

ORIGINAL STUDIES

Impact of sheath size and hemostasis time on radial artery patency after transradial coronary angiography and intervention in Japanese and non-Japanese patients: A substudy from RAP and BEAT (Radial Artery Patency and Bleeding, Efficacy, Adverse event) randomized multicenter trial

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Abstract

Background: During transradial (TR) access, it remains unclear whether differences in baseline patients characteristics and hemostasis care impact the rate of radial artery occlusion (RAO). We sought to compare the rate of RAO after TR access with the 6 French(Fr) Glidesheath Slender (GSS6Fr, Terumo, Japan) or a standard 5 Fr sheath in Japanese and non-Japanese patients.

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Methods and Results: The Radial Artery Patency and Bleeding, Efficacy, Adverse event (RAP and BEAT) trial randomized 1,836 patients undergoing TR coronary angiography and/or interventions to receive the GSS6Fr or the standard 5 Fr Glidesheath (GS5Fr, Terumo, Japan). Out of this study population, 1,087 were Japanese patients and 751 non-Japanese patients. The overall incidence of RAO was significantly higher in Japanese patients (3.6% vs. 1.2%, $P = 0.002$). Use of GSS6Fr was associated with higher rates of RAO than GS5Fr in Japanese patients (5% vs. 2.2%, $P = 0.02$) and with similar RAO rates in non-Japanese patients (1.3 vs. 1.1%, $P = 1$). The mean hemostasis time was significantly longer in Japanese patients (378 ± 253 vs. 159 ± 136 min, $P < 0.001$) and more Japanese patients had a hemostasis time of more than 6 hr (16.2% vs. 4.9%, $P < 0.0001$). Longer hemostasis time was an independent predictor of RAO (OR per additional hour 1.070, 95% CI 1.008–1.136, $P = 0.03$).

Conclusions: Use of GSS6Fr was associated with a higher rate of RAO than a standard 5 Fr sheath in Japanese patients but not in non-Japanese patients. Whether improvement in post-procedural care and reduced hemostasis time could impact the incidence of RAO in Japanese patients should be further assessed.

KEYWORDS

radial artery occlusion, slender sheath, transradial

1 | INTRODUCTION

Radial artery occlusion (RAO) remains a significant drawback of transradial (TR) access, restricting the use of the radial artery for future procedures [1,2]. An inherent limitation of TR access is related to the small size of the radial artery, suggesting that the use of a sheath larger than the inner lumen of the radial artery is a risk factor for radial artery injury and subsequent RAO [3–6]. Miniaturization of TR equipment has been advocated to reduce the occurrence and importance of the sheath-to-artery (S/A) mismatch. The 6 French (Fr) Glidesheath Slender (GSS6Fr, Terumo, Japan) is the first commercially available thin-walled radial sheath with an outer diameter (OD) smaller than the OD of current standard 6 Fr sheaths [7]. The Radial Artery Patency and Bleeding, Efficacy, Adverse event (RAP and BEAT) trial was a large randomized, multicenter trial, assessing non-inferiority of the GSS6Fr against the standard 5 Fr Glidesheath (GS5Fr, Terumo, Japan), and superiority of a patent hemostasis protocol against the institutional hemostasis protocol, in 1,836 patients undergoing TR coronary angiography and/or intervention [8]. The RAP and BEAT trial showed that use of the GSS6Fr was associated with a low event rate for the primary outcome (RAO) although non-inferiority against the GS5Fr was not met, due to a lower than expected rate of RAO in the GS5Fr group. Patients randomized to patent hemostasis had a similar rate of RAO to those assigned to institutional hemostasis. The study population was intercontinental and included 1,087 Japanese patients and 751 non-Japanese patients. As such, it provides an ideal opportunity to study whether patient-level differences affect RAO. For example, Japanese patients may have smaller radial arteries, resulting in a higher incidence of radial artery injury and occlusion when using larger sheaths [9–11]. Furthermore, little is known about the impact of hemostasis care on the rate of RAO in different populations undergoing TR access. The purpose of this study is therefore to compare the rate of RAO and

secondary clinical outcomes in Japanese and non-Japanese patients after TR coronary angiography and/or interventions with the GSS6Fr or the standard GS5Fr.

2 | METHODS

2.1 | Study design and participants

Radial Artery Patency and Bleeding, Efficacy, Adverse event was an international multicenter, prospective, single-blind, randomized clinical trial using a 2X2 factorial design, assessing non-inferiority of the GSS6Fr against the GS5Fr, and superiority of patent hemostasis against institutional hemostasis, in patients undergoing TR coronary angiography and/or interventions (ClinicalTrials.gov NCT02269449). The trial was conducted at 12 centers in Japan, Europe and the United States (US). Patients were eligible if they were to undergo TR coronary angiography and/or intervention. General exclusion criteria were as follows: (1) inability to puncture the radial artery, (2) presence of another medical illness that may cause non-compliance with the protocol or confound data interpretation, (3) hemodialysis patient, and (4) patients with acute coronary syndrome. The trial was approved by the institutional review board of each participating center, and all patients gave written informed consent.

2.2 | Study protocol and randomization

Patients were centrally allocated (1:1) via a web-based system to receive the GSS6Fr or the GS5Fr. Patients in each group were immediately allocated again (1:1) to undergo patent hemostasis protocol or the standard institutional hemostasis protocol. After successful sheath insertion, a vasolytic drug cocktail of calcium channel blockers and nitrates was given through the side-port of the sheath in all patients. A minimal initial dose of 5,000 IU unfractionated heparin bolus was

TABLE 1 Baseline clinical and procedural characteristics according to study population

	Japan (n = 1087)	Non-Japan (n = 751)	P value
Age, years	71.2 ± 10	64.5 ± 11	<0.001
Male (%)	754 (69.4)	522 (69.5)	0.959
Body height (cm)	161.5 ± 9	171.3 ± 12	<0.001
Body weight (kg)	62.7 ± 12.0	86.4 ± 18.3	<0.001
Hypertension	770 (70.8)	526 (70.0)	0.716
Diabetes mellitus	279 (27.0)	136 (19.2)	0.000
Dyslipidemia	701 (64.5)	505 (67.2)	0.231
Current smoking	145 (13.3)	135 (18.0)	0.007
Previous MI	169 (15.6)	129 (17.2)	0.368
Previous PCI	429 (39.5)	170 (22.7)	<0.001
Previous CABG	10 (0.9)	36 (4.8)	<0.001
Peripheral arterial disease	86 (7.9)	46 (6.1)	0.168
Previous stroke	125 (11.5)	49 (6.5)	<0.001
Previous homolateral radial access	377 (34.7)	126 (16.8)	<0.001
Heparin	1,062 (97.7)	738 (98.3)	0.505
Aspirin	607 (55.8)	583 (77.6)	<0.001
P2Y12 inhibitors	20 (1.8)	21 (2.8)	0.199
Glycoprotein IIb/IIIa inhibitors	3 (0.3)	8 (1.1)	0.059
Number of radial puncture	1.23 ± 0.7	1.19 ± 0.6	0.115
Catheter size (Fr)	4.3 ± 0.6	5.3 ± 0.5	<0.001
Proceed to PCI	82 (7.5)	168 (22.4)	<0.001
Overall Hemostasis time (min)	378 ± 253	159 ± 136	<0.001
Hemostasis time GSS6Fr (min)	398.9 ± 273	161.2 ± 143.1	<0.001
Hemostasis time GS5Fr (min)	356.6 ± 230	157.3 ± 128.1	<0.001
Hemostasis time >360 min	163 (16.2)	16 (4.9)	<0.0001

Abbreviations: MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting.

recommended in all patients. Diagnostic procedures were performed using 4 or 5 Fr catheters. In case of PCI, a 5 or 6 Fr guiding catheter was chosen according to patient allocation, operator preference, and lesion complexity. The use of a 5 Fr guiding catheter was recommended in case of ad-hoc PCI in patients assigned to GS5 Fr. In case of upsizing to a larger sheath, the protocol mandated the use of a standard Glide-sheath. An adjunctive bolus of Heparin was given during PCI if needed to achieve an activated clotting time range of 250–300 sec. After completion of the TR procedure, the arterial sheath was removed and hemostasis was performed according to patient randomization (patent hemostasis protocol versus institutional hemostasis protocol). Details regarding hemostasis protocols are described in the main article.

2.3 | Study outcomes

The primary endpoint was the rate of RAO at discharge, defined as the absence of a radial pulse assessed clinically together with the absence of flow on Doppler ultrasound examination of the radial artery. The

physician assessing radial patency was blinded to the assigned sheath. Secondary end-points were procedural success, vascular access-site complication, local bleeding, radial spasm, total procedural time, total amount of contrast dye, total radiation dose, sheath failure, and pain score. Procedural success was defined as completion of the planned procedure through the initially selected radial access route. A vascular access-site complication was defined as any documented vascular damage that included but was not limited to vessel perforation, arterial dissection, pseudoaneurysm, and local hematoma. Radial spasm was defined as an inability to manipulate the guidewire or catheter in a smooth and pain-free manner and also as an inability to remove the sheath in a similar way at the end of the procedure. The diagnosis of puncture site bleeding was made by visual assessment before discharge and classified according to the EASY criteria [7]. Sheath failure was defined as any device malformation leading to vascular complication and/or procedural failure. Pain score denoted the patient's assessment of pain during radial artery sheath removal (1 = none, 2 = slight, 3 = much, and 4 = extreme).

TABLE 2 Primary (RAO) and secondary endpoints according to study population

	Japan (n = 1087)	Non-Japan (n = 751)	P value
RAO (%)	39 (3.6)	9 (1.2)	0.002
Procedure duration, min	27.1 ± 18.5	29.9 ± 27.1	0.015
Total radiation dose, air kerma, mGy	759.4 ± 524.4	808.7 ± 1003.1	0.217
Total contrast volume, ml	74 ± 41.1	103.6 ± 61	<0.0001
Procedural success	1,071 (98.5)	749 (99.7)	0.013
Local bleeding (EASY criteria)			<0.0001
No bleeding	862 (79.3)	652 (86.8)	
Type 1	197 (18.1)	75 (10)	
Type 2	25 (2.3)	20 (2.7)	
Type 3	3 (0.3)	4 (0.5)	
Vascular access site complication	5 (0.5)	6 (0.8)	0.372
Spasm	50 (4.6)	41 (5.5)	0.444
Pain score			<0.0001
None	627 (57.7)	630 (83.9)	
Slight	396 (36.2)	96 (12.8)	
Much	59 (5.4)	24 (3.2)	
Extreme	7 (0.6)	1 (0.1)	
Sheath failure	16 (1.5)	2 (0.3)	0.013

Values shown are mean ± SD or number (%).

2.4 | Statistical analysis

Categorical data are presented as numbers and percentages and compared using the Chi-square test. Continuous data are presented as mean with standard deviation (SD) and compared using the Mann-Whitney *U* test. Potential risk factors for post-procedural RAO were investigated first by univariate logistic regression. A multivariate logistic regression model was used to identify predictors of RAO and was created using a stepwise selection procedure, assessing all variables with a univariate *P*-value <0.10 for difference between the RAO(+) and RAO(-) subgroups. In the stepwise selection procedure, variables were included, step by step, if they achieved a multivariate *P*-value of 0.30 and were retained if they maintained a multivariate *P*-value of <0.10.

As compared to the original analysis performed for the main trial, we added patient population (Japanese vs. non-Japanese patients), age effect per 10 years, and hemostasis time as a continuous variable (per hour) as covariates for the prediction of RAO. A two-sided *P* < 0.05 was considered significant for all tests. All analyses were performed using SAS version 9.4 (SAS Statistical Software, The SAS Institute, Cary, NC).

3 | RESULTS

The RAP and BEAT trial randomized 1,838 patients at 12 centers in Japan, Europe, and USA. Out of this study population, 1,087 patients

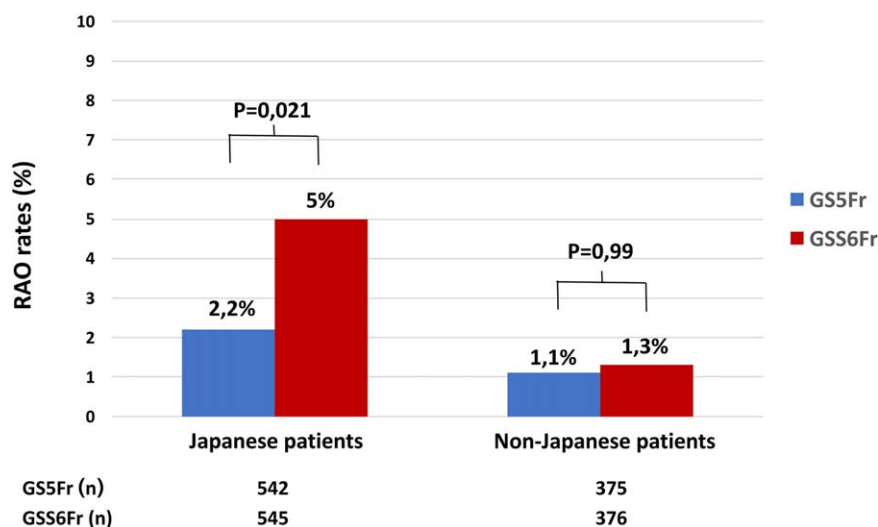


FIGURE 1 Primary end-point (RAO) according to study population and sheath type [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Univariate predictors of RAO

	Odds ratio	95% CI	P value
Male (vs. female)	0.56	0.31–0.99	0.05
Age (per 10 years)	0.75	0.59–0.95	0.02
Height (cm)	0.98	0.96–0.99	0.03
Weight (Kg)	0.98	0.96–0.99	0.04
Current smoker	1.89	0.97–3.69	0.06
Aspirin use	0.35	0.19–0.62	<0.01
P2Y12 inhibitors use	0.53	0.28–1.03	0.06
Previous homolateral radial access	0.78	0.39–1.55	0.48
Proceed to PCI	0.42	0.13–1.35	0.14
Catheter size	0.77	0.52–1.16	0.22
Use of GSS6Fr	2.03	1.10–3.72	0.02
Spasm	4.11	1.87–9.07	<0.01
Pain during procedure	3.13	1.75–5.61	<0.01
Vascular access site complication	8.60	1.81–40.94	<0.01
Bleeding	0.54	0.21–1.37	0.19
Procedural failure	4.82	1.08–21.58	0.04
Hemostasis time (hours)	1.11	1.06–1.17	<0.01
Japanese (vs. non-Japanese)	3.03	1.46–6.3	<0.01

Abbreviation: CI, confidence interval.

were enrolled in five Japanese centers, 601 patients in five European centers, and 150 patients in two US centers (non-Japanese study population = 751). Baseline clinical and procedural characteristics of the two study populations are shown in Table 1. Japanese patients were older (71.2 ± 10 vs. 64.5 ± 11 years, $P < 0.001$), shorter (161.5 ± 9 vs. 171.3 ± 12 cm, $P < 0.001$) and had lower body weight (62.7 ± 12 vs.

86.4 ± 18.3 kg, $P < 0.001$). Previous access on the same radial artery was noted in 34.7% in Japanese patients and 16.8% of non-Japanese patients ($P < 0.001$). Elective or ad-hoc PCI was significantly less frequent in Japanese patients (7.5% vs. 22.4%, $P < 0.001$) and the mean used catheter size was smaller in Japanese patients (4.3 ± 0.6 Fr vs. 5.3 ± 0.5 Fr, $P < 0.001$). Fewer Japanese patients were on Aspirin treatment at the time of randomization (55.8% vs. 77.6%, $P < 0.001$). Importantly, the mean hemostasis time was significantly longer in Japanese patients (378 ± 253 vs. 159 ± 136 min, $P < 0.001$) and more Japanese patients had a hemostasis time of more than 6 hr (16.2% vs. 4.9%, OR 3.73, 95% CI 2.58–5.39, $P < 0.0001$). In non-Japanese patients, there was no difference in the mean hemostasis time between GSS6Fr and GS5Fr (161.2 ± 143.1 vs. 157.3 ± 128.1 min, $P = 0.693$) whereas Japanese patients experienced longer hemostasis time with GSS6Fr (398.9 ± 273 vs. 356.6 ± 230 min, $P = 0.0058$). The study end-points are shown in Table 2. The overall incidence of RAO at discharge was significantly increased in Japanese patients (3.6% vs. 1.2%, $P = 0.002$). Use of the GSS6Fr was associated with higher rates of RAO than the GS5Fr in Japanese patients (5% vs. 2.2%, $P = 0.02$) and with similar RAO rates in non-Japanese patients (1.3 vs. 1.1%, $P = 0.99$) (Figure 1). Japanese patients were also associated with significantly more access-site bleeding (OR 1.72, 95% CI 1.33–2.22, $P < 0.0001$), pain during the procedure (OR 3.82, 95% CI 3.04–4.8, $P < 0.0001$) and procedural failure (OR 5.6, 95% CI 1.28–24.4, $P = 0.013$). Univariate predictors of RAO are shown in Table 3. On multivariate analysis, hemostasis time was found to be an independent predictor of RAO (OR per additional hour 1.070, 95% CI 1.008–1.136, $P = 0.03$) whereas Japanese patients had borderline significance (OR 2.31, 95% CI 0.980–5.432, $P = 0.06$) (Figure 2). Rates of RAO for GSS6Fr and GS5Fr according to different hemostasis time category in the total study population are depicted in Figure 3. Other independent predictors of RAO included the use of GSS6Fr, age, Aspirin pretreatment, spasm, pain during the procedure and vascular complications. Rates of RAO were significantly lower in patients with Aspirin pretreatment than in patients without pretreatment (19/1190 vs. 29/648, 1.6% vs. 4.48%, $P < 0.0001$).

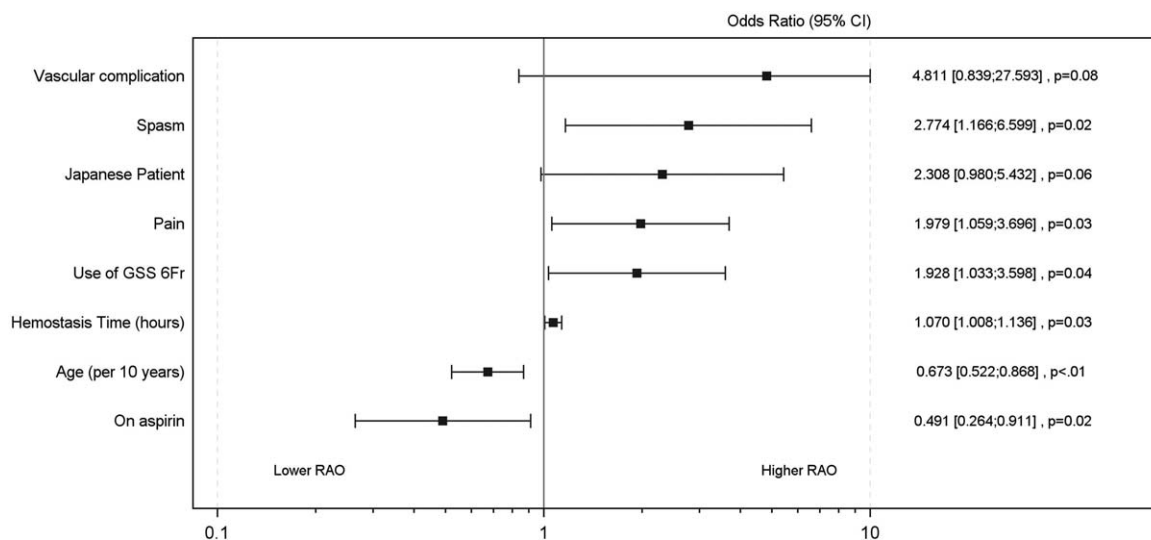


FIGURE 2 Multivariate predictors of RAO

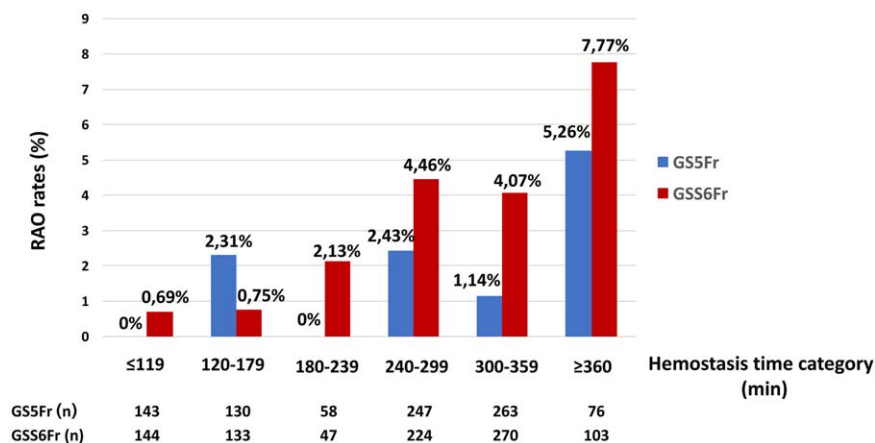


FIGURE 3 Rates of RAO according to sheath type and hemostasis time category in the total study population [Color figure can be viewed at wileyonlinelibrary.com]

4 | DISCUSSION

From a large intercontinental randomized multicentre trial on TR access, we have assessed the impact of sheath size and hemostasis care on the rate of RAO and secondary clinical outcomes in two different populations. The main findings of this study are the followings: (1) use of GSS6Fr resulted in a higher rate of RAO than a standard 5 Fr sheath in Japanese patients but in similar RAO rates in non-Japanese patients, (2) the overall hemostasis time was significantly longer in Japanese patients and use of GSS6Fr resulted in a longer hemostasis time than standard 5 Fr sheath only in Japanese patients, and (3) hemostasis time was an independent predictor of RAO.

During TR access, use of a sheath larger than the inner lumen of the radial artery promotes vascular injury and is a strong predictor of RAO [5,6,10]. Radial artery size has been shown to vary between different study populations with Asian patients being associated with smaller radial artery diameters than Caucasian patients [9–13]. Using ultrasound imaging, Horie et al. have shown that the mean diameter of the radial artery was 2.20 ± 0.45 mm in a Japanese population of 300 patients undergoing TR PCI with GSS6Fr. As such, use of GSS6Fr resulted in the occurrence of a S/A ratio >1 in 74% of patients and a mean S/A ratio of 1.17 ± 0.27 . In their study, use of the GSS6Fr was associated with a higher combined rate of RAO and spasm than a 6.5 Fr Sheathless guiding catheter (0.7% vs. 3.7%, $P = 0.021$) [11]. Similarly, we can assume that the small difference in OD between the GSS6Fr (2.46 mm) and the GS5Fr (2.29 mm) was likely associated with a higher rate of radial artery overstretch and subsequent injury in our Japanese study population. This is further supported by the significant increase in pain score noted in these patients. Of note, Aspirin pretreatment was independently associated with a lower rate of RAO. Since acute RAO is thought to be due to a thrombotic process, the positive impact of Aspirin pretreatment on RAO should be assessed in future studies. Our finding that Japanese patients had significantly longer hemostasis time represents an important aspect to consider. It could partially be explained by differences in bleeding susceptibility and procedural anticoagulation. Although the vast majority of Japanese patients (92.5%)

underwent diagnostic procedures, requiring a lower level of procedural anticoagulation, Asian patients may respond differently to unfractionated heparin. Indeed, Shimada et al have compared activated clotting times following initial administration of weight-adjusted unfractionated heparin among different races of patients undergoing PCI [14]. They found that Asian patients showed higher ACT compared to other racial groups, warranting reduced heparin dosage in this population. Thus, we cannot exclude that a higher sensitivity to unfractionated heparin has contributed to longer hemostasis time in Japanese patients, although post-procedural ACT levels were not recorded in our study. Importantly, longer hemostasis time was found to be an independent predictor of RAO on multivariate analysis. The average difference in hemostasis time between Japanese and non-Japanese patients was approximately three hours. This amount of prolongation in hemostasis time would correspond with an odds ratio of 1.225 to develop RAO. Moreover, 16.2% of Japanese patients had a hemostasis time of more than 6 hours. Pancholy et al. have previously demonstrated that a hemostasis time of 6 hr was associated with a higher rate of early RAO as compared to a shorter duration of compression of 2 hr (12% vs. 5%, $P = 0.025$) [15]. In their study, maintenance of radial artery patency, but not hemostasis time, was shown to be an independent predictor of RAO and to protect against the adverse effects of long hemostatic compression. The negative impact of a long hemostasis time on RAO will thus be increased in case of occlusive compression during radial hemostasis. In other words, achieving early radial artery patency may protect against the detrimental effect of long compression time. In support of this argument, Edris et al. have recently shown in a non-randomized study the benefit of applying a simple rapid deflation technique (minimal pressure applied in the TR Band 15 min after sheath removal, mean final TR band volume = 8.1 ± 2 cc), leading to a very high rate of patent hemostasis and a low rate of early RAO, as compared to a standard deflation technique (2% vs. 14.5%, $P = 0.005$) [16]. In another recent trial that has included pooled data from 3,616 patients randomized to three consecutive protocols, the rate of RAO was markedly reduced when hemostatic compression was soft (10 cc of air in the TR Band) and short (1.5 hr), resulting in a 2.3% rate of

RAO versus 9.4% when applying 13 cc of air and 4 hr of compression [17]. In our large population of Japanese patients, the combination of smaller radial arteries and longer hemostasis time has likely contributed to the higher rate of RAO observed with the GSS6Fr. Our results further support the importance of reducing occlusive compression and hemostasis time in populations at increased risk of RAO such as Japanese patients, especially when using larger sheath sizes. In non-Japanese patients, we found the opposite in that the GSS6Fr had similar clinical outcomes to that of a standard 5 Fr sheath, including a similar rate of RAO, that may be related to the combination of shorter hemostasis time and potentially larger radial artery diameters [18].

5 | LIMITATIONS

Some limitations to our study must be acknowledged. Despite the inclusion of a large sample size of Japanese patients, the distribution was still uneven with more patients in the Japanese compared to the non-Japanese group. In our multivariate analysis of the predictors of RAO, we have attempted to adjust for relevant clinical and nonclinical variables, but we could not adjust for unmeasured confounders. Radial artery diameter was not measured in this trial so we could not confirm the difference in radial artery diameter between Japanese and non-Japanese patients, although the finding of a higher rate of RAO with the GSS6Fr represents a strong surrogate for smaller radial arteries in Japanese patients.

6 | CONCLUSION

In this large multicenter trial, use of the GSS6Fr was associated with a higher rate of RAO than a standard 5 Fr sheath in Japanese patients but not in non-Japanese patients. Whether improvement in post-procedural care and reduced hemostasis time could impact the incidence of RAO in Japanese patients should be further assessed.

CONFLICT OF INTEREST

Ian C. Gilchrist, Shigeru Saito, and Sunil Rao have received fees from Terumo Interventional Systems for educational talks and consulting. The other authors have no conflicts of interest to declare.

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