CLINICAL STUDY SUMMARY

Prospective, Multicenter Registry to Assess Safety and Efficacy of Radial Access for Peripheral Artery Interventions

A summary of the recently published Terumo R2P study evaluating radial access for endovascular lower extremity intervention.

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STUDY OBJECTIVE

To prospectively evaluate the safety and feasibility of radial access (RA) for complex endovascular lower extremity interventions.

STUDY DESIGN

- Prospective, multicenter, observational, postmarket study
- Designed to assess the safety and efficacy of RA for endovascular lower extremity interventions
- Eligible patients with peripheral artery disease (PAD) scheduled for intervention through RA were enrolled

PRIMARY ENDPOINTS

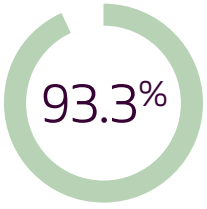
- Procedural success, defined as successful completion of the intended procedure without conversion to femoral access and without RA complications periprocedure
- The primary safety endpoint included evaluation of RA-related complications at 30 days

RESULTS

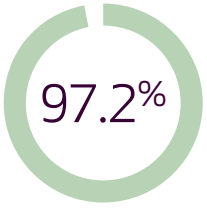
- The 224 lesions treated were in iliac (12.9%), femoropopliteal (55.3%), isolated popliteal (11.9%), and tibial (19.5%) vessels.
- The primary efficacy endpoint was achieved in 112 (93.3%) patients.
- No serious adverse events were adjudicated to the procedure.
- Mean procedure time and time to ambulation were 74 minutes and 3 hours 30 minutes, respectively, with 93.3% same-day discharge.
- At 30 days, 97.2% of patients recorded ultrasound-confirmed RA patency.

EDITORIAL

The study's findings demonstrate that RA is a safe and effective approach for treating complex multilevel PAD.[1] The technique allowed for early ambulation and same-day discharge for most patients, further enhancing patient satisfaction and reducing health care costs.[2]



Primary efficacy endpoint of procedural success without access complications was achieved in 112 (93.3%)



At 30 days, arterial duplex ultrasound showed radial artery patency in 97.2% of the patients with follow-up data (104/107)

TABLE 1. PROCEDURAL CHARACTERISTICS (N = 120)

Radial Artery Access Obtained	120 (100)
Additional access sites	30 (25)
Femoral	5 (4.2)
Tibial	7 (5.8)
Pedal	17 (14.2)
Other	3 (2.5)
Devices Used	
R2P 0.018 Crosstella Balloon (Terumo Interventional Systems)	85 (70.8)
R2P 0.035 Metacross Balloon (Terumo Interventional Systems)	50 (41.7)
R2P Misago SES (Terumo Interventional Systems)	46 (38.3)
Orbital atherectomy	64 (53.3)
Laser atherectomy	3 (2.5)
Procedural Times, HH:MM	
Procedure length	1:14 ± 0:37
Time to ambulation	3:30 ± 2:55
Time to discharge (all patients)	3:57 (0:40-145:18)*
Time to discharge (radial access only)	3:41 (1:35-145:18)*
Same-Day Discharge	
Total population	104 (86.7)
Radial access group only	84/90 (93.3)

Note: Values are presented as mean ± SD or n (%).
Abbreviations: SES, self-expanding stent.
*One patient had a preplanned multiday stay for a separate condition.

TABLE 2. PRIMARY EFFICACY AND SAFETY ENDPOINTS (N = 120)

Primary Periprocedural Efficacy Endpoint	
Procedural success	112 (93.3)
Required femoral conversion*	1 (0.8)
Radial access complication periprocedure†	7 (5.8)
Primary Safety Endpoint (30 D)	
Serious adverse events	0
Nonserious access site complications	20 (16.7)
Access site minor bleeding	9 (7.5)
Access site hematoma	6 (5.0)
Radial artery spasm	4 (3.3)
Access site swelling	3 (2.5)
Pseudoaneurysm	1 (0.8)
Radial artery thrombosis	1 (0.8)

Note: Values are presented as n (%).
*Owing to excessive iliac tortuosity and calcification.
†One pseudoaneurysm, four vessel spasm, and two access site bleeding.

CONCLUSION

In this prospective, multicenter registry, we show the safety and efficacy of the RA approach for the treatment of complex multilevel PAD. The RA approach allowed same-day discharge for most patients with no serious adverse events. Future randomized trials should examine the clinical and cost-effectiveness of this approach compared to femoral access for patients with PAD. ■

1. Castro-Dominguez Y, Li J, Lodha A, et al. Prospective, multicenter registry to assess safety and efficacy of radial access for peripheral artery interventions. J Soc Cardiovasc Angiogr Interv. 2023;2:101107. https://doi.org/10.1016/j.jscai.2023.101107
2. Nanjundappa A, Dieter EG, Dieter RS, et al. Transradial access for peripheral endovascular interventions: a leap toward improved patient safety and improved clinical outcomes. J Soc Cardiovasc Angiogr Interv. 2023;2:101179. https://doi.org/10.1016/j.jscai.2023.101179]