A Randomized Comparison of Radial Artery Occlusion and Symptomatic Radial Artery Spasm Associated with Elective Transradial Coronary Intervention Using Two Novel Guiding Catheters

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■ **I have the following** potential conflicts of interest to report:

- □ Research contracts
- ■ Consulting- Kaneka, Tokai medical
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- □ Other(s)

□ **I do not have any potential conflict of interest**

JCR 2019

Background

- ✓ Transradial coronary intervention (TRI) has been associated with significant reduction of vascular complications and improvement in resuming patient mobility, compared with the transfemoral approach.

Valgimigli M, et al. Lancet 2015;385:2465-76

- ✓ Use of TRI is expanding, but wider adoption seems to be limited by occurrence of radial artery occlusion (RAO) and radial artery spasm (RAS).

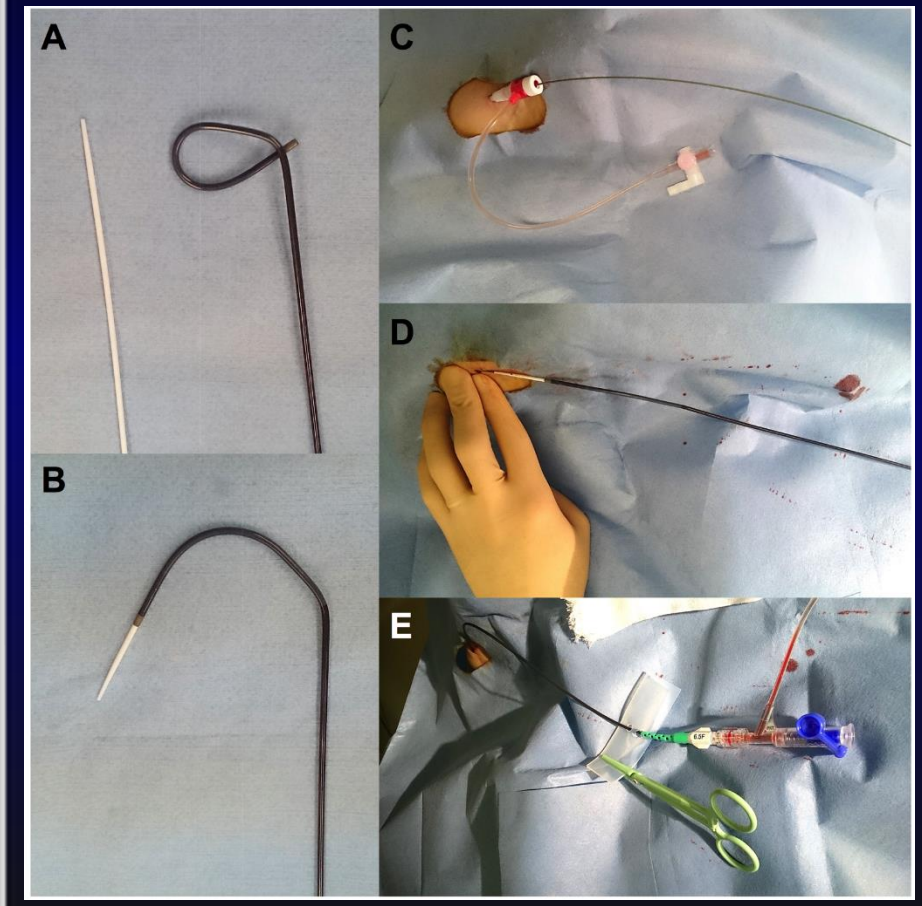
Bertrand OF, et al. JACC Interv. 2010;3:1022-31

- ✓ The presence of smaller radial arteries than the external diameter of a 6.0-Fr introducer sheath is an inherent risk of post-procedural radial complications.

Saito S, et al. CCI 1999;46:173-8

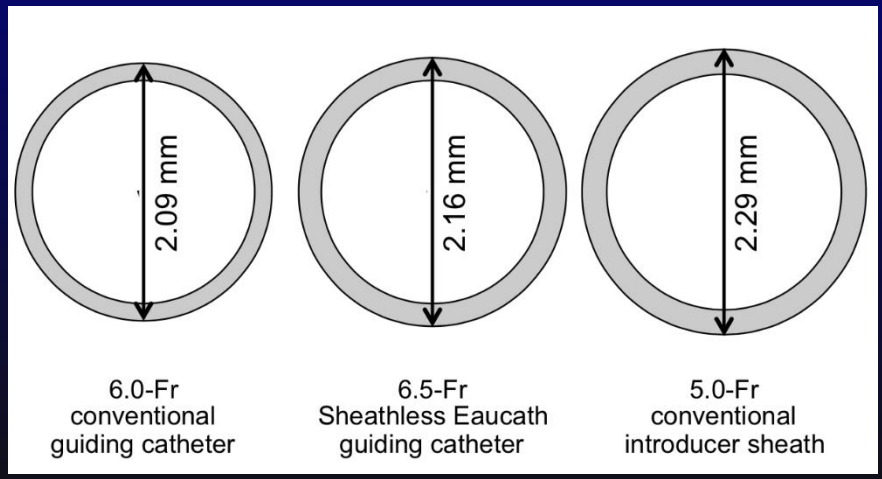
6.5-Fr Sheathless Catheter

- ✓ The Sheathless Eaucath hydrophilic-coated guide catheter™ (SH-GC; Asahi Intecc, Japan) has a small external diameter and hydrophilic coating, which can be inserted directly into radial arteries.



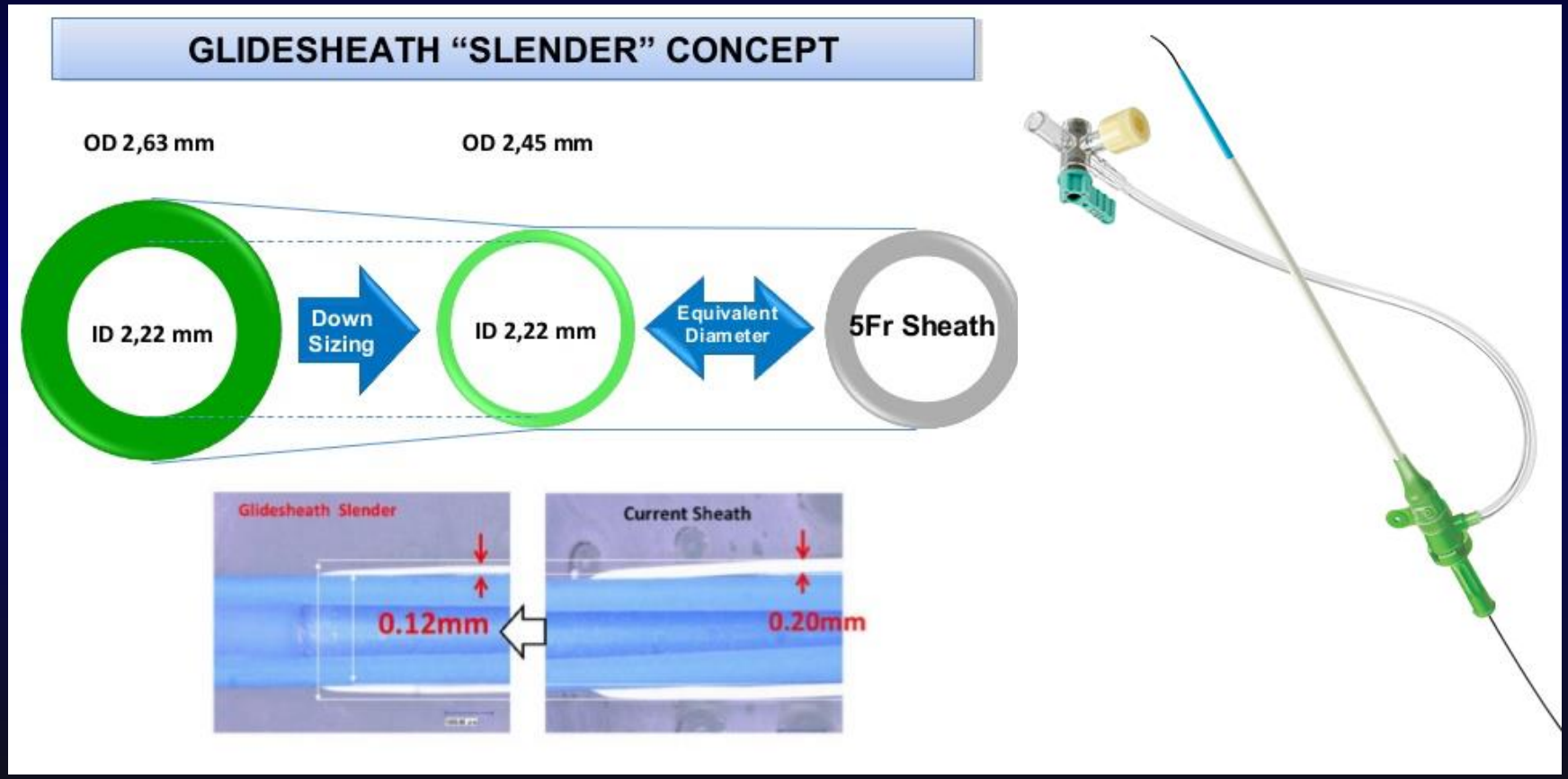
The external diameter

6.5-Fr SH-GC	2.16 mm
5.0-Fr sheath	2.29 mm
6.0-Fr sheath	2.62 mm



6.0-Fr Glidesheath Slender

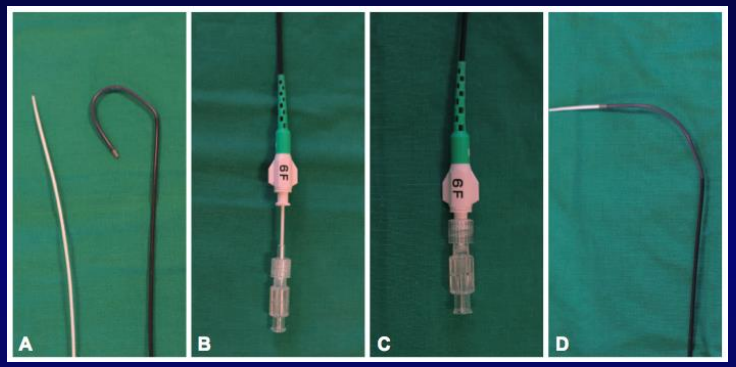
- The Glidesheath Slender™ (GSS; Terumo, Japan) is a dedicated radial sheath compatible 6.0-Fr catheters with small external diameter (2.46 mm) because thickness of sheath walls is reduced from 0.20 to 0.12 mm.



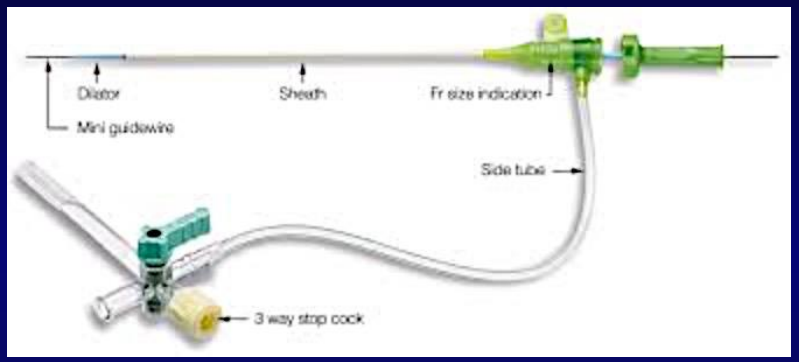
Less Invasive TRI Devices

- ✓ Although the feasibility of both devices has been confirmed individually, no study has conducted a direct comparison of the incidence of procedure-related RAO and RAS with the 6.5-Fr SH-GC and 6.0-Fr GSS.

6.5-Fr SH-GH



6.0-Fr GSS



The outer diameter:	2.16 mm	2.46 mm
RAO evaluated ultrasound:	0.7%	0.9%
Symptomatic RAS:	0.0%	4.4%
Procedural success rate:	95.2%	99.1%

Chiam PT, et al. Eurointerv 2011;7:930-5

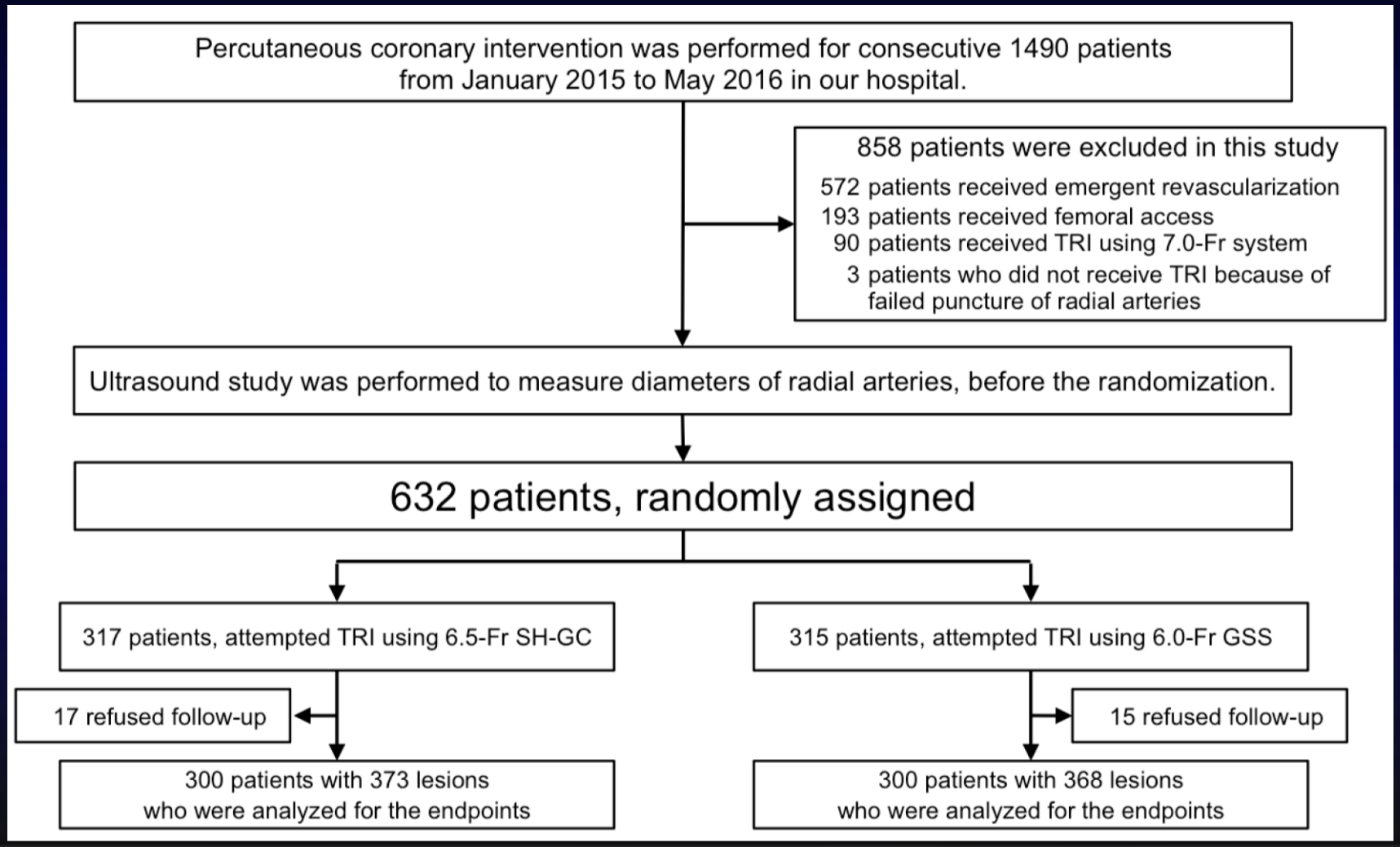
Aminian A, et al. CCI 2014;3:436-42

Objective

- ✓To compare the incidence of RAO and symptomatic RAS associated with TRI using 6.5-Fr SH-GC vs. 6.0-Fr GSS by randomized control study, registered in Japan Primary Registries Network as UMIN000019739.

Methods

Study Flow Chart



Methods

Study Endpoints

- Primary endpoints:
  - The primary endpoint was the composite of RAO 30 days after TRI, defined as the absence of antegrade flow on Doppler ultrasound, and symptomatic RAS during TRI.

RAS Grade

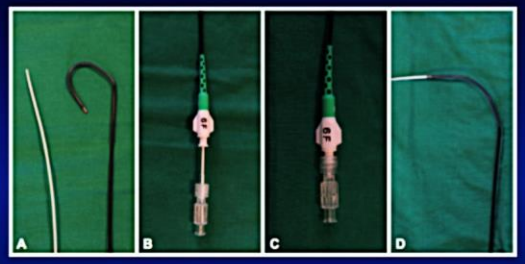
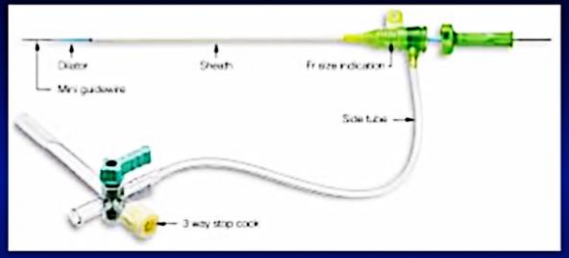
a) No spasm (Grade-0): Absence of arm pain or discomfort during and immediately after the procedure.
b) Mild spasm(Grade-1): Minimal local pain and discomfort during catheter movement and/or immediate post procedure period.
c) Moderate spasm(Grade-2): Significant local pain and discomfort during catheter movement and/or immediate post procedure period. However, movement was possible to complete the procedure.
d) Severe spasm(Grade-3): Severe local pain and discomfort during catheter movement compelling the operator to stop the procedure and cross-over to the other route.
e) Very severe spasm(Grade-4): Severe local pain and discomfort associated with catheter trapping.

Goldsmit A , et al. CCI 2014;83:32-6

- Secondary endpoints:
  - Procedural success
  - Major adverse cardiac events (MACE) within 30 days including cardiac death, definite stent thrombosis, and target lesion revascularization
  - Vascular access site complications within 30 days except for RAO and RAS

Statistical Power Test

- ✓ The trial was powered to test superiority of the primary composite outcome.
- ✓ We expected composite of RAO and RAS rates of 0.7% in the 6.5-Fr SH-GC and 5.3% in the 6.0-Fr GSS group.
- ✓ A total of 264 patients per group were chosen to provide >80.0% power and two-sided α of 5.0% to detect a significant difference of the primary outcome.

	6.5-Fr SH-GH	6.0-Fr GSS
		
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Chiam PT, et al. Eurointerv 2011;7:930-5 *Aminian A, et al. CCI 2014;3:436-42*

Baseline Patient Characteristics

Variable	SH-GC (*n* = 300)	GSS（*n* = 300）	*P* value
Age (years)	70.2 ± 10.0	69.2 ± 10.1	0.246
Acute coronary syndrome	32 (10.7)	24 (8.0)	0.261†
Male gender, n (%)	251 (83.7)	234 (78.0)	0.077†
Body mass index (kg/m^2)	24.5 ± 3.2	24.4 ± 3.4	0.624
Hypertension, n (%)	265 (88.3)	261 (87.0)	0.619†
Dyslipidemia, n (%)	254 (84.8)	246 (82.0)	0.381†
Diabetes mellitus, n (%)	150 (50.0)	144 (48.0)	0.624†
Current smoker, n (%)	63 (21.0)	55 (18.3)	0.491†
Chronic renal disease, n (%)	60 (20.0)	57 (19.0)	0.757†
Prior myocardial infarction, n (%)	91 (30.3)	91 (30.3)	1.000†
History of CABG, n (%)	6 (2.0)	6 (2.0)	1.000‡
Anticoagulant agent, n (%)	36 (12.0)	31 (10.3)	0.517†
Beta-blocker, n (%)	97 (32.3)	101 (33.7)	0.728†
Calcium channel blocker, n (%)	159 (53.0)	148 (49.3)	0.369†
Statin, n (%)	214 (72.1)	212 (71.1)	0.805†
Insulin, n (%)	18 (6.0)	22 (7.3)	0.512†
Median SYNTAX score	9.11 ± 6.33	9.29 ± 6.37	0.732
Radial artery diameter (mm)	2.20 ± 0.47	2.20 ± 0.45	0.979

Data given as mean ± SD or n (%). †x2 test; ‡Fisher's exact test.

CABG; coronary artery bypass graft, SYNTAX; Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery.

Baseline Lesion Characteristics

Variable	SH-GC (*n* = 373)	GSS（*n* = 368）	*P* value
De novo, n (%)	314 (86.5)	308 (84.2)	0.379†
AHA/ACC lesion morphology			0.848†
A/B1, n (%)	141 (37.7)	143 (38.9)	
B2, n (%)	55 (14.8)	49 (13.3)	
C, n (%)	177 (47.5)	176 (47.8)	
Target vessel			0.525†
Left main trunk, n (%)	12 (3.2)	12 (3.3)	
Left anterior descending, n (%)	153 (41.1)	162 (44.0)	
Left circumflex, n (%)	88 (23.7)	92 (25.0)	
Right coronary artery, n (%)	118 (31.7)	102 (27.7)	
Saphenous vein graft, n (%)	1 (0.3)	0 (0.0)	
Bifurcation lesion, n (%)	109 (29.3)	122 (33.2)	0.248†
Calcified lesion, (%)	45 (12.1)	47 (12.8)	0.770†
Aorto-ostial stenosis, n (%)	14 (3.8)	13 (3.5)	0.873†
Measurements of QCA			
Lesion reference diameter, (mm)	2.93 ± 0.47	2.92 ± 0.50	0.667
Lesion diameter stenosis, (%)	80.5 ± 9.5	80.7 ± 8.8	0.776
Lesion length, (mm)	20.7 ± 9.7	20.8 ± 9.3	0.891

Data given as mean ± SD or n (%). †x2 test; ‡Fisher's exact test.
AHA/ACC; American Heart Association/American College of Cardiology, QCA; Quantitative coronary angiography.

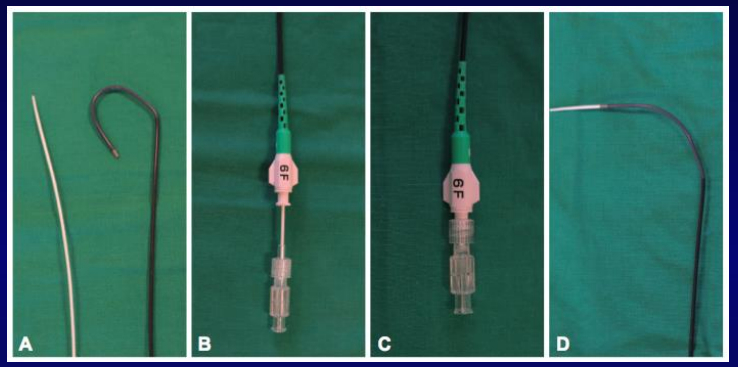
Procedural Characteristics

Variable	SH-GC (*n* = 300)	GSS（*n* = 300）	*P* value
Mean sheath/radial artery (S/RA) ratio	1.03 ± 0.23	1.17 ± 0.27	<0.001
Number of guiding catheters, n (%)			0.903†
1	261 (87.0)	262 (87.3)	
2 or more	39 (13.0)	38 (12.7)	
Stent implantation, n (%)	280 (93.3)	284 (94.7)	0.594†
Intravascular ultrasound, n (%)	227 (75.7)	211 (70.3)	0.141†
Kissing balloon inflation, n (%)	3 (1.0)	4 (1.3)	1.000‡
Rotablator, n (%)	19 (6.3)	19 (6.3)	1.000†
Distal protection, n (%)	10 (3.3)	12 (4.0)	0.664‡
Child in Mother technique, n (%)	17 (5.8)	15 (5.0)	0.716†
Intra-aortic balloon pumping, n (%)	1 (0.3)	1 (0.3)	1.000‡
Procedural time, (min)	46.9 ± 21.3	45.3 ± 20.4	0.343
Contrast used, (ml)	109.4 ± 48.6	109.7 ± 49.1	0.939
ACT at the end of TRI, (sec)	363.4 ± 184.9	366.9 ± 179.4	0812
Ostial dissection due to GC, n (%)	3 (1.0)	1 (0.3)	0.624‡

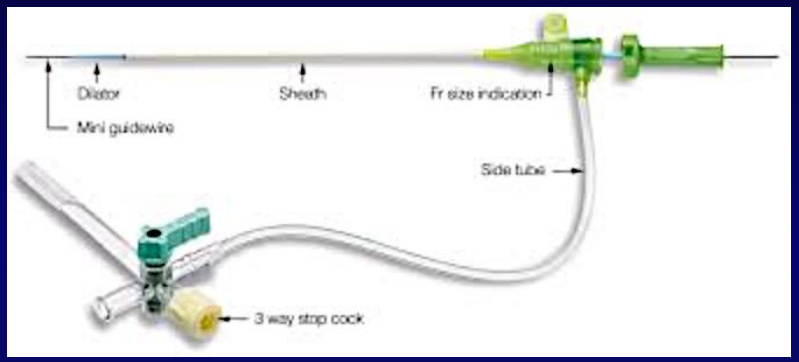
Data given as mean ± SD or n (%). †x2 test; ‡Fisher's exact test.
ACT; activated clotting time.

Results of Endpoints

6.5-Fr SH-GH



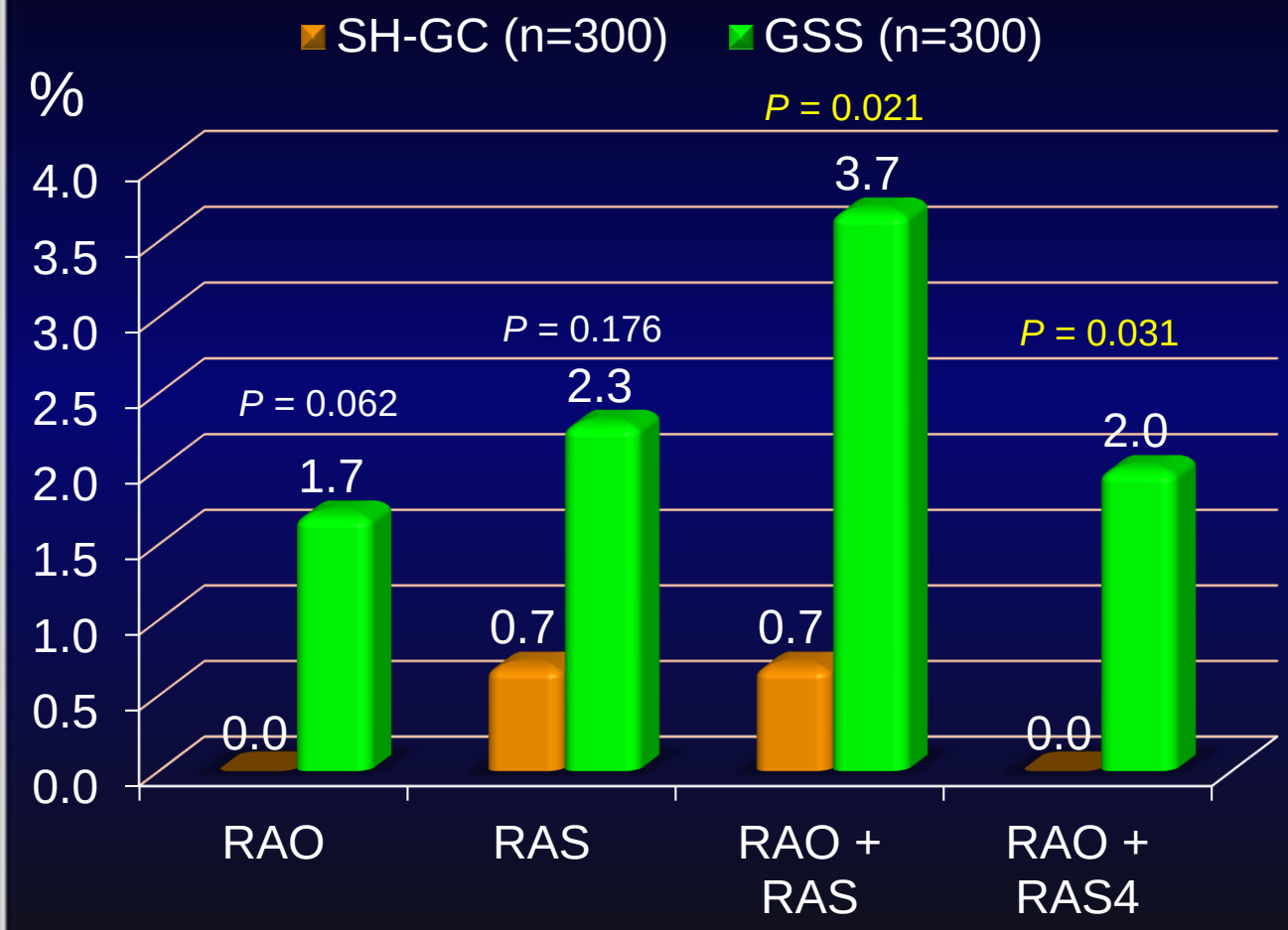
6.0-Fr GSS



RCT of 6.0-Fr compatible slender devices

Primary Endpoint

Composite of RAO and symptomatic RAS



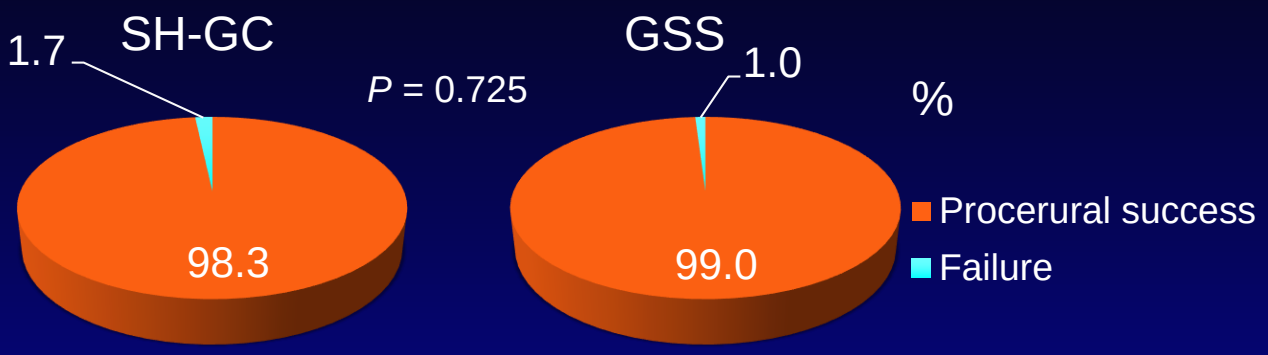
	SH-GC	GSS
RAS, n (%)		
Grade 2	2 (0.7)	2 (0.7)
Grade 3	0 (0.0)	3 (1.0)
Grade 4	0 (0.0)	2 (0.7)

Data given as n (%). Fisher's exact test.

Secondary Endpoints

Procedure Success without System Crossover

Procedural Success Rate



	SH-GC (*n*=300)	GSS（*n*=300）	*P* value
Access site crossover, n (%)	0 (0.0)	2 (0.7)	1.000
Crossover to other systems, n (%)	5 (1.7)	2 (0.7)	0.450
Reasons of system crossover, n (%)			
Failed engagement	3 (1.0)	0 (0.0)	0.249
Weak back-up force	2 (0.7)	0 (0.0)	1.000
Catheter trapping due to RAS	0 (0.0)	1 (0.3)	1.000
Insertion Failure due to RAS	0 (0.0)	1 (0.3)	1.000

Data given as n (%). Fisher's exact test.

Secondary Endpoints

MACE and the Other Access site Complications

	SH-GC (*n* = 300)	GSS （*n* = 300）	*P* value
Radial complications, n (%)			
Arteriovenous fistula	1 (0.3)	4 (1.3)	0.373
Pseudoaneurysm	1 (0.3)	0 (0.0)	1.000
Access site hemorrhage, n (%)	3 (1.0)	12 (4.0)	0.033
Major/Minor	1 / 2	2 / 10	
Blood transfusion, n (%)	1 (0.3)	2 (0.7)	1.000
MACE at one month, n (%)	4 (1.3)	3 (1.0)	1.000
All-cause death	0 (0.0)	0 (0.0)	
Procedure-related MI	2 (0.7)	3 (1.0)	
Definite stent thrombosis	1 (0.3)	0 (0.0)	
Target lesion revascularization	1 (0.3)	0 (0.0)	

Data given as n (%). Fisher's exact test.

Multivariate Analysis

The Predictors of RAO and RAS (*n* = 13)

	Univariate	Multivariate		
	P value	OR	95% CI	*P* value
Age	0.863			
Female	0.287‡			
Body mass index	0.521			
Dyslipidemia	0.140‡			
Diabetes	0.051‡	3.254	0.918 to 15.328	0.069
Chronic kidney disease	0.294‡			
Anticoagulant agent	0.163‡			
Statin	0.123‡			
6.5-Fr SH-GC	0.021‡	0.297	0.044 to 1.210	0.094
Mean S/RA ratio (per 0.1)	<0.001	1.354	1.144 to 1.614	<0.001
Procedure time	0.188			
History of TRI	0.262‡			
History of CABG	0.025‡	6.567	0.543 to 42.646	0.124

Data given as mean ± SD or n (%). †x2 test; ‡Fisher's exact test.
CABG; coronary artery bypass graft, OR; odds ratio, CI; confidence interval.

Summary

- ✓ Among 725 patients undergoing elective TRI, we included the consecutive 600 patients who scheduled to receive 6.0-Fr TRI, and conducted direct comparison between the 6.5-Fr SH-GC and 6.0-Fr GSS.

- ✓ The primary endpoint
  - ➢ RAO: 0.0% in SH-GC and 1.7% in GSS group ($P = 0.062$)
  - ➢ RAS: 0.7% and 2.3% ($P = 0.176$)
  - ➢ RAO + RAS: 0.7% and 3.7% ($P = 0.021$)
  - ➢ RAO + RAS 4: 0.7% and 2.0% ($P = 0.031$)

- ✓ The secondary endpoint
  - ➢ Procedural success rate and MACE were comparative.
  - ➢ The rate of access site hemorrhage: 1.0% and 4.0% ($P = 0.033$).

- ✓ The multivariate regression analysis found that a larger S/RA ratio was independently associated with composite of RAO and RAS ($P < 0.007$).

Limitations

- ✓ This trial was a single centre study and even though the sample size was adequate to compare the primary outcome of the study groups, it was relatively small.
- ✓ The primary endpoints were evaluated by independent observers in this study, but not by an external core laboratory.
- ✓ This study included only Asian patients, who have small radial arteries; therefore, the radial diameter and S/RA ratio may not be same as those of other races.
- ✓ Because our hospital is a highly experienced TRI centre and we are familiar with the SH-GC, the results may not be easily applicable to every operator.

Tada N, et al. J invasive Cardiol. 2015;27:237-41
Miyasaka M, et al. CCI. 2016;87:1111-7

Conclusions

- ✓ The 6.5-Fr SH-GC was effective as an initial GC to perform elective TRI and was associated with a significantly lower rate of radial complications than the 6.0-Fr GSS.
- ✓ SH-GC is a promising alternative to conventional TRI approaches.
- ✓ SH-GC can be used for distal radial approach