Radial Compression Devices Used After Cardiovascular Interventions

Discussing the design and function of radial artery compression technologies used for a safe closure of radial access after percutaneous cardiovascular intervention.

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Radial artery access for cardiovascular diagnostics and intervention represents a breakthrough in modern interventional cardiology. The main advantages of utilizing the radial artery over the femoral artery are the smaller caliber of the artery and an easier position for safe compression with a reduced risk of major access site bleeding, which may negatively impact prognosis. For this reason, routine implementation of radial artery access, especially with concomitant use of potent antithrombotic agents, has been demonstrated to reduce both access site bleeding and all-cause mortality.[1,2] Owing to the superficial position and ease of compression, radial access complications are rare, making access site management after intervention easier compared with femoral access.[3] Additionally, the radial artery is too small to be closed with intravascular closure devices and it is exclusively managed with mechanical compression. Yet, despite being safe in most cases, radial artery catheterization has been shown to be almost invariantly associated with acute wall injuries, including radial artery acute dissection, pseudoaneurysm, and thrombus formation.[4]

Most importantly, radial artery catheterization has a considerable rate of acute and late radial artery occlusion (RAO), which occurs in up to 10% to 12% of cases.[5] Although RAO is clinically silent in most cases, it precludes use of the radial artery for future interventions from the same access site, prevents radial harvesting for coronary artery bypass grafting, and may impede arteriovenous fistula preparation in cases of hemodialysis.[6] In addition, RAO may limit the use of a ipsilateral forearm vascular access site (eg, ulnar artery) due to a perceived risk of hand ischemia.[7] As such, RAO prevention has been central in the development of the radial artery technique, and appropriate radial artery hemostasis has been demonstrated to be closely associated with this outcome. Therefore, the central objective of radial artery hemostasis, apart from preventing bleeding from the access site, is the prevention of RAO. A series of strategies have been shown to reduce the risk of RAO after intervention (Table 1)[4,8-14] and most can be achieved with proper hemostasis practices.[15]

Since its introduction in 1989, radial artery access closure has been managed with manual or elastic bandage compression; however, these options are suboptimal because manual compression is time and personnel consuming, and elastic bandage compression does not allow for complete control of hemostasis.[16] For this reason, a number of dedicated compression devices, most in the form of wristbands exerting a controlled and adjustable compression to the radial artery, have been developed for use after sheath removal (Table 2). Although these devices all basically exert a continuous pressure to the artery to allow hemostasis, the different designs and technologies applied for compression have specific advantages and disadvantages linked to the device complexity, cost, and patient comfort.

TABLE 1. STRATEGIES TO REDUCE THE RISK OF RAO AFTER PERCUTANEOUS CORONARY PROCEDURES PERFORMED VIA RADIAL ACCESS

Strategy	Rationale	Technique
Patent hemostasis (Pancholy et al[8])	Maintenance of an antegrade flow after sheath removal reduces the risk for local thrombosis	▪ Place a pulse oximeter sensor over the index finger; the compression device is used and the sheath is removed ▪ While ipsilateral ulnar artery is manually occluded, the compression device is loosened until the plethysmographic signal reappears, confirming radial artery antegrade flow ▪ If bleeding occurs, the pressure is increased to control bleeding while trying to maintain radial artery patency
Ipsilateral ulnar artery compression (Pancholy et al[9])	Occlusion of the ipsilateral ulnar artery favors antegrade radial flow	▪ Implementing patent hemostasis of the radial artery while maintaining occlusive compression of the ulnar artery at the level of the Guyon's canal by a compression device or a compressive bandage
Reduce compression time (Pancholy et al[10])	Reduces the risk for artery trauma and thrombosis	▪ Implementation of a decompression protocol with total removal of the device as soon as hemostasis is achieved and possibly within 2 hours from sheath removal
Reduce sheath size (sheath/artery diameter ratio) (Saito et al[11])	Reduces artery wall traumatism; an artery-to-sheath diameter ratio < 1 is a predictor of RAO	▪ Transradial procedures should be performed using the lowest-profile system available to successfully complete the procedure and perform optimal angiography
Reduce number of punctures (Costa et al[4])	Reduces artery wall traumatism; each unsuccessful puncture of the radial artery increases the risk of RAO by 3.5-fold	▪ Careful radial artery anatomy evaluation; imaging support in case of difficult access
Adequate procedural anticoagulation (Spaulding et al[12]; Hahlis et al[13])	Reduces the risk for local thrombosis	▪ Administer a dose of at least 50 U/kg or 5,000 U of unfractionated heparin ▪ Full dose of 100 U/kg is more effective and may be considered
Nitroglycerin infusion at the end of the procedure (Dharma et al[14])	Vessel vasodilation and prevention of spasm reduces artery wall traumatism	▪ Administration of 500 µg nitroglycerin from the radial sheath before removal

Abbreviation: RAO, radial artery occlusion.

ASSESSING RADIAL COMPRESSION DEVICES

The main design of compression devices include (1) tourniquet, screw-based compression of a hard surface toward the radial artery; (2) mechanical compression obtained by the adjustable size of the wristband that closes up, which augments the local compression to the radial artery; or (3) localized compression of an air-inflatable bladder included in the wristband that can adjust the amount of pressure exerted on the radial artery by regulating the amount of air introduced in the system (Figure 1). Other important characteristics to be considered in the design of these devices are the opportunity to directly see the puncture site through a transparent observation window or the presence of wrist support to prevent flexing movements of the wrist.

Dedicated compression devices have demonstrated superior efficacy as compared with elastic compressive bandages in one randomized study of 1,650 patients comparing a compressive elastic dressing with a pneumatic compression device (TR Band, Terumo Interventional Systems) or a rotary compression device.[17] The time to achieve hemostasis was longer with the compression dressing as compared with the two compression devices (306 ± 65 vs 263 ± 62 and 237 ± 58 minutes; $P < .0001$) and the incidence of RAO at 24 hours after radial cannulation was also higher in the pressure dressing group (15.6% vs 5.8% and 4.5%; $P < .0001$), although no statistical difference was observed between the two compression devices.[17]

To date, the most commonly used radial compression devices implement pneumatic compression. Yet, several

TABLE 2. CURRENTLY AVAILABLE RADIAL HEMOSTASIS DEVICES				
Company Name	**Product Name**	**Mechanism of Hemostasis**	**Compression Site Visible?**	**Available Market**
Abbott Vascular	RadiStop	Mechanical (tightening)	No	EU, US
Advanced Vascular Dynamics	RadAR 4160	Mechanical (tightening)	No	EU, US
	Zephyr 9100	Pneumatic	Yes	EU, US
	Zephyr 9200	Pneumatic	Yes	EU, US
Ates Group—Benrikal	Bengal	Mechanical (tightening)	No	EU, US
Forge Medical, Inc.	VasoStat	Mechanical	No	EU, US
HemoBand, Inc.	HemoBand 1-M	Mechanical (tightening)	No	EU, US
Kewei Rising Medical Co., Ltd	Air Power	Mechanical	Yes	EU
	Radiquick	Mechanical	Yes	EU
	Water Ring	Hydraulic	Yes	EU
Marine Polymer Tech	SyvekRadial	Pneumatic	Yes	US
Medplus Inc.	Tourniquet Helix T2	Mechanical	Yes	EU, US
Medtronic	TRAcelet	Pneumatic	Yes	EU, US
Merit Medical Systems, Inc.	Finale	Mechanical	No	EU, US
	PreludeSync	Pneumatic	Yes	EU, US
	PreludeSync Distal	Pneumatic	Yes	EU, US
	RadStat	Support device	Not applicable	EU, US
	Safeguard Radial	Pneumatic	No	EU, US
Teleflex	D-Stat Rad-Band	Mechanical (tightening)	Yes	US
	Vasc Band Hemostat	Pneumatic	Yes	US
Terumo Interventional Systems	TR Band	Pneumatic	Yes	EU, US
TZ Medical Inc.	Comfort Band	Mechanical (tightening)	No	EU, US
Vascular Perspectives Ltd	Helix	Mechanical	Yes	EU

Abbreviations: EU, European Union; US, United States.

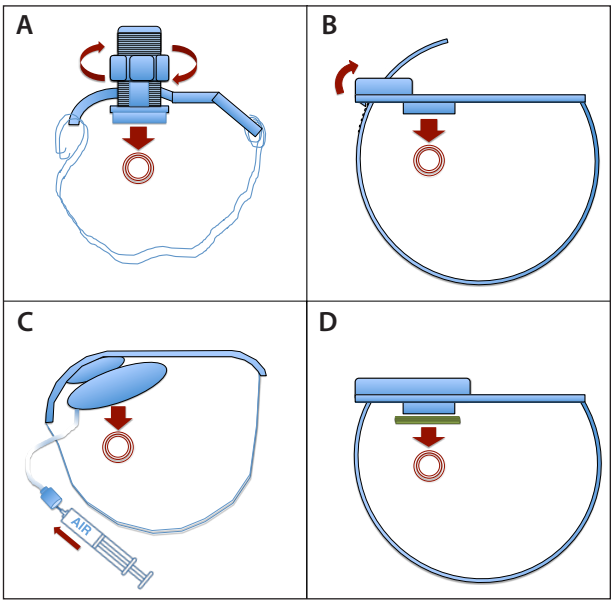

Figure 1. Different designs and technologies for compression wristbands: mechanical compression through a screw press (A), mechanical compression through a band-tightening press (B), pneumatic compression through an inflatable air bladder (C), and additional implementation of a hemostatic pad for faster hemostasis (D).

trials have compared the safety and efficacy of various compression devices with different results. In a randomized comparison of 709 patients undergoing transradial coronary procedures, an inflatable compression device (TR Band) and a mechanical strap-based compression device with rigid wrist support (RadiStop, Abbott Vascular) were compared.[18] No difference in early or late RAO was observed between the two devices. Although the time to achieve hemostasis was slightly longer with the TR Band system, the rate of discomfort and pain was higher with the RadiStop device.[18]

Two additional randomized studies comparing two pneumatic compression devices (TR Band vs Safeguard Radial [Merit Medical Systems, Inc.]) showed no significant differences in the occurrence of late RAO after transradial procedures.[19,20] Both devices were equally effective in achieving patent hemostasis; however, the Safeguard Radial device was associated with less patient-reported discomfort but a higher rate of hematoma, with equal rates of minor bleeding between the two devices.[20]

In a recent randomized controlled trial, the use of mechanical compression devices showed similar results as compared with manual compression implementing patent hemostasis.[21] Although there was no difference in the rates of RAO between the two techniques, manual compression obtained faster hemostasis of the radial artery as compared with the mechanical compression device.[21] Because compression of the radial artery requires dedicated personnel, manual compression of the radial artery after cardiovascular procedures is probably not feasible within most busy cath labs; however, the similar rate of RAO compared with mechanical compression is reassuring regarding the effectiveness and safety of these devices.

The use of compression devices has also been tested in association with hemostatic pads filled with procoagulant material (eg, kaolin, chitosan) with the rationale that accelerating clotting may achieve a more rapid local hemostasis and potentially reduce the rate of RAO. The use of these hemostatic pads in association with mechanical compression devices was able to reduce the time to hemostasis to 30 minutes after sheath removal.[22] Other similar studies have demonstrated a more rapid time to hemostatis.[23-25] In a single-center, open-label, randomized controlled trial of 600 patients in whom a pneumatic compression device (TR Band) was used with or without a chitosan-based procoagulant pad, the time to hemostasis was reduced with the use of the hemostatic pad without an excess of local bleeding.[26] The rate of early and late RAO, as measured by two-dimensional ultrasound, occurred less with the implementation of the hemostatic pad (10% vs 5%; $P < .05$).[26] Similarly, a smaller randomized study of 120 patients randomized to an ultrashort compression protocol with a pneumatic device for 15 minutes, with or without a kaolin-based hemostatic pad (QuikClot, Z-Medica, LLC), or a standard compression protocol for 120 minutes showed that the ultrashort compression protocol was associated with active bleeding in 20% and 90% of cases with and without the hemostatic pad, respectively, as compared with 2% in the standard compression protocol. In addition, the rates of RAO (as assessed by Barbeau test at 24 hours after the procedure) were lower with the ultrashort compression protocol with or without the hemostatic pad as compared with the standard compression protocol (0% and 5% vs 10%, respectively; $P = .05$).[27]

CONCLUSION

The choice of optimal hemostasis method after a radial access intervention may be dependent on the level of familiarity that the catheterization lab staff has with specific devices, even though no difference in the effectiveness of radial compression devices has been demonstrated. With the many available hemostasis devices, clinicians have the opportunity to implement best practices associated with RAO prevention, especially with regard to patent hemostasis. ■

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