The Safety and Efficacy of Peripheral Vascular Procedures Performed in the Outpatient Setting

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ABSTRACT: Objectives. This study sought to evaluate the safety and efficacy of peripheral vascular interventions performed in a private, outpatient catheterization laboratory. **Background.** Peripheral vascular interventions have been traditionally performed in the inpatient setting. However, there has been a recent shift away from hospital-based vascular interventions toward outpatient-based procedures. Data are scarce on the efficacy and safety of such procedures being performed in the outpatient setting. **Methods.** We performed a retrospective chart review of the first 500 consecutive procedures that were performed at an outpatient catheterization laboratory from February 2012 through February 2013. We separated the procedures into arteriovenous fistula (AVF)-related procedures, peripheral arterial disease (PAD)-related procedures, and miscellaneous procedures. The primary endpoint was procedure success rate, defined as postintervention residual stenosis of <30% on angiography. The secondary endpoint was procedure-related adverse events. **Results.** The success rate for AVF-related interventions was 90%, and 93% when including partially successful interventions. The success rate for PAD-related interventions was 82%, and 92% when including partially successful interventions. The procedure success rate for miscellaneous interventions was 89%. Five AVF-related procedures suffered an adverse event (1.49%). Two PAD-related procedures suffered an adverse event (1.3%), while no adverse events were noted among miscellaneous procedures. One patient required immediate postprocedure hospitalization due to iliac artery perforation. **Conclusion.** Peripheral vascular procedures performed in the outpatient setting are safe and effective. A comparison of outcomes between outpatient and inpatient facilities when performing similar peripheral vascular interventions is needed in order to determine whether a transition of further vascular procedures into an outpatient setting is justified.

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There has been a steady growth in the number of outpatient catheterization centers nationwide in the United States. Multiple factors have contributed to this growing trend, including the increasing cost of hospitalization coupled with the decreasing rates of hospital reimbursement, development and improvement of endovascular techniques, relative ease of scheduling office-based procedures as opposed to dedicating operating room (OR) time, and increased convenience to the patients. However, data from large trials assessing the safety and efficacy of outpatient peripheral vascular procedures are scarce. The original articles on this topic primarily described the feasibility of performing outpatient endovascular procedures. It should be noted, however, that these studies were not performed in a true outpatient setting. Instead, the endovascular procedures were performed in the hospital, and the patients were discharged to home after an uneventful recovery period in the emergency room.[1-5] Finally, new data are emerging from small, single-center studies that describe the experience of practitioners in their community-based offices.[6-8]

The purpose of this study was to assess the efficacy and safety of outpatient peripheral vascular interventions. We also evaluated the characteristics of successful, unsuccessful, and partially successful peripheral vascular interventions that were performed in the outpatient setting. In addition, we compared our results with historical data on the safety and efficacy of peripheral vascular interventions performed in the inpatient setting.

Methods

Study design. After obtaining approval from the Western Institutional Review Board (WIRB), we conducted a retrospective chart review of the first 500 consecutive procedures that were performed at a private, outpatient catheterization laboratory in downtown Los Angeles. This catheterization center only performs peripheral vascular procedures. Patients are monitored in the center's recovery area for 20 minutes after arteriovenous fistula (AVF)-related procedures and 6 hours after peripheral arterial disease (PAD)-related procedures. All procedures were performed by four interventional cardiologists between February 2012 and February 2013. A breakdown of each operator's historical inpatient procedural volume is provided in Table 1. Patient demographics and medical history were obtained from electronic medical records. The details of each procedure including indication, description, device(s) used, outcomes, complications, amount of contrast used, and fluoroscopy time were obtained from the procedure report. Procedure reports were obtained from the

Table 1. Historical procedural volume for each of the four operators involved in this study.

	Number of Inpatient Peripheral Endovascular Procedures in 2012	Number of Inpatient Peripheral Endovascular Procedures in 2013
Operator 1	97	58
Operator 2	193	140
Operator 3	125	77
Operator 4	11	98

Table 2. Baseline patient demographics.

	Patients Undergoing AVF-Related Procedures	Patients Undergoing PAD-Related Procedures	Patients Undergoing Miscellaneous Procedures
Number of patients	163	111	14
Median age (years)	70	75	74
Gender			
Male	56.4%	51.3%	57%
Female	43.5%	48.6%	43%
Race			
Caucasian	11%	20.7%	7%
Black	6.7%	6.3%	7%
Hispanic	65%	50.4%	50%
Asian	12.2%	19.8%	36%
Pacific Islander	4.9%	2.7%	0%
Hypertension	88.9%	94.5%	92.8%
Diabetes mellitus	62.5%	66.6%	57.1%
Dyslipidemia	48.4%	81.9%	71.4
End-stage renal disease	100%	18%	28.5%
Peripheral arterial disease	17.7%	100%	14.2%
Congestive heart failure	6.7%	16.2%	0%
Coronary artery disease	22.7%	40.5%	28.5%
Current smoker	1.2%	6.3%	7.1%
Previous smoker	6.7%	28.8%	21.4%
Aspirin	66	59	5
Warfarin	11	15	2
Clopidogrel	23	51	3
Prasugrel	0	1	0
Ticagrelor	0	0	0
Statin	72	77	9
Insulin	38	28	2
Oral DM agents	38	44	5
Beta-blocker	97	62	6
Calcium-channel blocker	82	50	6
ACE-I/ARB	72	64	7
Diuretic	31	43	2
Nitrates	26	18	0
Cilostazol	1	16	0
Pentoxifylline	0	0	0

Data presented as absolute number for medications and as percentage for gender, race and disease states.

electronic medical record system. Selected angiograms were reviewed in order to confirm procedural details mentioned in the procedure report. A 2-page form was generated for each procedure, and included the patient and procedure details. The information from all 500 forms was then entered into a database, which we used to perform our analyses. In compliance with the Health Insurance Portability and Accountability Act (HIPAA), all patient identifying information including name, medical record number, and date of birth were deleted from our records. Procedures were consecutively assigned a number starting at 1 to 500. The first 500 procedures performed at this catheterization center were included and no procedures were excluded from the analysis. The procedures were categorized into AVF-related, PAD-related, and miscellaneous procedures. The primary endpoint of this study was angiographic success rate. The angiographic success rate for each procedure type was calculated separately. The secondary endpoint of this study was procedure-related adverse events. Likewise, the rate of adverse events was separately calculated for each procedure type. In addition, the rate of postprocedure hospitalization was calculated. Adverse events and postprocedure hospitalizations were identified from the procedure reports.

The secondary analysis included characterization and comparison of successful, partially successful, and unsuccessful AVF-related interventions. The same characterizations and comparisons were performed for PAD-related and miscellaneous interventions. The number of repeat AVF-related procedures, including their indications and the time interval between them, were identified. In addition, the AVF-related and PAD-related procedures that were complicated with an adverse event were characterized. Finally, patients were asked to voluntarily complete a satisfaction survey after the completion of the procedure.

Definitions. *Successful interventions* resulted in postintervention residual stenosis of <30% as determined on angiography, regardless of the procedure type or the device(s) used. The amount of postintervention residual stenosis was determined by the operating physician. *Unsuccessful interventions* resulted in a postintervention residual stenosis of ≥30%. Procedures that

Table 3. All miscellaneous procedures.

Procedure Description	Procedures Performed (n)
Diagnostic upper extremity angiogram	4
Temporary hemodialysis catheter insertion	2
Mesenteric angiogram	2
Subclavian artery angioplasty and stenting	2
Brachial to axillary artery angioplasty	1
Brachial artery angioplasty, stenting, and thrombus aspiration	1
Diagnostic bilateral subclavian and carotid artery angiogram	1
Inferior vena cava filter removal	1
Brachial artery angioplasty	1
Carotid and brachial artery angiogram	1
Unsuccessful attempt to angioplasty subclavian artery	1

required intervention on >1 lesion were categorized as successful only if all lesions intervened upon were left with <30% residual stenosis at the completion of the procedure. If a procedure that required intervention on multiple sites was only successful for some of the lesions, it was categorized as partially successful. Procedures that did not involve a therapeutic intervention were categorized as diagnostic. Procedures that were intended to evaluate or intervene upon an AVF were categorized as AVF-related procedures. Procedures that were meant to evaluate and intervene upon vascular lesions in the lower extremities resulting from PAD were categorized as PAD-related procedures. If a procedure did not fit into either of these categories, it was categorized as a miscellaneous procedure.

Statistical analysis. Statistical analysis was performed using SAS version 9.4. Frequency and percentage were calculated to describe the data. Mixed effects regression models were developed to assess the relationship between subject level characteristics (prior procedures, comorbidities, and percent occlusion) on the outcome of procedure success (defined as successful or partially successful versus unsuccessful). These models included random effect to account for the fact that some subjects had multiple procedures. In the case of the model for procedure success in the PAD subgroup, the model for percent occlusion failed to converge and a Fisher's exact test was used as an alternative.

Results

Patient and procedure demographics. A total of 288 patients underwent 500 procedures between February 2012 and February 2013. A total of 163 patients (57%) underwent AVF-related procedures, 111 patients (38%) underwent PAD-related procedures and 14 patients (5%) underwent miscellaneous procedures. Out of the 500 procedures, 335 (67%) were AVF related, 148 (30%) were PAD related, and 17 (3%) were miscellaneous procedures. There were 164 repeat AVF-related procedures, 38 repeat PAD-related procedures, and 3 repeat miscellaneous procedures. Baseline patient demographics are provided in Table 2.

Primary endpoint. Out of the 335 AVF-related procedures, 261 procedures were successful interventions, 19 were unsuccessful interventions, 9 were partially successful interventions, and 46 were diagnostic. The procedural success rate for AVF-related interventions was 90% if diagnostic procedures were excluded. The procedural success rate for AVF-related interventions was 93% if partially successful interventions were included and diagnostic procedures were excluded.

A total of 148 PAD-related procedures were performed: 89 were successful interventions, 9 were unsuccessful interventions, 10 were partially successful interventions, and 40 were diagnostic. The procedural success rate for PAD-related procedures was 82% if diagnostic procedures were excluded. The procedural success rate for PAD-related interventions was 92% if partially successful interventions were included and diagnostic procedures were excluded. Finally, out of a total of 17 miscellaneous procedures, 8 were successful interventions, 1 was an unsuccessful intervention, and 8 were diagnostic. There were no partially successful miscellaneous interventions. The procedural success rate for miscellaneous interventions was 89% if diagnostic procedures were excluded. A complete list of all miscellaneous procedures is provided in Table 3.

Secondary endpoint. Out of all 335 AVF-related procedures, only 5 (1.49%) suffered an adverse event. If diagnostic procedures were excluded, 1.7% of AVF-related procedures suffered an adverse event. These adverse events included 1 instance of embolization of a pushable coil into the central circulation, 3 cases of focal AVF perforation post angioplasty, and 1 case of focal AVF perforation caused by an angled glide catheter. The patient who suffered embolization of a pushable coil into the central circulation was able to tolerate the procedure well and was discharged to home 4 hours after the completion of the procedure. All 3 cases of focal AVF perforation post angioplasty were successfully sealed with a Fluency covered stent (Bard Peripheral Vascular). The AVF perforation caused by an angled glide catheter was completely resolved after 5 minutes of external compression.

Only 2 out of 148 PAD-related procedures (1.35%) experienced an adverse event. Excluding diagnostic procedures, 1.8% of PAD-related procedures suffered an adverse event. One patient suffered from a focal perforation in the left superficial femoral artery post angioplasty. This perforation was successfully treated with the placement of a covered Viabahn stent (Gore Medical) and the procedure was overall successful. A second patient, who had undergone a successful PAD-related intervention and was under observation in the recovery area, developed acute hypotension coupled with

Table 4. Characteristics of AVF-related procedures.

	≥1 Previous Procedures		No Previous Procedures		*P*-Value
Successful + partially successful	150 (95%)		120 (92%)		.14
Successful	145 (92%)		116 (89%)		
Partially successful	5 (3%)		4 (3%)		
Unsuccessful	8 (5%)		11 (8%)		
	≤4 Comorbidities		≥5 Comorbidities		*P*-Value
Successful + partially successful	148 (94%)		122 (92%)		.82
Successful	143 (91%)		118 (89%)		
Partially successful	5 (3%)		4 (3%)		
Unsuccessful	9 (6%)		10 (8%)		
	100% Occlusion	90% Stenosis	80% Stenosis	<80% Stenosis	*P*-Value
Successful + partially successful	39 (83%)	42 (96%)	94 (99%)	176 (97%)	.01
Successful	36 (77%)	39 (89%)	89 (94%)	173 (95%)	
Partially successful	3 (6%)	3 (7%)	5 (5%)	3 (2%)	
Unsuccessful	8 (17%)	2 (5%)	1 (1%)	6 (3%)	

Data presented and number (percentage).
P-values were calculated using mixed model for binomial outcome (successful and partially successful vs unsuccessful) with repeated measures.
This table does not include diagnostic procedures.

tachycardia and loss of pulse in the right foot. This patient was urgently transferred to a nearby hospital.

There were no adverse events associated with miscellaneous procedures.

Characteristics of AVF-related procedures. The number of previous procedures, number of comorbidities, and percent occlusion of the lesion that was intervened upon were calculated for successful, partially successful, and unsuccessful AVF-related interventions. A prior history of 1 or more previous AVF-related interventions did not affect the chance of having a successful or a partially successful AVF-related intervention (Table 4). It was found that 89% and 3% of AVF-related procedures with no history of prior procedure were, respectively, successful and partially successful. Successful and partially successful AVF-related interventions with no prior procedure were combined and were then compared with successful and partially successful interventions with at least 1 prior procedure. There was no statistically significant difference between these two groups for the chance of having a successful intervention (*P*=.14). Similarly, the number of comorbidities did not affect the chance of having a successful AVF-related intervention (Table 4). The number of successful and partially successful AVF-related interventions with ≥5 and ≤4 comorbidities was calculated. Since comorbidities were so common in our patient population, we used 4 as the lower number of comorbidities. Successful and partially successful interventions in these two groups were combined and compared for the chance of having a successful intervention. There was no statistically significant difference between successful and partially successful interventions with ≥5 comorbidities vs similar procedures with ≤4 comorbidities (*P*=.82). Finally, four groups were created for the percent stenosis (100%, 90%, 80%, and <80%) of the lesions that were treated in the AVF-related interventions. Successful and partially successful interventions were combined, and the four groups were compared for the chance of having a successful or a partially successful intervention. The angiographic success rates for the combination of successful and partially successful AVF-related interventions with <80%, 80%, 90%, and 100% occlusion were 97%, 99%, 96%, and 83%, respectively. The difference in success rate for these interventions was statistically significant (*P*=.01). The characteristics of AVF-related procedures are demonstrated in Table 4.

Characteristics of PAD-related procedures. The number of previous procedures, number of comorbidities, and percent occlusion of the lesions was determined for successful, partially successful, and unsuccessful PAD-related interventions. A history of 1 or multiple previous PAD-related procedures did not affect the chance of a successful PAD-related intervention (Table 5). Out of all PAD-related interventions with no history of prior procedures, 82% were successful and 8% were unsuccessful. Eighty-three percent and 11% of PAD-related interventions with at least 1 prior procedure were successful and partially successful, respectively. Successful and partially successful interventions in the two groups were combined, and a comparison did not reveal a statistically significant difference between them (*P*=.50). Likewise, the number of comorbidities did not affect the chance of a successful or partially successful PAD-related intervention (Table 5). Successful and partially successful PAD-related interventions with ≥5 comorbidities were

Table 5. Characteristics of PAD-related procedures.

	≥1 Previous Procedures		No Previous Procedures		*P*-Value
Successful + partially successful	34 (94%)		65 (90%)		.50*
Successful	30 (83%)		59 (82%)		
Partially successful	4 (11%)		6 (8%)		
Unsuccessful	2 (6%)		7 (10%)		
	≤4 Comorbidities		≥5 Comorbidities		*P*-Value
Successful + partially successful	25 (96%)		74 (90%)		.36*
Successful	24 (92%)		65 (79%)		
Partially successful	1 (4%)		9 (11%)		
Unsuccessful	1 (4%)		8 (10%)		
	100% Occlusion	90% Stenosis	80% Stenosis	<80% Stenosis	*P*-Value
Successful + partially successful	33 (81%)	37 (100%)	28 (100%)	38 (100%)	<.001†
Successful	24 (59%)	37 (100%)	28 (100%)	37 (97%)	
Partially successful	9 (22%)	0 (0%)	0 (0%)	1 (3%)	
Unsuccessful	8 (20%)	0 (0%)	0 (0%)	0 (0%)	

Data presented and number (percentage).
*P-value is calculated using mixed model for binomial outcome (Successful and partially successful vs unsuccessful) with repeated measures.
†The model analysis for repeated measures was initially tried but because a number of cells have zeros, the model did not converge which did not allow for a successful calculation of significance. As an alternative, we performed the Fisher's exact test which is not a good substitute for the mixed model, but it is the only one that is possible in this situation.
This table does not include diagnostic procedures.

Table 6. Type and number of devices used in PAD-related procedures.

Devices Used in PAD-Related Procedures	Quantity (n)
Balloon angioplasty	77
TurboHawk excisional atherectomy device	34
Diamondback orbital atherectomy device	19
Nitinol self-expanding stent	15
Balloon-expanding stent	2
Covered stent	1
Distal protection device	19

combined and compared with the combination of successful and partially successful PAD-related interventions with ≤4 comorbidities. There was no statistically significant difference between these 2 groups (*P*=.36). Finally, four groups were created for the percent stenosis of the lesions that were treated in PAD-related cases (100%, 90%, 80%, <80%). Successful and partially successful interventions in each of the four groups were combined and then compared for the chance of having a successful or a partially successful intervention. The angiographic success rates for the combination of successful and partially successful PAD-related interventions with <80%, 80%, 90%, and 100% occlusion were 100%, 100%, 100%, and 81%, respectively. The difference between these four groups was statistically significant (*P*<.001). The characteristics of PAD-related procedures are demonstrated in Table 5.

Ninety-six PAD-related procedures were performed on patients suffering from claudication, whereas 52 procedures were performed on patients with critical limb ischemia. Fourteen PAD-related procedures were performed on the iliac arteries, 62 on femoropopliteals, and 42 on arteries below the knee. Seventy-seven of the PAD-related procedures involved angioplasty, 53 involved atherectomy, and 18 involved stent implantation. A breakdown of the number of devices used in PAD-related procedures is provided in Table 6.

Association between risk of adverse events and antiplatelet medications or anticoagulants. None of the 5 patients who suffered an adverse event while undergoing an AVF-related intervention were on antiplatelet or anticoagulation regimen. One of the patients who suffered an adverse event during a PAD-related intervention was on a daily regimen of low-dose aspirin. The patient who required postprocedure hospitalization was on a daily regimen of clopidogrel.

Repeat AVF-related procedures. Out of a total 335 AVF-related procedures, 164 (49%) were repeat procedures. The repeat AVF-related procedures were divided among 65 patients. Of these 65 patients, 17 patients (26%) required 1 repeat AVF-related procedure, 24 patients (37%) required 2 repeat procedures, 11 patients (17%) required 3 procedures, 6 patients (9%) required 4 procedures, 4 patients (6%) required 5 procedures, 2 patients (3%) required 7 repeat procedures, and 1 patient (2%) required 8 repeat AVF procedures. The median time interval between repeat AVF-related procedures was 41 days. Forty-five of the 164 repeat AVF-related procedures

Table 7. Top indications for repeat AVF-related procedures.

Indication for Repeat AVF-Related Procedures	Procedures (n)
Malfunctioning AVF	59
Occluded AVF	45
Failure of AVF to mature	20

Table 8. Indications for repeat PAD-related procedures.

Indication for Repeat PAD-Related Procedures	Procedures (n)
Claudication	26
Critical limb ischemia	12

(27%) were performed within the 3-month follow-up period. The top three indications for repeat AVF-related procedures are provided in Table 7.

Repeat PAD-related procedures. Out of a total 148 PAD-related procedures, 38 (26%) were repeat procedures. The repeat PAD-related procedures were divided among 24 patients. Out of these 24 patients, 14 patients (58%) required 1 repeat PAD-related procedure, 6 patients (25%) required 2 repeat PAD-related procedures, and 4 patients (17%) required 3 repeat PAD-related procedures. The indications for repeat PAD-related procedures are provided in Table 8.

Patient satisfaction surveys. After the completion of each procedure, patients were asked to complete a voluntary, anonymous satisfaction survey before leaving our office. Patients were asked to indicate their degree of satisfaction about various aspects of their experience using a scale of 1 to 5, with 5 indicating most satisfied. We were able to obtain a total of 188 surveys during the period of this study. A great majority of the patients expressed great satisfaction regarding their experience at our office. The results of the patient satisfaction survey are provided in Table 9.

Discussion

The main findings of this study are that peripheral vascular interventions performed at an outpatient catheterization center yielded procedural success rates of 90%, 82%, and 89% for AVF-related, PAD-related, and miscellaneous interventions, respectively. The inclusion of partially successful interventions resulted in higher procedural success rates for both AVF-related and PAD-related interventions (93% and 92%, respectively). Another perhaps equally important finding of this study was the very low rate of adverse events for all procedure types (1.49% for AVF-related, 1.3% for PAD-related, and 0% for miscellaneous procedures). Finally, out of the first 500 procedures performed in our outpatient catheterization laboratory, there was only a single procedure that required immediate postprocedure hospitalization.

Although slowly accumulating, data on the safety and efficacy of peripheral vascular interventions performed at an outpatient facility are still scarce. To the best of our knowledge, the first published data that described the success rates of such procedures was from Arnold,[2] who only analyzed AVF-related procedures. Interestingly, the success rate for

Table 9. Results of the patient satisfaction surveys.

	Satisfaction Level						
Questions	5	4	3	2	1	N/A	Blank
Ease of scheduling today's procedure?	170	12	3	0	1	2	0
Ease of obtaining preprocedure laboratory tests?	149	12	1	1	1	21	3
Ease of finding the office from directions and map received?	164	15	1	0	2	6	0
Friendliness of receptionist and ease of checking in for your procedure?	176	6	3	1	1	0	1
Friendliness and communication skills of nursing staff?	178	6	0	1	1	0	2
Explanation of procedure by your physician?	176	8	1	0	2	0	1
Friendliness and care provided by your nurses and physician?	182	3	0	1	1	0	1
Comfort during the procedure?	164	15	6	1	1	1	0
Comfort following the procedure?	169	15	2	1	1	0	0
Explanation of postprocedure care and follow-up prior to discharge?	177	8	1	0	2	0	0
Overall experience with your medical procedure today?	177	6	2	1	1	0	1
Did the availability of music with the personal headphones make your experience more enjoyable:							
During the procedure?	18	1	0	0	0	11	6
After the procedure in the recovery room?	27	1	0	0	0	6	2

A score of 5 indicates "Most Satisfied", and a score of 1 indicates "Least Satisfied." We were able to obtain a total of 188 surveys during the period of this study (From February 2012 until February 2013).

AVF-related procedures reported by Arnold (93%) is essentially identical to our procedural success rate when partially successful procedures are included in the calculation (93%). In addition, Mayeda et al reported significantly lower complication rates for orbital atherectomy treatment of PAD in the outpatient setting.[9]

Although data regarding the feasibility and cost effectiveness of outpatient peripheral interventions has been steadily growing, there are no randomized controlled trials that have compared the safety and efficacy of outpatient procedures with similar procedures performed in the inpatient setting. Our group previously reported an angiographic success rate of 93% for inpatient AVF-related procedures. The same study also reported an adverse event rate of 11.9% for inpatient AVF-related procedures.[10] Moreover, an angiographic success rate of 89% for inpatient PAD-related procedures along with a 3% rate for dissection and 5% for embolization has already been reported.[11] Although we realize that a direct comparison between the current study and our inpatient data would be incorrect, it is worth mentioning that the inpatient procedures were performed by the same interventional cardiologists and staff who contributed to this study. Therefore, we believe that the success rate for peripheral vascular procedures performed in the outpatient setting is comparable to the success rate of inpatient procedures at our institution. A prospective, randomized, controlled trial is needed to fully clarify this matter. Additionally, some evidence has emerged suggesting that postintervention residual stenosis has direct implications in the intervention-free survival rate of AVF-related procedures.[12,13] Such considerations could also be taken into account for future prospective, randomized, controlled trials of outpatient procedures.

Study limitations. This is a single-center study. In addition, the study is unable to perform a direct, one-to-one comparison between peripheral vascular interventions performed in the outpatient setting vs the inpatient setting.

Conclusion

In our experience, peripheral vascular interventions can be performed effectively and safely on most patients in an outpatient catheterization center. More research is required to compare the results of inpatient vs outpatient peripheral vascular interventions.

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