Safety, Efficacy, and Comfort of the Transradial Approach Using the Radial to Peripheral Destination Slender Guiding Sheath for Peripheral Endovascular Procedures

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Abstract: Background. The transradial artery (TRA) approach is well established and preferred over the transfemoral artery (TFA) approach for coronary angiography and intervention. Evidence is scarce for the TRA approach for peripheral intervention. **Aim.** In this descriptive study, we sought to determine the feasibility of the TRA approach for peripheral intervention using the Radial to Peripheral (R2P) Destination Slender Guiding Sheath (Terumo Medical Corporation). **Methods.** In a single-center descriptive study, we studied the characteristics of patients who underwent peripheral angiography and intervention using the TRA approach with an R2P Destination Slender Guiding Sheath during a study period from September 2017 through May 2019. **Results.** For the specified study period, 66 patients (62.1% men) underwent peripheral angiography with or without intervention. For 38 patients, the TRA approach was the only access site; for the rest of the patients, a second or third access site was used. None of the patients required a secondary access site due to an inability to intervene from the TRA. Two patients (3%) developed radial artery spasms requiring secondary access. Three patients (4.5%) developed hematoma that was reduced with manual compression. None of the patients experienced a major adverse cardiac event or loss of limb during the hospitalization. **Conclusion.** Based on our experience, TRA access for peripheral angiography and intervention using an R2P Destination Slender Guiding Sheath appears to be both feasible and a safer alternative to the TFA approach. Further studies are needed to conclusively determine the feasibility and safety of this approach.

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Background

The transradial artery (TRA) approach to percutaneous coronary angiography was first described in 1989 as an alternative to cut-down arteriotomy of the brachial artery and the percutaneous axillary artery and femoral artery technique.[1] Since then, numerous prospective and retrospective studies have firmly established the superiority of the TRA approach over the transfemoral artery (TFA) approach for coronary angiography and percutaneous intervention (PCI).[2] However, the efficacy of the TRA approach to peripheral intervention is fraught with challenges that need to be addressed. Data are scarce on the safety and efficacy of the TRA approach to peripheral intervention. A new guiding sheath, the Radial to Peripheral (R2P) Destination Slender Guiding Sheath (**Figure 1**) (Terumo Medical Corporation), was approved by the FDA in 2017. In this retrospective chart review, we report the safety and efficacy of the R2P Destination Slender Guiding Sheath for peripheral intervention.

Methods

All patients who underwent peripheral angiography and/or endovascular intervention from September 2017 through May 2019 using a 6 Fr R2P Destination Slender Guiding Sheath at Lafayette General Medical Center were included in this observational study. We obtained an exemption for informed consent by the Institutional Review Board as this was an observational study and no patient identifiers were collected during data collection.

All patients underwent Allen's test to check for collateral circulation prior to the procedure. The radial artery was accessed using a modified Seldinger technique with the R2P Destination Slender Guiding Sheath. After obtaining access, the sheath was flushed with a radial cocktail to prevent vasospasm. Where necessary, secondary access was obtained in a standard fashion via common femoral, popliteal, or posterior tibial artery. All study patients were anticoagulated with heparin during the procedure and loaded with aspirin and clopidogrel prior to the procedure.

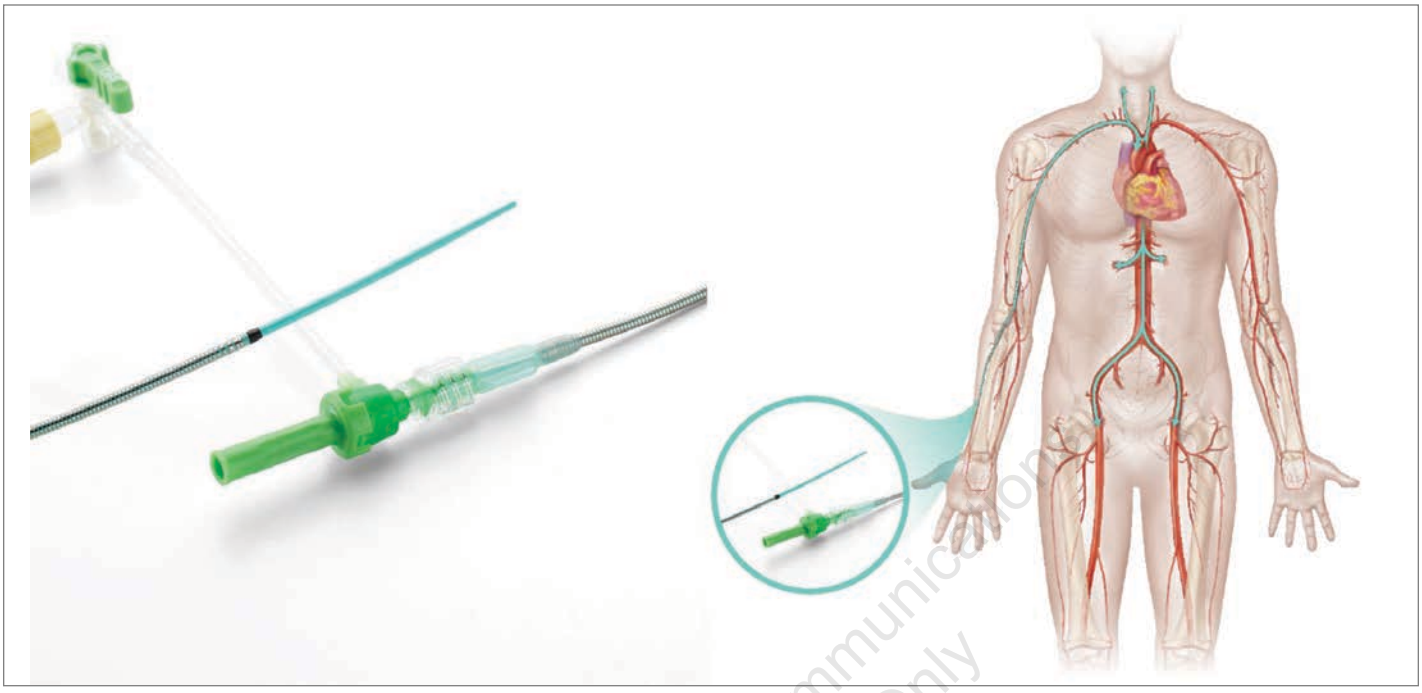

Figure 1. 6 Fr Radial to Peripheral (R2P) Destination Slender Guiding Sheath (Terumo Medical Corporation) with hydrophilic coating designed to provide transradial access to the peripheral vasculature for interventional procedures.
Reproduced with permission from Terumo Medical Corporation.

Results

For the specified study period, 66 patients underwent peripheral procedures using the R2P Destination Slender Guiding Sheath. Among the 66 patients (62.1% men and 37.9% women; 63.6% White and 36.4% Black), the average age was 70.3 ± 9.7 years. Dyslipidemia (94%), hypertension (92.4%), coronary artery disease (66.6%), and diabetes (41%) were the major associated comorbidities. Other characteristics of the study patients can be found in **Table 1**. Indication for the procedure was claudication in 65 patients and critical limb ischemia in one patient. Radial access was the only access site for 38 patients (57%), and more than 1 access site was obtained for the rest of the patients. Two patients required secondary access due to radial artery spasms. Other access sites in addition to radial were common femoral, popliteal, and posterior tibial (**Table 2**). Sixty-two patients were discharged on the same day. Out of the 66 patients, 10 had diagnostic angiography and the remaining 56 required interventions. Seven patients had 2 or more lesions requiring interventions. The interventions included 6 percutaneous transluminal angioplasties (PTAs), 1 direct stenting, 7 PTAs with stent placement, 11 atherectomies and stent placements, and 39 PTAs aided by atherectomy (**Table 3**). The location of lesions was femoral (42), femoral and aortoiliac (6), aortoiliac (4), and below the knee (8) (**Table 4**). Average fluoroscopy time was 17.5 (±14.7) minutes, and average contrast volume used was 271.6 (±424.5) mL. Successful hemostasis was obtained using a TR Band (Terumo Medical Corporation) in 60 patients and by manual compression in 6 patients (**Table 5**). Three patients (4.5%) had radial artery hematoma, out of which the TR Band was used in 2 patients. Radial artery spasm was noted in 2 patients during the procedure (**Table 6**). No death, major adverse cardiac event (MACE) defined as the composite of total death, myocardial infarction, stroke, hospitalization because of heart failure, and revascularization (including percutaneous coronary intervention and coronary artery bypass graft), or major vascular complications were reported in any of the study patients.

Discussion

Since the advent of coronary angiography there has been a paradigm shift in the arterial access from TFA to TRA. This was driven by robust evidence from multiple randomized controlled trials with proven superiority.[3] However, evidence is limited for peripheral endovascular interventions.[4] Small caliber of the radial vessels, tendency of radial vessels to spasm, and lack of anatomic proximity are some of the limitations to the TRA approach. On the other hand, the TFA approach may not be an ideal choice for every patient. The TFA approach often necessitates puncture of the already diseased vessel and is challenging in patients who previously underwent aorto-bifemoral bypass. Femoral access is prone to bleeding complications and incidence of groin hematoma, and in rare cases, life-threatening retroperitoneal bleeding.

Observational data from our center show that the TRA approach is a feasible and safer alternative to the TFA approach. Transpedal access is another alternative, but this approach also has limitations. Densely calcified distal vessels in a patient with

Table 1. Patient characteristics

Characteristics	All Patients (n = 66)
Age (years)	70.3 ± 9.7
Gender (male)	41 (62.1%)
Gender (female)	25 (37.9%)
Race (White)	42 (63.6%)
Race (Black)	24 (36.4%)
Height (cm)	170.48 ± 9.9
Weight (kg)	85.52 ± 22
Body mass index (kg/m2)	29.6 ± 6.3
Hypertension	61 (92.4%)
Dyslipidemia	62 (94%)
Diabetes	27 (41%)
Coronary artery disease	44 (66.6%)
History of myocardial infarction	5 (7.5%)
Congestive heart failure	1 (1.5%)
History of stroke, transient ischemic attack	14 (21%)
Arrhythmias	18 (28%)
Current tobacco use	21 (32%)
Former tobacco use	36 (54%)
Prior coronary artery bypass surgery	23 (35%)
End-stage renal disease on dialysis	2 (3%)
Chronic kidney disease stage 3 or higher	4 (6%)
Outpatient	63 (95%)

Table 2. Access site for the procedure

Access	Number of Patients
Radial only	38
Radial and femoral	7
Radial and popliteal	10
Radial and posterior tibial	7
Radial, popliteal, and femoral	1
Radial, femoral, and posterior	1
Radial, popliteal, and posterior	2

Table 3. Procedures performed

Procedure	Number
Diagnostic angiogram	10
Balloon angioplasty	6
Balloon angioplasty + stent	7
Balloon angioplasty + stent + atherectomy	11
Balloon angioplasty + atherectomy	39

Table 4. Anatomic location of diagnostic and treatment sites

Location	Number
Aortoiliac	4
Femoral	42
Aortoiliac + femoral	6
Below the knee	8

severe peripheral arterial disease make it extremely difficult to access these vessels. Only 2 patients (3%) required secondary access due to radial artery spasms. None of the study patients had a MACE or complications that led to compromise of the limb. Only 3 patients (4.5%) had a radial artery hematoma, which resolved after manual pressure. None of the patients needed a secondary access due to inability to intervene from radial access. When secondary access was obtained, it was done in order to provide extra support during intervention; the R2P Destination Slender Guiding Sheath 6 Fr inner lumen was sufficient and provided enough support for atherectomy catheters. Of our study patients, 50 patients (76%) underwent atherectomy through the radial sheath. Only 2 patients (3%) needed a secondary access due to radial artery spasm.

There are significant benefits of radial access for peripheral endovascular procedures. Notable among them are the ability for early discharge due to rapid control of access site bleeding and increased patient comfort. Radial artery spasm can be reduced by keeping the sheath wet during insertion and using a radial cocktail. We strongly recommend using a dilator and 0.035" wire during sheath removal for increased safety.

Despite the well-established superiority of the TRA approach over the TFA approach, there are still a few risks associated with the TRA approach. One of the most prevalent complications, with a reported incidence of 4%, is occlusion of the radial artery.[5] In addition, repeated radial artery access can lead to intimal hyperplasia, leading to luminal narrowing. Radial artery cannulation from the dorsal aspect of the anatomical snuff box has been proposed and validated in small studies[6,7] that aim to address complications related to radial artery occlusion and luminal narrowing from intimal hyperplasia. Ultrasound-guided TRA access has shown higher first-attempt success and lower failure rate when compared with TRA access by palpation alone.[8]

Our study is a single-centered observational descriptive study. Our findings could only be hypothesis-generating and need further investigation, preferably in a randomized controlled trial.

Conclusion

Our data show that radial access using the R2P Destination Slender Guiding Sheath is safe and effective in patients undergoing peripheral angiogram and endovascular intervention,

Table 5. Methods of postoperative radial hemostasis

Method	Number
Radial TR Band	60
Radial manual compression	6

Table 6. Complications

Complication	Number
Radial spasm	2
Radial hematoma	3

with an excellent safety profile. Further studies using a randomized controlled trial design with head-to-head comparison between TRA and TFA approaches is needed to conclusively prove this.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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