Multifactorial Benefits of Transradial Access (TRA) in Endovascular Interventions to Treat Peripheral Arterial Disease — Critical Limb Threatening Ischemia

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Abstract

Introduction. A paradigm shift appears to be occurring with overwhelming evidence of transradial access (TRA) being a safe and feasible approach for peripheral interventions compared to transfemoral access (TFA). Our study explores the additional, multifactorial benefits of TRA regarding perioperative times, radiation, contrast administration, and cost-savings for patients and hospitals. **Methods.** A retrospective review of all radial to peripheral interventions performed between April 2018-October 2022 was collected to outline the advantages and limitations of the TRA approach compared to TFA approach. Patient demographics, procedural time, contrast usage, and radiation dose were recorded and analyzed. **Results.** A total of 184 procedures performed via transradial access were evaluated and compared to a similar control population of transfemoral access procedures. Procedural success rate for all interventions was 100% with 17.9% of cases presenting with acute limb ischemia and 79.8% presenting with critical limb ischemia. A significant decrease in procedural time for TRA was evident in our analysis compared to the procedures conducted via TFA (80.1 ± 43.1 mins vs. 154.0 ± 28 mins, respectively). Furthermore, contrast and radiation absorption in TRA (150.7 ± 79.6 mL, 629.3 ± 845 mGy) proved superior to TFA (177.0 ± 28 mL, 1078 ± 78 mGy), adding to the potential cost-saving and safety measures for the patient and hospital system. **Conclusion.** While current TRA limitations include operator experience, length of devices, and sheath sizes, the overall benefits of TRA over traditional TFA management should not be ignored. As is demonstrated in our study, TRA boasted decreased perioperative times, contrast use, and radiation exposure. The TRA approach is undoubtedly a safe, feasible, efficient, and cost-saving route for peripheral interventions. It is here to stay as the present and future of diagnosing and treating peripheral arterial disease.

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Key words: contrast media exposure, critical limb ischemia, radiation exposure

Introduction

With the increased prevalence of obesity, diabetes, and hypertension in the United States, there has been a proportional rise of patients with peripheral artery disease (PAD) and critical limb threatening ischemia/critical limb ischemia (CLTI/CLI). Over 200 million people worldwide are diagnosed with PAD, causing asymptomatic disease in some while resulting in devastating pain and disability in others as it progresses to the terminal form, critical limb threatening ischemia (CLTI). This debilitating disease necessitates amputation in 3%-4% of patients, making it a leading cause of limb loss in the developed world.[1,2]

Revascularization to treat PAD can occur surgically or endovascularly with approximately 69% performed endovascularly.[3] Traditionally, endovascular management of PAD and CLTI was achieved by interventionalists via the gold standard transfemoral access (TFA). However, in the wake of the global COVID-19

pandemic, our hospital alongside many other hospitals around the United States experienced a severe shortage of hospital beds due to the influx of COVID-19 patient admits and new policies placing limits on patient admission as well as outpatient bed hospitalization. During this period of extreme restrictions, TFA proved to be an impassable obstacle for many PAD/CLTI patients requiring crucial treatment for this progressive chronic leg disease. TFA interventions were inefficient in providing optimal discharge times which required longer patient stay and potentially preventable admissions.[4-5] Additionally, complex sheath removal alongside groin-related complications required extra staff report and bed usage, preventing critical treatment of other patients that was simply not feasible during a worldwide pandemic.[6,7] Furthermore, the accumulation of admissions created an exponential rise in costs for both patients and hospitals. As such, there was a halt to many PAD procedures for the catheterization lab to perform. Such limitations with TFA necessitated a safe, more efficient, and less time consuming approach for the treatment of peripheral vascular disease that did not require hospitalization. This provided an optimal setting for practitioners to increase their utilization of the newly innovative radial-to-peripheral or trans-radial access (TRA) approach in peripheral interventions.

Although TRA has been extensively studied and determined to be a safe and feasible technique in percutaneous coronary interventions (PCI), little attempt has been made to adopt TRA in peripheral vascular interventions, possibly due to limitations in equipment lengths. During the height of COVID-19 however, TRA became a desperately needed method to provide a continuity of care for many PAD patients. Due to the unavailability of beds for postoperative hospitalization, TRA was the sole alternative and often necessary option for the management and treatment of PAD/CLI. Given the apparent shortcomings of TFA during COVID and the limited number of studies on TRA outcomes in peripheral interventions, further investigation into TRA patient outcomes and cost efficacy for PAD treatment and care is warranted. Our study aims to investigate the impact on procedural and clinical characteristics and explore potential multifactorial benefits from utilizing TRA in peripheral interventions in regard to perioperative times, radiation absorption, contrast administration, and cost-savings for patients and hospitals.

Methods

We examined all patients presenting with PAD and/or CLTI who underwent peripheral interventions via TRA access from April 2018 to October 2022 at the Texas Tech University Health Sciences Center-University Medical Center in Lubbock, Texas. This study is part of an ongoing initiative from our Lonestar PAD Registry to investigate the safety, efficacy, and cost-effectiveness of TRA compared to TFA in peripheral, endovascular interventions indicated for PAD. Inclusion criteria included patients diagnosed with PAD by history and physical examination, ankle brachial index (ABI) with less than or equal to 0.90 for symptomatic patients, and duplex arterial ultrasonography showing evidence of peripheral arterial occlusions. Patients less than 18 years of age and greater than 90 years of age as well as pregnant women were excluded from the study. All participants gave informed consent over the study with authors conforming to guidelines and ethics from the institutional review board. Information from patient records were collected and analyzed including patient demographics (age, gender), comorbidities (diabetes, hypertension, coronary artery disease, chronic heart failure, tobacco usage, etc.), clinical characteristics (acute limb ischemia, chronic limb ischemia, stent placement, balloon angioplasty, thrombectomy, atherectomy, below the knee intervention, above the knee intervention), and procedural data (procedure time, contrast administration, radiation exposure).

Patient demographics and clinical characteristics were reported as frequencies for categorical variables and mean (± standard deviation) for continuous variables. To assess the safety, cost-effectiveness, and efficacy of TRA access, data on procedure time, contrast usage, and radiation exposure were compared to a control population who underwent peripheral angiography/interventions via TFA. Two-sample independent T-tests comparing mean results from each procedural characteristic mentioned were used to investigate statistical differences between TRA and TFA for peripheral angiography/interventions. All statistical analysis was performed using IBM SPSS Statistics Version 28 and Microsoft 365 Excel Version 2206. $P<.05$ was

Table 1. Demographics And Comorbidities

	Overall (n=184)
Age	66.2 ± 10.0
Males	65.2%
Females	34.8%
Tobacco history	70.1%
Diabetes	33.7%
Hypertension	41.3%
Coronary artery disease	32.1%
Coronary arterial bypass graft	13.0%
Chronic heart failure	7.1%
Chronic kidney disease	5.4%
Aortic disease	48.4%
Hyperlipidemia	60.3%
Atrial fibrillation	6.5%
COPD	37.5%

Patient demographics and comorbidities. The above table denotes the patient demographics and comorbidities of all procedures that have undergone peripheral angioplasty/intervention via TRA in this study.

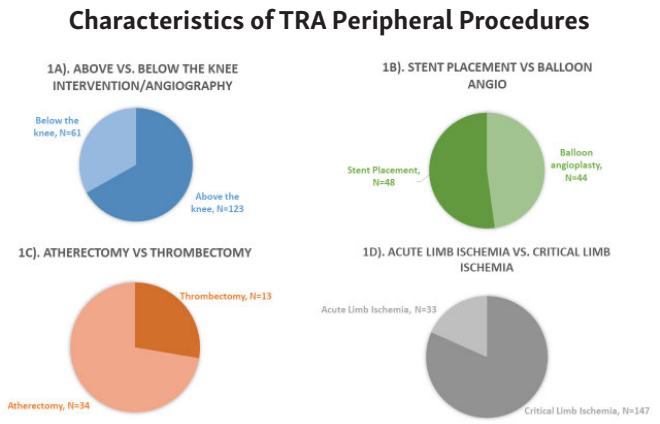

FIGURE 1. Occurrences of varying TRA interventions as characterized by distinguishing indications. (1A) Interventions/angiographies above the knee are reported as greater than below the knee. (1B) Stent placement usage was slightly higher than balloon angioplasty. (1C) Atherectomies were utilized to a greater extent than thrombectomies. (1D) Additionally, TRA usage was greater among critical limb ischemia patients than acute limb ischemia patients.

considered statistically significant. An independent body was selected by two faculty members to independently review, calculate, analyze, and recheck all data and study-related analyses to confirm the findings.

Results

A total of 184 peripheral cases performed via TRA were collected and analyzed. The mean age of all patients was 66.2 ± 10 with 65.2% (n=120) being male and 34.8% (n=64) being female. Demographics and comorbidities of all patients with peripheral TRA procedures are shown in **Table 1**. Tobacco history (70.1%) stood out as the number one comorbidity among the patient population followed by hyperlipidemia (60.3%), history of aortic disease (48.4%), and hypertension (41.3%). As seen in **Figure 1D**, a majority of TRA peripheral procedures were indicated for patients with chronic limb ischemia (79.8%, n=147) while 17.9%, n=33 were for patients diagnosed with acute limb ischemia. Furthermore, when closely examining the characteristics of the TRA peripheral procedures performed in **Figure 1**, **A-C**, above the knee (66.8%, n=123), and atherectomy (18.4%, n=34), interventions/angiography were the most common. The rates of stent placement and balloon angioplasty performed for TRA peripheral procedures were unremarkable. All patients gained right ultrasound guided radial access using the 6-Fr sheath system. Procedural success rate for all interventions was 100% with no complications noted.

To assess safety, efficacy, and cost-savings metrics, procedural data including time, amount of contrast usage during the case, and radiation absorption were analyzed in **Figure 2**. Of the peripheral angiography/intervention cases, TRA displayed superiority in all three metrics of study with significant drop in contrast usage, procedure time, and radiation absorption compared to the TFA control population (TRA: 150.7 ±79.6 ml Visipaque vs. TFA: 177.0 ±28 ml Visipaque, P<.01, TRA: 629.3 ± 845 mGy vs. TFA: 1078.0 ± 78 mGy, $P < .01$ and TRA: 80.1 ± 43.1 minutes vs. TFA: 154.0 ± 28 minutes, $P < .01$). Furthermore, these findings follow similar trends seen in TRA vs TFA coronary angiography/intervention in a side by side comparison. Interestingly, procedural time when utilizing the TRA approach displayed a drastic decrease only in peripheral interventions further corroborating the multitude of benefits from this novel technique.

Discussion

In addition to the previously discussed benefits of transradial access (TRA) over transfemoral access (TFA) in the endovascular management of PAD and CLTI during COVID-119, the focus of our investigation was the comparison of contrast administration, operative times, and radiation exposure for a wide variety of patients and treatments as demonstrated in **Table 1** and **Figure 1**. Our data corroborates prior studies in PCI as well as expands upon the benefits of TRA over TFA when contrast, radiation, and procedure time are compared, all of which are central to patient safety and treatment efficacy.

In regard to contrast use as demonstrated in **Figure 2A**, the TRA technique was shown to utilize less contrast when compared to TFA controls in both peripheral intervention (150.7 ± 79.6 mL vs. 177.0 ± 28 mL, respectively) and coronary intervention. The benefits of limited contrast use cannot be overstated, not only from the perspective of limiting risk of adverse immune reactions in patients, but also in the cost-effectiveness of procedure systems and in the severe contrast shortages experienced nationwide secondary to the COVID-19 supply chain disruption. As shown in **Figure 2B**, the procedure time for peripheral interventions that utilized TRA were dramatically reduced in comparison to TFA controls (80.1 ± 43.1 min vs. 154.0 ± 28.0 min, respectively). The benefits that arise from reduced procedure times as seen with TRA are multifactorial. Patient safety is of utmost priority and reduced operative times have consistently been shown across all fields of medicine to be associated with reduced operative complications. In regard to **Figure 2C**, the radiation levels experienced by the patient were significantly lower than those experienced by TFA controls (629.3 ± 845 mGy vs. 1078.0 ± 78 mGy, respectively). The utilization of a technique that lowers radiation exposure is understandably preferential, as reducing the high radiation exposure risk posed to patients and the medical staff during the long peripheral intervention cases is always an important safety consideration.

The benefits of TRA are numerous and include reduced contrast use, operative times, radiation exposure, access-related complications compared to femoral access, improved endovascular treatment when there is severe tortuosity and heavy calcification of the iliac

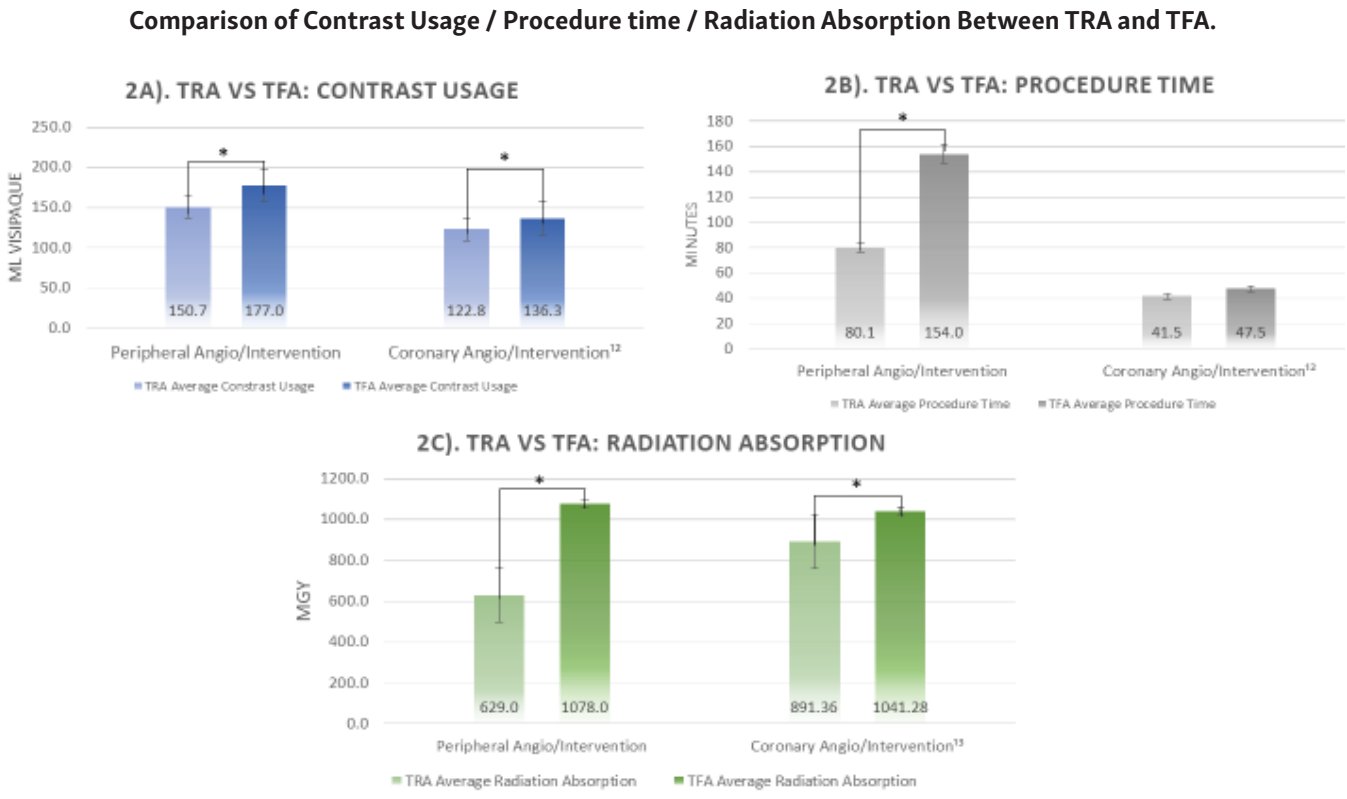

FIGURE 2. Significant differences reported favoring TRA over TFA techniques. Figure (**2A**) indicates less contrast usage during both peripheral and coronary TRA interventions. Procedure time (**2B**) was substantially reduced with peripheral TRA. Additionally, patient exposure (**2C**) was significantly less for both peripheral and coronary TRA cases.

[14] Data from Hirzallah H, Amro A, Kusmic D, et al. Comparison of transradial and transfemoral approaches for coronary angiography and percutaneous intervention in patients with coronary bypass grafts. *Cardiovasc Revasc Med.* 2020;21(1):2-5.

[15] Data from Tarighatnia A, Mohammad AH, Ghojazadeh M, and Farajollahi AR. Comparison of the patient radiation exposure during coronary angiography and angioplasty procedures using trans-radial and trans-femoral access. *J Cardiovasc Thorac Res.* 2016;8(2):77-82.

arteries, elimination of the need of costly compression device employment, and it allows for more immediate ambulation and same-day discharge. In the height of COVID, the TRA procedure was crucial to maintain continuity of care in patients when the TFA procedure was unavailable. With regard to these benefits and those of the recent technological/manufacturing advancements reducing the primary limitations of TRA, transradial access is an endovascular technique that is here to stay in the successful management and treatment of peripheral arterial disease.

Economic Benefits - Cost Effectiveness

Figure 3 represents a summarized breakdown of the advantages of TRA compared to TFA. These encapsulate the increased perioperative times associated with TFA, an important component of this can be attributed to groin related complications (potential bleeding, hematoma, and fistula formation), necessitating increased hospital admission, extra staff report, and prolonged bed occupation. Additionally, by reducing the net perioperative time, both operators and hospital systems are poised to serve the growing demand for PAD/CLTI interventions. With a near two-fold reduction in time allowance (reducing major hospital associated costs by more than half), the safety, cost-effectiveness, and efficiency of TRA over TFA cannot be ignored. Due to high postoperative CAPCU costs, the lower postoperative times from TRA drastically reduce the cost burden on patients by nearly a two-fold decrease shown in **Figure 3**. This, along with lower complication risks and reduced risks of readmission, further acknowledges the cost-savings value seen not only for the hospital system but also for the patient and their family members.

Survey And Score Benefits

In addition to the observed economic benefits of the transradial approach, review of our TRA metrics demonstrated significantly improved patient satisfaction as was evident from improved Press Ganey scores — an independent scoring system implemented in the 1980s that evaluated hospital staff and systems based on patient care, experience, safety, and privacy. With reduced patient costs, better time to recovery and ambulation, and the ability to provide patients with necessary care during COVID restrictions, TRA-related Press Ganey scores were markedly

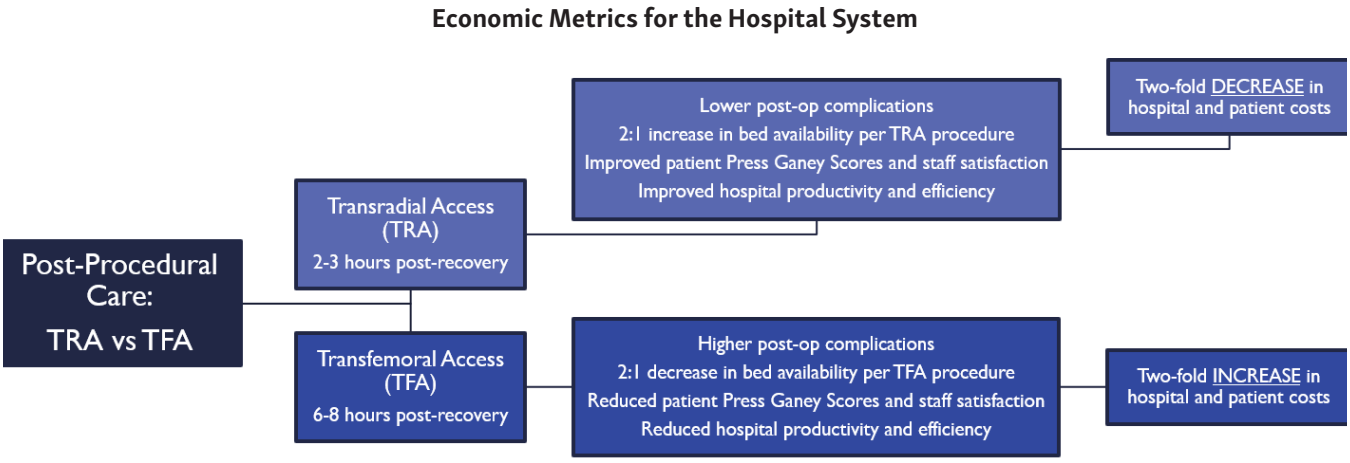

FIGURE 3. Cost-saving measures of hospital system in post-operative care of TRA vs TFA peripheral procedures. TRA results in an increase of hospital savings nearly twice as much compared to TFA with post recovery time between 2-3 hours for TRA and 6-8 hours for TFA.

higher than TFA-related metrics across all spectrums. Equally important to the improved patient satisfaction, the transition to TRA interventions also demonstrated improved employee satisfaction and reduced turnover rates in the catheterization lab and holding area staff. The ability to maintain hospital positions, to reduce postoperative demands on auxiliary staff, and to create more predictive work scheduling, all contributed to a significant increase in staff-related work satisfaction indices. The quality of life improvements in both patients and medical staff should not be ignored when considering the advantages that TRA provides over the traditional TFA approach.

Current And Future Devices

Initial reports of the transradial access approach for coronary angiography were first described by Campaue in 1989 and PCI by Kiemeneij in 1992.[8,9] Following the decades since, TRA has consistently shown numerous advantages in cost-effectiveness and patient safety over TFA for coronary catheterizations, affirming a spotlight for TRA as the dominant preferred route of choice.[10,11] With over 3 decades of coronary TRA advances, a similar paradigm shift in peripheral vascular interventions is warranted in at least non-complex cases.

The major limitations for peripheral TRA have been a lack of devices fulfilling the needs of complicated peripheral vascular disease procedures. Many equipment sizes and lengths available were not designed for long distance navigation through peripheral vasculature from the TRA approach. In recent years, however, there have been major innovations on the market to bridge the unmet needs and improve operator experience for radial-to-peripheral interventions. Currently, the following devices designed for radial-to-peripheral utilization are classified by their device type in **Table 2**. Each device carries its own unique characteristics and benefits to approaching radial-to-peripheral interventions.

Additionally, several groundbreaking trials have demonstrated the potential radial-to-peripheral devices carry for peripheral interventions. A great research trial named "REACH PVI" study sheds light on the extended length devices such as the Extended Length Orbital Atherectomy System for lower extremity peripheral arterial disease.[12] This study further facilitates transradial endovascular procedures by increasing its spectrum of application. Another interesting trial named "FARMI" demonstrated that the radial approach decreased peripheral arterial complication rates and allowed earlier ambulation in the patients.[13] The findings from these trials show great promise for the future of radial-to-peripheral interventions. With continued industry innovation and operator experience, peripheral TRA is on track to become the preferred route for diagnosis and treatment of PAD and CLI.

Building a Successful Radial-To-Peripheral Program

In light of the increasing proportion of emerging interventionalists being trained in transradial access, as well as the numerous advantages that TRA has over the traditional transfemoral approach, it is important to highlight the fundamental steps of building a radial-to-peripheral program. As with any new initiative, the first step includes securing hospital support via the assembly of a multidisciplinary and collaborative team of healthcare professionals (eg, interventional cardiologists, interventional radiologists, vascular surgeons, cath lab staff, and administration including nurses and pre/post care staff). Following program support and assembly, all staff should receive radial-to-peripheral relevant training, reflective of their medical responsibilities, in a step-by-step process. By including all staff, this seeks to provide them with necessary knowledge and skills to achieve optimal patient outcomes in all domains. For any proceduralists performing the radial-to-peripheral intervention, knowledge and expertise with traditional TFA methods is a nec-

Table 2: Details on Current Radial to Peripheral Devices Stratified by Device Type

Device Company	Sheaths	Balloon Catheters	Stents	Wires	Radial to Peripheral Catheters	Atherectomy Devices	Drug-Coated Balloon
Terumo Interventional Systems	**Glidesheath Slender** • 5,6,7 Fr • 10cm, 16cm **R2P Destination Slender** • 6 Fr • 119cm, 149cm **R2P SlenGuide** • 7 Fr • 120cm, 150cm	**R2P Metacross RX 035** • 6 Fr • 3-8mm diameter x 20-200mm length • 200 cm **R2P Crosstella RX 018** • 5 Fr • 2-6mm diameter x 40-200mm length • 200cm	**R2P Misago** • 6 Fr • 6-8 mm diameter x 40-150mm length • 200cm	**Glidewire** • 0.0035' Straight,Angled, 1.4mm and 3mm J Tip • 350cm, 400cm, 450cm			
Cordis	**Brite Tip Radianz** • 6 Fr • 110cm, 135cm **Rain Sheath Trans-radial Thin-Walled Introducer** • 4,5,6,7 Fr • 10cm, 16cm		**S.M.A.R.T Radianz** • 6 Fr • 150,190 cm		**SABERX Radianz** • 4,5,6 Fr • 190cm		
Surmodics	**Sublime Radial Access** • 5,6 Fr • 120cm, 150cm	**Sublime RX PTA 014** • ≥ 5 Fr • 250 cm **Sublime RX PTA 018** • ≥ 5 Fr • 220cm					
CSI: Cardiovascular Systems Inc.				**ViperWire Advance** • 475 cm	**ViperCath XC** • 5 Fr • 200 cm; Straight; Angled	**Diamondback 360 System Crown** • 5 Fr • 180 cm, 200cm **Diamondback 360 System Exchange Series** • 5 Fr • 180cm, 200cm	
Medtronic							**IN. PACT 018** • 5,6 Fr • 200cm

essary prerequisite of peripheral endovascular intervention to prepare for unexpected outcomes. While many are well-versed in performing radial access for coronary interventions, proceduralists should consider mastery of non-complex radial-to-peripheral angiograms first, with a gradual increase in difficulty of cases. This includes performing selective angiograms with incremental progression from diseased iliac arteries to superficial femoral arteries to popliteal arteries and beyond. Following proficiency, proceduralists should progress to more difficult cases involving chronic total occlusions and other complex pathologies. Though much detail has been spared, we believe these to be the fundamentals in bringing about a successful radial-to-peripheral program. Our next aim in a subsequent paper is to provide a more thorough and detailed discussion on these specifics.

Study Limitations

The study limitations are as follows: first, this study only covers TRA procedures dating back to April 2018. However, this study was a pilot project to compare TRA vs TFA peripheral procedures and analyze the potential benefits that TRA brings to the hospital from both a quality care and operational standpoint. We intend to further analyze the multifaceted benefits of TRA over an extended period in future studies. Second, TRA metrics such as procedure time can vary based on operator experience, length of devices, and sheath sizes. However, our statistical analysis indicates that any variability introduced by these factors is minor and would have no significant impact on the conclusions mentioned in this study. Thirdly, the majority of peripheral TRA procedures performed in our study did not include advanced CLI cases with a Rutherford classification of V and/or VI.

Conclusion

Since the beginning of the 2000s, there have been several trials and studies comparing the traditional TFA approach to the new and upcoming transradial access (TRA) approach for PCIs. Such studies demonstrated not only the cost-effectiveness of TRA over TFA, but also the diagnostic superiority of TRA and its ability to bypass the most common adverse event (vascular access) of TFA interventions with limited literature on the potential benefits seen in peripheral interventions.[7-9] Traditionally, endovascular management of peripheral arterial disease (PAD) and critical limb ischemia (CLI) was primarily achieved via transfemoral access (TFA). However, COVID-19 compelled interventionalists to take an out-of-the-box approach to treating peripheral interventions, shedding a spotlight on this groundbreaking radial-to-peripheral technique. Needless to say, radial-to-peripheral access has gained popularity in recent years as it has been shown to be a safe and effective route for the treatment of PAD and CLI.

Future Directions

Future direction includes expanding our research database within the PAD Lonestar Registry to include more patients to improve care and to further delineate the differences between transradial and transfemoral approaches. Additionally, we are interested in quantifying the true benefit-cost ratio of

TRA vs TFA from an economic perspective. Furthermore, as peripheral intervention via TRA entails a great learning curve for many, we anticipate future training programs designed for physicians interested in further developing and honing their skills in this innovative technique. As such, we intend on outlining how the TRA technique can be implemented and utilized in peripheral vascular interventions through future literature regarding our experience and lessons learned from building a radial-to-peripheral program. Finally, with the increased popularity of peripheral TRA interventions, we foresee further innovation in device technology for radial to peripheral interventions.

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