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ORIGINAL ARTICLE

Randomized Clinical Trial

Randomized study comparing incidence of radial artery occlusion post-percutaneous coronary intervention between two conventional compression devices using a novel air-inflation technique

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Author contributions: Voon V performed data collection, analyzed and interpreted data, and wrote manuscript; Ayyaz Ul Haq M, Cahill C, Mannix K, Ahern C, Hennessy T, Arnous S performed and conducted data collection; Kiernan T contributed to the conception and design of study and wrote manuscript; all authors critically reviewed the manuscript and approved it.

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Abstract

AIM

To compare post-percutaneous coronary intervention (PCI) radial artery occlusion (RAO) incidence between two conventional radial artery compression devices using a novel air-inflation technique.

METHODS

One hundred consecutive patients post-PCI were randomized 1:1 to Safeguard or TR band compression devices. Post-radial sheath removal, each compression device was inflated with additional 2 mL of air above index bleeding point during air-filled device application and gradually down-titrated accordingly. RAO was defined as absence of Doppler flow signal performed at 24 h and at 6 wk post-PCI. Patients with missing data were excluded. Statistical significance was defined as $P < 0.05$.

RESULTS
All patients had 6F radial sheath inserted. No significant differences were observed between Safeguard Radial (*n* = 42) *vs* TR band (*n* = 42) in terms of age (63 ± 11 years *vs* 67 ± 11 years), clinical presentation (electives, *n* = 18 *vs n* = 16; acute coronary syndrome, *n* = 24 *vs n* = 26) and total procedural heparin (7778 ± 2704 IU *vs* 7825 ± 2450 IU). RAO incidence was not significantly different between groups at 24 h (2% *vs* 0%, *P* = 0.32) and 6 wk (0%, both).

CONCLUSION
Safeguard Radial and TR band did not demonstrate significant between-group differences in short-term RAO incidence. Lack of evidence of RAO in all post-PCI patients at 6 wk follow-up, regardless of radial compression device indicate advantage of using the novel and pragmatic air-inflation technique. Further work is required to more accurately confirm these findings.

Key words: Radial artery; Arterial occlusive disease; Cardiac catheterization

Core tip: Radial artery occlusion (RAO) is a rare but significant complication post-transradial percutaneous coronary intervention (PCI). We found that post-PCI Doppler flow signal-detected RAO incidence was not significantly different between Safeguard Radial and TR band compression devices. However, with the use of a novel air-inflation technique, we observed significantly lower incidence of RAO in all patients regardless radial compression device, in the short-term compared to current literature. Therefore, this novel air-inflation technique may offer a pragmatic and effective solution in reducing RAO incidence.

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INTRODUCTION

Radial artery occlusion (RAO) is an increasingly recognized and significant vascular complication among those observed post-hemostatic compression device application for transradial percutaneous coronary intervention (PCI), the recommended access route in current guidelines[1]. As a consequence of RAO, ipsilateral limb transradial access may be rendered unusable for future procedures. This may be particularly crucial in post-PCI patients, a cohort at higher risk of requiring further coronary angiography, conduit for coronary artery bypass surgery or arterio-venous fistula formation for hemodialysis. Furthermore, ipsilateral ulnar artery access may be unusable due to ischemic limb risk on arterial cannulation.

Several studies have reported rates of RAO from 1%-30%[2-9]. These figures reflect the complex pathophysiology involved in RAO, particularly impaired vascular remodeling and thrombo-inflammatory alterations post-arterial injury. In addition, reports to date have been confounded by multiple external factors. These factors include heterogeneity of study designs, targeted patient populations, parameters for assessing RAO, anticoagulation as well as compression devices and techniques[10].

While several compression bands and techniques tested have demonstrated a modest reduction in RAO, a more pragmatic and effective approach remains to be defined[11]. Therefore, we aimed to prospectively compare incidence of RAO between two conventional hemostatic compression devices (Safeguard Radial and TR band) using a pragmatic and novel air-inflation technique, in patients post-transradial PCI.

MATERIALS AND METHODS

Ethics approval was obtained from University Hospital Limerick Ethics committee for our study, which conformed to the principles of the Helsinki Declaration. A total of 107 consecutive patients who had undergone transradial percutaneous coronary intervention at University Hospital Limerick, were screened and eligible patients were recruited into the study. Patients gave written informed consent prior to PCI and were prospectively randomized to either Safeguard Radial or TR band compression device *via* a pre-specified 1:1 automated randomization. Exclusion criteria were patients less than 18 years old, pregnancy, inability to consent, inability to attend follow-up clinic and difficult radial access requiring femoral access. Patient demographics and angiographic profiles were collected. All patients received dual anti-platelet therapy prior to PCI. Radial artery procedural preparation and management as well as RAO assessment are described below.

Radial artery cannulation

After sterile preparation, 1% lidocaine was injected at puncture site. The radial artery was punctured at the anterior wall with a 21-gauge arterial needle through which a 0.018-inch straight floppy tip guidewire (40-cm length) was advanced upon appearance of pulsatile flow. Following this, the needle was withdrawn and a hydrophilic 6F introducer sheath (11-cm length) with dilator length of 16 cm (Prelude, Merit Medical

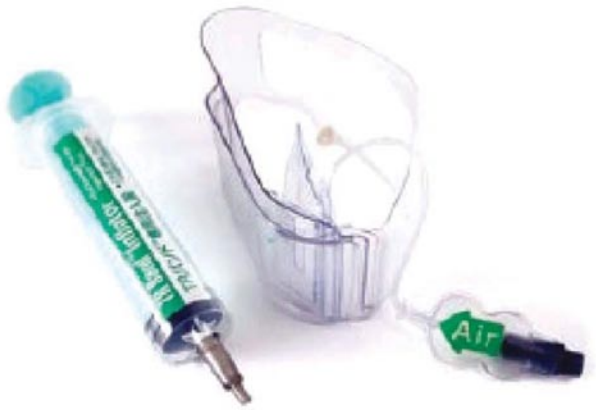

Figure 1 TR band compression device.

Systems) was inserted over the guidewire into the radial artery. Subsequently, the wire and dilator were removed. According to operator preference, a "radial cocktail" consisting of intra-arterial 100-200 mcg nitroglycerin, 250 mcg verapamil and heparin 2000-4000 IU, was given. All patients had total procedural heparin 70-100 IU/kg given as part of the PCI procedure.

Radial sheath removal and hemostatic compression technique

Patients were randomized to either TR band (Terumo Interventional Systems) or Safeguard Radial (Merit Medical) hemostatic compression device groups (Figures 1 and 2). Immediately post-PCI, the radial sheaths were pulled out 4-5 cm and chosen hemostatic compression device band was placed around wrist, with the transparent bladder immediately over the puncture site. We utilized a novel and pragmatic air-inflation technique that involved initial syringe-guided inflation of 2-5 mL of air into device transparent bladder *via* a cuff-valve system, with careful simultaneous removal of sheath. Continued inflation up to 5-10 mL of air was done to stop bleeding after complete removal of sheath. This was followed by immediate release of air, using similar syringe until bleeding/oozing point, at which an additional 2 mL of air was inflated into device bladder. This is contrary to current non-personalized air-inflation techniques utilizing standard 15 mL and 7 mL of air in TR band and Safeguard respectively, as per manufacturer's instructions. Subsequent gradual down-titration of air (1 mL of air removed every 30 min) was performed by nursing staff until completion of hemostasis.

Activated clotting time measurement

Activated clotting time (ACT) is the routine method of choice for monitoring heparin therapy during PCI. At the end of PCI, for all patients, 5 mL of fresh arterial blood sample was obtained in a 5 mL syringe after initially discarding 10 mL of blood from radial sheath prior to sheath removal. The fresh blood was immediately measured for ACT, by using a disposable single-use point-of-care assay. The assay consists of a cuvette containing manufacturer reagents and is measured by the accompanying battery-operated, hand-held device Hemochron Jr Signature + Whole Blood Microcoagulation System (International Technidyne) as per manufacturer's instructions.

RAO assessment

The handheld ultrasonic Doppler signal flow detector 2 MHz (FD1, Huntleigh, Sonicaid) probe was applied above the puncture site of radial artery of resting and extended forearm. RAO was defined as absence of Doppler signal flow. This was performed at 24 h and 6 wk post-PCI by operators blinded to randomization process.

Outcome measures

Primary endpoint was RAO at 24 h post-procedure and 6 wk follow-up. Secondary endpoints were bleeding requiring transfusion/surgical intervention, hematoma and pain/numbness at radial access site.

Statistical analysis

As a pilot study evaluating this technique, exploratory analyses was performed. Continuous normal data were expressed as mean ± SD. Continuous non-normal and categorical variables were expressed as mean (25^{th}, 75^{th} percentile) or frequencies (and percentages). Accordingly, between-group comparisons were compared using unpaired t-testing, Mann-Whitney rank sum test or Pearson chi-square tests. All patients with missing data were excluded from analyses. All analyses were performed using SPSS version 18 statistical software (SPSS Inc, Chicago, IL, United states). $P < 0.05$ was considered significant (two-tailed significance).

RESULTS

Baseline demographics of patient cohort are presented in Table 1. A total 84 patients were included for analyses after excluding patients who were not eligible ($n = 5$)/refused ($n = 2$), had missing data ($n = 16$). No significant differences were observed between-groups in terms of demographics or procedural profiles (Table 2). Approximately 60% of patients presented with an acute coronary syndrome. All patients had 6F radial sheaths inserted. Despite no significant between-group differences in post-procedural outcomes measures, both Safeguard Radial and TR band groups demonstrated very low incidence of RAO at 24 h (2% *vs* 0%) and 6 wk (0%, both) (Table 3). No significant

Figure 2 Safeguard Radial compression device.

Table 1 Clinical and angiographic profiles of Safeguard Radial *vs* TR band groups at baseline-total patient cohort

Variables	Safeguard radial, *n* = 42	TR band, *n* = 42	*P* value
Age, years	63.8 ± 10.9	66.8 ± 10.8	0.21
Gender, male/female ratio	31/11	37/5	0.16
BMI, kg/m^2	29.2 ± 3.9	29.0 ± 5.7	0.88
Diabetes	4 (10%)	8 (19%)	0.22
CKD	1 (2%)	2 (5%)	0.56
PAD	0%	1 (2%)	0.32
Indication			
Elective	18	16	0.88
UA	6	8	0.9
NSTEMI	13	8	0.7
STEMI	5	10	0.6

BMI: Body mass index; CKD: Chronic kidney disease; PAD: Peripheral arterial disease; UA: Unstable angina; NSTEMI: Non-ST elevation myocardial infarction; STEMI: ST-elevation myocardial infarction.

differences in secondary outcome measures were observed.

DISCUSSION

This study has demonstrated no significant difference in incidence of short-term RAO between Safeguard and TR band devices. However, we have for the first time demonstrated significantly lower incidence of RAO at 24 h and at 6 wk post-PCI compared to current literature, regardless of type of conventional hemostatic compression device using the novel air-inflation technique. Among the few studies that have reported short-term RAO, some have observed RAO incidence as high as 9.2% at discharge[9]. Pancholy and colleagues reported RAO incidence of 4.4% at 24 h and 3.2% at 30 d using TR band in a cohort using 5F radial sheaths[8]. Dai *et al*[11] demonstrated that in post-transradial PCI patients, incidence of RAO was at least 11% at 24 h and 10% at 30 d. The study showed that air titration based compression strategy using TR band was superior to non-air titration strategies. However, the study utilized a non-specific, non-personalized method using manufacturer's instructions.

In our experience, additional 2 mL of air above point of bleeding/oozing provides personalized and adequate temporary patent hemostasis without the need of conventional methods to monitor radial patency. This has been shown despite different surface area of compression bladder of both devices. This magnitude of air may provide sufficient compression on muscle, adipose tissue and artery although impact of higher magnitudes of air remains to be determined. This technique requires confirmation in future studies.

To further support this technique, our study involved a cohort presenting predominantly with acute coronary syndrome, a more prothrombotic state, compared to previous studies. Only 29.7% of transradial PCI-treated patients presented with acute coronary syndrome in a study by Rathore and colleagues[9]. The study demonstrated a higher incidence of RAO as aforementioned with manufacturer's technique of compression device air inflation. However, several techniques to measure RAO were used and only 50% of patients had hydrophilic radial sheaths compared to our study. Some may argue that lack of sheath hydrophilicity may account for such results.

Furthermore, sheath size has also been a regarded as a contributing factor to RAO. Larger diameter sheaths have been reported to have increase RAO

Table 2 Procedural profiles of Safeguard Radial *vs* TR band groups

Variables	Safeguard radial, *n* = 42	TR band, *n* = 42	*P* value
Pre-procedure			
IR verapamil, %	(86%)	(83%)	0.77
IR nitroglycerine, %	(31%)	(45%)	0.18
Procedural			
Heparin, IU	7778 ± 2704	7825 ± 2450	0.94
Number of target vessels treated with PCI			
1			
2	39	39	1
≥ 3	3	3	1
	0	0	1
Target vessels			
LM	1	0	0.98
LAD/Diagonal	19	22	0.87
LCx/OM	7	7	0.96
RCA	18	12	0.64
IM	0	2	0.77
VG	0	2	0.77
Fluoroscopy times, min	15.3 ± 8.4	15.0 ± 6.9	0.88
Post-procedure			
GP2B3A inhibitor, %	1 (2%)	0%	0.32
ACT (s)	197 ± 38	197 ± 47	0.97

IR: Intra-radial; LM: Left main artery; LAD: Left anterior descending artery; LCx: Left circumflex artery; OM: Obtuse marginal artery; RCA: Right coronary artery; IM: Intermediate artery; VG: Vein graft; GP2B3A: Glycoprotein 2B 3A receptor; ACT: Activated clotting time.

Table 3 Post-procedural outcomes in Safeguard Radial *vs* TR band groups

Variables	Safeguard radial, *n* = 42	TR band, *n* = 42	*P* value
Bleeding requiring blood transfusion/surgical intervention	0%	0%	1
Hematoma	7%	0%	0.07
Pain/numbness	2%	0%	0.32
Radial artery occlusion at 24 h	2%	0%	0.32
Radial artery occlusion at 6 wk	0%	0%	1

incidence[12-14]. This effect was not observed in our study which used 6F sheaths in all patients who required PCI. Despite that, further studies involving improved imaging modalities are required to more accurately characterize vessel to sheath ratio. This is because the higher prothrombotic effects due to possible oversized sheaths may be offset by heparin therapy that all patients received in our study.

Heparin itself has been shown to reduce incidence of RAO. The lack of procedural heparin is an independent predictor of RAO[9]. Rathore and colleagues demonstrated RAO incidence of 24.1% at 4-6 mo follow-up in those without heparin administration. The study showed that in 92% of patients who had transradial PCI with 6F sheaths, RAO incidence was 8.9% at discharge and 5.6% at follow-up in the TR band group, which demonstrated lesser RAO between compression devices compared. Lefvre *et al*[15] reported 30% RAO with 1000 IU of heparin. This requires further confirmation, particularly at different comparator doses. However, the results of our study again emphasize the impact of the novel air-inflation technique in reducing RAO beyond conventional anticoagulation.

Several limitations were observed during the study. Firstly, we observed a high prevalence of missing data due to procedures performed out-of hours. However, both groups were well matched in baseline demographics to negate group bias effects. Second, as with all exploratory studies, type Ⅰ error may contribute to the results. Despite our study demonstrating consistent results at discharge and follow-up, this requires further confirmation. Third, Allen's test was not routinely performed pre-PCI. However, conventional methods of assessment *via* plethysmography and oximetry have not yielded consistent results due to influence of collaterals from palmar arches and recanalization[6,16]. Lastly, a known confounding factor that was not measured but critical for vascular management, was increased vigilance using our personalized air-inflation strategy to reduce RAO.

In conclusion, Safeguard Radial and TR band did not demonstrate significant between-group differences in short-term RAO incidence. Lack of evidence of RAO in all post-PCI patients at 6 wk follow-up, regardless of radial compression device indicate advantage of

using the novel and pragmatic air-inflation technique. Further work is required to more accurately confirm these findings.

COMMENTS

Background

Radial artery occlusion is a rare but significant complication post-transradial percutaneous coronary intervention, which is increasing in its use, globally. Therefore, better radial artery compression techniques are required to reduce such complication.

Research frontiers

Conventional radial artery compression devices by varying air-inflation techniques have shown different results in reducing the incidence of radial artery occlusion post-percutaneous coronary intervention. These suggest that novel air-inflation techniques using such devices may yield better results in reducing incidence of radial artery occlusion.

Innovations and breakthroughs

The authors have shown a much lower short-term incidence of post-percutaneous coronary intervention radial artery occlusion, compared to current literature, using a novel and pragmatic air-inflation technique in two conventional radial compression devices, Safeguard Radial and TR band.

Applications

This pilot study's methods and results of this study could be used in a larger prospective study aiming to the impact of this novel air-inflation technique with two conventional radial compression devices in different settings of transradial percutaneous coronary intervention.

Terminology

Radial artery occlusion is a rare but significant complication of transradial percutaneous coronary intervention. Novel and pragmatic radial compression techniques are required to reduce the incidence of such complication.

Peer-review

This is an interesting manuscript about the comparison of post-percutaneous coronary intervention radial artery occlusion incidence between two conventional radial artery compression devices using a novel air-inflation technique, Safeguard Radial and TR band.

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