Prospective, Multicenter, Core Lab Adjudicated Registry to Evaluate Safety and Efficacy of Radial to Peripheral Interventions

Mehdi Shishehbor, DO, PhD, MPH on behalf of the R2P Registry investigators

University Hospitals, Cleveland, OH

Aim

- To evaluate the safety and efficacy of dedicated radial devices in patients with complex lower extremity vascular disease.

Study overview

R2P:
168 patients screened
120 successfully enrolled, and 46 received a Misago stent.

↓

30 days post procedure – primary safety and efficacy endpoints
111 (92.5%)

↓

1 year efficacy endpoint – Misago subjects only
Projected 43 (93%)

R2P™ DESTINATION SLENDER™ Guiding Sheath key features:

- ✓ Slender technology reduces the OD while maintaining ID to reduce spasm and enable providers to continue with the treatment algorithm
- ✓ Full Hydrophilic coating & 5cm dilator protrusion

R2P™ MISAGO® RX Self-Expanding Peripheral Stent key features:

- ✓ 6-8mm x 40-150 mm length
- ✓ Rapid Exchange (Rx) technology
- ✓ Distal Hydrophilic Coating
- ✓ Continuous spine free, open 8 cell with double link design

Results

Table 1. Baseline patient characteristics

	Patient Nb 120	Misago Subset N = 46
Age, years	68.7 ± 9.5	69.0 ± 8.4
Gender – females, %	31.7%	30.4%
Body mass index, kg/m^2	29.8 ± 6.6	28.9 ± 5.9
CAD, %	56.7	52.2
Renal Insufficiency, %	13.3	13.0
Diabetes, %	49.2	30.4
Hypertension, %	85.8	91.3
Hyperlipidaemia, %	92.5	95.7
Previous Amputation, %	5.0	6.5

Table 2. Lesion characteristics and Procedural time

Lesion characteristics		Lesion N =224
Lesion Location	Iliac, %	12.9
	SFA/SFA-Popliteal %	48.2
	Popliteal, %	12.1
	BTK, %	18.3
	Other, %	8.5
Treated Limb – Right, %		50
Pre-Treatment % Stenosis		83.2
Pre-Treatment Total Occlusion, %		33.5
Procedural times (HH:MM)		
Mean Procedure Length		1:14
Mean Time to Ambulation		3:31
Mean Time to discharge (total population)		7:29
Mean Time to discharge (Radial Access Only)		6:46
Same day discharge		
Same day discharge – total population, %		86.7
Same day discharge – radial access only, %		92.3

Table 3. Primary efficacy endpoint.

	All Subjects
Procedural Success (Successful procedure without conversion to femoral access or transradial access site complications)	95.0% (114/120)
Patients requiring Femoral Conversion	0.8% (1/120)
Patients with Transradial Access Site Complication[1] at Procedure	4.2% (5/120)

[1]1/5 patients experienced pseudoaneurysm, 4/5 vessel spasm and 2/5 access site bleeding. Please note reporting is per subject.

Table 4. Primary safety endpoint (at anytime point up to 30 days)

	All Subjects
Any radial access site complications[2]	20.8% (25/120)
Serious transradial access site complications	0.0% (0/120)
Non-serious transradial access site complications	20.8% (27/120)

[2]Reported access site complications include arterial spasm, arthralgia, peripheral artery thrombosis, peripheral swelling, skin bacterial infection, vascular access site discharge, vascular access site hematoma, vascular access site hemorrhage, vascular access site swelling, vascular pseudoaneurysm, and vasospasm

Table 5. Patency of radial artery

	All Subjects
Subjects with Radial Artery Patency at 30 Day FU	97.1% (102/105)

Conclusion

- Radial approach allowed for 92.3% same day discharge w/ no serious adverse events
- No serious transradial access site complications reported at any time during the study
- Pending 12-month patency data for Misago subset

ISET 2022: TIS2019-01