, and the majority of the patients were men (67.6%).

TR Band® and PSD were used in 76 (54.7%) and 63 patients (43.2%), respectively. The overall complication rate of the TR

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Table 1. Baseline characteristics and coronary catheter procedures between the two groups.

Device	TR Band®	PSD	*P*-value
Characteristic			
Age (mean ± SD, years)	59.12±10.09	58.38±10.07	0.462
Sex (n, %)			0.343
Male	54 (71.05)	40 (63.49)	
Female	22 (28.95)	23 (36.51)	
BMI (Mean ± SD, kg/m^2)	27.19±2.88	27.30±2.53	0.513
Comorbid conditions (n, %)			
Type 2 diabetes mellitus	29 (38.16)	23 (36.51)	0.841
Hypertension	37 (48.68)	35 (55.56)	0.420
Dyslipidemia	47 (61.84)	38 (60.32)	0.854
Chronic kidney disease	8 (10.53)	4 (6.35)	0.383
Smoking	19 (25.00)	11 (17.46)	0.282
Antiplatelet therapy (n, %)			0.446
Aspirin	39 (51.32)	35 (55.56)	
Clopidogrel	4 (5.26)	6 (9.52)	
Dual antiplatelet	33 (43.42)	22 (34.92)	
Coronary procedure (n, %)			0.477
Angioplasty	26 (34.21)	18 (28.57)	
Angiography	50 (65.79)	45 (71.43)	
Sheath size (n, %)			0.830
5 Fr	46 (60.53)	37 (58.73)	
6 Fr	30 (39.47)	26 (41.27)	
Activated clotting time (Mean ± SD, s)	134.88±17.05	132.00±14.98	0.157
Hemostasis time (Mean ± SD, min)	256±20	254±19	0.373

BMI - body mass index; TR Band® - Terumo radial band; PSD - PreludeSYNC DISTAL device; SD - standard deviation

Band® was higher that of PSD (52.6% vs. 23.8%), and the difference was statistically significant (p=0.020). Similarly, significant differences were seen in minor hematoma (p=0.020), neurological sequelae (p=0.005), and RAO (p=0.018). Bleeding and major hematoma were statistically not significant. Associated complications with both compression devices are shown in Table 2.

Minor hematoma was significantly associated with the duration of hemostasis (0.001), hypertension (0.009), and dyslipidemias (0.002), whereas no association was seen with age, sex, smoking, BMI, chronic kidney disease, diabetes, size of the radial sheath, and antiplatelet medication intake. Neurological symptoms were associated with diabetes (p=0.013) and hypertension (p=0.011). No other parameters were associated with neurological symptoms. RAO was associated with diabetes (p=0.047). Major hematoma was not statistically significant.

Table 2. Complications with TR Band® and PSD.

Device	PSD	TR Band®		
Complication	**n (%)**	**n (%)**	**OR (95% CI)**	***P*-value**
Radial artery occlusion	6 (9.53)	19 (25.00)	3.17 (1.18-8.51)	0.018
Minor hematoma	5 (7.93)	17 (22.37)	3.34 (1.16-9.66)	0.020
Major hematoma	5 (7.93)	12 (15.79)	2.18 (0.72-6.55)	0.160
Pseudoaneurysm	0 (0.00)	1 (1.32)	N/A	0.361
Neurological sequelae	3 (4.76)	16 (21.05)	5.33 (1.47-19.26)	0.005

TR Band® - Terumo radial band; PSD - PreludeSYNC DISTAL device; OR - odds ratio

Discussion

Several radial hemostatic compression devices have been used following angiography or PCI. Most of them are effective, safe, and well-tolerated. Previous studies have demonstrated different time for hemostasis and local vascular complications. The devices compared in these studies were used for FRA only (10, 11). For the first time, we compared hemostasis and vascular and neurological complications for FRA using the TR Band® and DRA with a relatively new PSD. Both the TR Band® and PSD, with their transparent structure, are designed for a controlled compression of the radial puncture sites. This allows blood return and prevents RAO. Many studies have established these findings for the TR Band® (11, 12). However, there is a paucity of literature on the PSD device and its associated complications, and no study has compared the two different anatomical radial access site compression devices in terms of local complications.

Despite effective hemostasis, the incidence of bleeding, including minor or major hematoma during the application of TR Band® radial compression device was between 14.2% and 26.3% in previous studies (11, 13, 14). Our study indicated that 22.3% and 15.7% of patients developed minor and major hematomas, respectively, with the application of TR Band®, whereas only 7.9% of patients had this complication with PSD. However, both devices were effective in achieving hemostasis with no significant time difference.

In our study, the PSD demonstrated excellent patient comfort, with patients more relaxed due to the flexible hand movement on the wrist compared with TR Band®. Patient suffering is less with PSD because it alleviates the discomfort of the wrist compression device and allows a more relaxed hand position. Because TR Band® is applied by injecting a fixed amount of air into the balloon, the pressure on the puncture site fluctuates. Thus, some patients may perceive tightness. This instability has some sequelae. It causes numbness and temporary loss of motor functions of the small muscles of the hands in some patients as seen in our study. The incidence of neurological symptoms development in TR Band® was higher than that in

PSD (4.7% vs. 21%, p=0.005). Second, the loss of pulse at the compression site in PSD was significantly lower than that in TR Band®. In TR Band®, too much compression on the radial artery can cause loss of arterial pulse distal to the compression device. A study showed that too much compression on the artery can cause local vascular complications.

RAO is one of the frequent complications of FRA cannulation. Previous studies have reported that RAO occurs in 3% to 12% (13, 15, 16). Our study suggested that RAO occurred more frequently in TR Band® compared with PSD. This is contrary to the results of a previous study, wherein RAO rates were lower compared with other FRA compression devices (17).

Our study has shown that neurological symptoms were associated with diabetes and hypertension. This can be explained by the presence of peripheral arterial disease in these patients and weak vessel walls due to microvascular damage in diabetes and high shear stress in hypertension (18, 19).

In summary, both PSD and TR Band® can efficiently achieve hemostasis after transradial coronary catheterization. However, minor hematoma and neurological complications were more frequently seen in our study population with TR Band®. Pulse loss in the artery and RAO were significantly lower with the new device.

Study limitations

This study has several limitations. It was a single-center register that was conducted as a non-randomized interventional study assessing the feasibility of two different access site compression devices for radial artery cannulation. The mode of assignment to each device might have an influence on the results. This could be overcome by proper randomization in future studies. Another major limitation is the relatively short observation period of 20 days as RAO can occur after several months post-procedure. Patients with radial diameters of <2 mm were excluded. By changing this threshold, different results might be obtained. Finally, a controlled prospective and randomized trial with a longer follow-up period would be useful for a conclusion.

Conclusion

This study showed a clear benefit of using distal radial access and the compression device compared with TR Band®. Local vascular and neurological complications were more common with the conventional forearm radial access, and more coronary catheterization procedures should be encouraged with the distal approach in suitable patients.

Conflict of interest: None declared.

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