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Safety of day-case endovascular interventions for peripheral arterial disease in a rural, underserved area

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Abstract

Background: We aimed to investigate the safety of endovascular procedures undertaken in a single outpatient center located in a rural, underserved area. Endovascular procedures for Peripheral Arterial Disease (PAD) have become increasingly common in outpatient settings; their safety is yet to be determined in a rural, underserved area with no stand-by vascular surgeon on site.

Methods: We undertook a retrospective case review of endovascular procedures for the investigation and management of lower extremity PAD between December 2012 and August 2015. Patients were classified by Rutherford score, degree of stenosis and length of lesions. Complications were major (requiring hospitalization) or minor, including perforation, distal embolization, hematoma, and allergic reactions, which could be treated immediately in the catheterization laboratory with no sequelae. Patients were monitored in the facility and followed up using clinical, biochemical and radiological parameters at 24 h and 1 month.

Results: A total of 692 patients underwent endovascular procedures for the investigation and/or treatment of PAD, of which 608 were interventional. Of these patients, 10.20% experienced procedural complications, of which 0.66% were classified as major, including wire retention and retroperitoneal hemorrhage. In total, 99.34% were discharged safely on the same day as the procedure. No adverse events were reported at follow up.

Conclusion: Endovascular procedures for PAD can be performed safely in a rural outpatient setting with low complication rates. Most complications are minor and do not require hospitalization. Outpatient procedures for PAD are safe and may widen access to specialist procedures in areas of socio-economic deprivation.

Keywords: atherectomy, balloon angioplasty, chronic limb threatening ischemia, claudication, endovascular intervention, endovascular treatment/therapy, outpatient, patient safety, peripheral vascular disease

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Introduction

Peripheral arterial disease (PAD) affects approximately 371 million people worldwide, and, over two decades, has seen a global increase in prevalence of 25%.[1,2] Epidemiological trends indicate that this course is set to continue, due particularly to the well-established burden of the ageing population. Endovascular procedures, including balloon angioplasty and stent insertion, have been carried out widely, with patients being monitored overnight following completion of the intervention. Technological advancements in procedural materials and the minimally invasive nature of endovascular intervention have allowed for the provision of this service as a day-case, with a recent surge in this practice over recent years.[3]

Spiliopoulos *et al.* demonstrated the feasibility of day-case procedures with a particular focus on balloon angioplasty.[4] In addition, Lin *et al.*, successfully showed safety of endovascular intervention in office-based setting.[5] Peyman *et al.*, carried out a retrospective case review of patients undergoing vascular procedures in a busy, urbanized outpatient clinic.[6] However, the benefits of this practice have yet to be demonstrated in a rural, underserved area where there is no local tertiary center, catheterization laboratory, or additional stand-by endovascular interventionist or vascular surgeon. The main advantages of this lie in increased patient satisfaction, reduced exhaustion of resources, decreased financial burden on healthcare services, and widening of healthcare access to disadvantaged areas; all without compromising patient safety.[7] In this study, we further the evidence base for this practice and explore the safety of day-case endovascular procedures, with particular focus on patients with lower extremity PAD in a rural, underserved area.

Methods

We conducted a single-center, retrospective case review of 692 procedures carried out at an outpatient clinic in Southern California. Our aim was to investigate the safety of endovascular procedures for lower extremity PAD carried out in a laboratory that covers a rural and underserved area, with no local tertiary center. A variety of procedures were carried out consecutively between December 2012 and August 2015 by a single interventional cardiologist, including diagnostic angiography, excisional atherectomy, laser atherectomy, orbital atherectomy and balloon angioplasty. SilverHawk and/or TurboHawk devices were utilized for excisional atherectomy (Medtronic, Minneapolis, MN, USA), Boston Scientific devices for rotational atherectomy, Cardiovascular Systems, Inc. (CSI, Saint Paul, MN, USA) for orbital atherectomy, NanoCross Elite (Medtronic) for balloon angioplasty, and EverFlex (Medtronic) for stenting. Inclusion criteria included patients with lower extremity PAD undergoing the aforementioned interventions. Patients with upper extremity PAD, requiring inpatient management or lost to follow up, were excluded from our analysis. Patients were admitted and discharged on the same day and followed up at 24–72 h, and again at 1 month. This included examination of peripheral pulses using a 4-point grading system, duplex ultrasound scanning and measurement of renal function. The following information was collected from patient and procedural notes: patient demographics, past medical history, type of procedure, location of lesion, length of lesion, degree of stenosis, equipment used, fluoroscopy time, and volume of contrast administered. The previously mentioned data were logged electronically for further analyses. Patients were stratified by their Rutherford Criteria Score, suffering from intermittent claudication (Rutherford 1–3) or chronic limb threatening ischemia (CTLI) (Rutherford 4–6). Complex cases were analyzed separately and defined as those involving long lesions (>10 cm), total occlusions, and/or severely calcified vessels. Lesion lengths were determined by measurement with an electronic ruler, and by factoring in balloon length where appropriate. Degree of stenosis, as determined by the cardiologist, was stratified into four categories and expressed as a percentage: moderate stenosis (50–70%), severe stenosis (70–90%), critical stenosis (90–99%), and total occlusion (100%). For the purposes of data analysis, the location of each lesion was referred to as either supra-popliteal or infra-popliteal. Exact vessel locations included: common iliac, external iliac, superficial femoral, popliteal, profunda femoris, anterior tibial, tibio-peroneal trunk, posterior tibial, and peroneal and dorsalis pedis. Immediate procedural success was defined as post-procedure residual stenosis of <30%, although efficacy of intervention is not the focus of this research at this time. Complications were defined as major and minor: major complications were those requiring inpatient hospitalization and included bleeding and wire retention. Additional criteria for major bleeding was a drop in hemoglobin of >3 g/dl and/or requiring transfusion. Minor complications were those treated within the facility with no sequelae, including minor perforation, distal embolization, allergic reactions, flow limiting dissection, and arteriovenous (AV) fistula formation. These were monitored and further assessed at follow up. Mortality was logged at 0 and 28 days. Our primary endpoint was defined as safe discharge on the day of procedure with no subsequent complications, and the secondary endpoint was any adverse event as a result of the procedure. Statistical analysis was carried out using SPSS version 1. We hypothesized that endovascular procedures for peripheral arterial disease could be carried out safely in a rural, outpatient setting.

Table 1. Baseline characteristics.

	Claudicants ($n = 310$)	Chronic limb threatening ischemia ($n = 298$)	p-value
Age	73 (9.2)*	73 (10.4)*	0.69
Gender			
Male	63.87 (198/310) †	65.10 (194/298) †	0.80
Female	36.13 (112/310) †	34.90 (104/298) †	
History + risk factors			
Diabetes mellitus	38.39 (119/310) †	51.68 (154/298) †	0.001
Current/former smoker	35.20 (107/310)	38.30 (113/298) †	0.40
Hypertension	54.55 (166/310) †	57.38 (171/298) †	0.37
Coronary artery disease	36.45 (113/310) †	38.59 (115/298) †	0.62
Hyperlipidemia	42.26 (131/310) †	41.28 (123/298) †	0.87
Renal insufficiency – dialysis	9.68 (30/310) †	11.74 (35/298) †	0.43
Renal insufficiency – not requiring dialysis	8.71 (27/310) †	10.40 (31/298) †	0.49
Rutherford classification			
1	3	-	
2	41	-	
3	266	-	
4	-	131	
5	-	136	
6	-	31	

*Mean (SD).
†% (*n*/*N*).
Categorical data are presented as mean (SD). Continuous data are presented as %(*n*/*N*).
SD, standard deviation.

Results

A total of 692 procedures were carried out between December 2012 and August 2015 at an outpatient center in Southern California. For the purposes of this research, we will refer only to those undergoing interventions in our statistical analysis. A total of 608 patients underwent lower extremity arterial intervention, while 84 were diagnostic angiograms. There were 1168 lesions in total, of which 369 were chronic total occlusions and 559 were classified as long. This yielded a total occlusion rate of 31.6%. There were 310 patients classified in the Claudicants group and 298 in the CTLI group; demographics and comorbidities are shown in Table 1. We stratified these separately in both groups by location, length and presence of occlusion. In the suprapopliteal group, 27.4% of lesions were completely occluded and 36.3% were above 10 cm. This resulted in 63.7% complex lesions in this cohort. In the infrapopliteal group, 25.1% were total occlusions and 51.3% were above 10 cm, yielding, according to our criteria, 76.4% complex lesions (Table 2). In total, 954 atherectomies were carried out,

Table 2. Lesion locations.

Suprapopliteal	*N*
Total	442
Occlusions	132
Length	%(*n*/*N*)
<10 cm	64.5 (288/442)
>10 cm	36.30 (154/ 442)
Infrapopliteal	*N*
Total	726
Occlusions	237
Length	%(*n*/*N*)
<10 cm	44.21 (321/726)
>10 cm	55.79 (405/726)

Absolute data are presented as (*N*). Continuous data are presented as %(*n*/*N*).

1052 balloon angioplasties, and 63 stents. This produced a total of 2069 endovascular interventions across all patients while also accounting for multiple procedures on each lesion (Tables 3 and 4). The average dose of contrast administered for interventions was 198 ml, and mean fluoroscopy time was 8 min and 6 s. The femoral approach was used for all patients in this study. Our major complication rate was 0.66%, which included two cases of hemorrhage and two cases of wire retention. Both hemorrhages were retroperitoneal, did not result in a drop in hemoglobin of >3 g/dl, did not require blood transfusion and resolved spontaneously. However, they have been included as major complications due to admission to an inpatient facility. In cases of wire retention, one device was retrieved endovascularly with no further sequelae. Surgical removal was required for one case of wire retention, and this did not have any associated complications. The minor complication rate was 9.54%, the most frequent of which were distal embolization and minor perforation (Table 5). All minor complications were managed within the outpatient center and patients were discharged safely thereafter. Other complications included extravasation of contrast, detachment of device and bradycardia. A total of 604/608 patients were discharged on the same day, resulting in a day-case rate of 99.34%. On follow up at 24 h and 1 month, none of the patients experienced worsening of Doppler ultrasound findings, reduction in peripheral pulses, or acute kidney injury. There were no deaths reported at 0 and 28 days.

Discussion

The results of this study demonstrate the safe provision of endovascular procedures in a rural and underserved area. Previously, access to PAD treatments has been limited mostly to large in-patient centers in built-up regions. Efficacy was not determined in our study due to lack of follow up at 6 months; however with high rates of immediate success and few complications, we were able to reproduce results comparable with large-scale, multi-center trials. Specifically, the DEFINITIVE LE Study by McKinsey *et al.* evaluated the use of directional atherectomy for lower extremity revascularization with in-patient follow up.[8] Across 799 interventions, their procedural success was 99% and major complication rate 1.6%. While a direct comparison is of limited value, it is important to consider the respective populations and severity of PAD. Total occlusions and long lesions for their cohort were 20.8% and 27.8%, respectively. The evidence base for endovascular procedures in an outpatient setting also focuses on urban areas with wider access to healthcare. In the aforementioned study by Peyman *et al.*, a success rate of 82% was seen across 148 peripheral vascular procedures, and 92% with the addition of partial successes. Both studies were carried out

Table 3. Above knee interventions.

Lesions	Common iliac	External iliac	Common femoral	Superficial femoral	Profunda
Atherectomy	0	0	21	227	0
Angioplasty	5	14	20	150	71
Stent	9	9	0	43	0

Table 4. Below knee interventions.

Lesions	Popliteal	Anterior tibial	Tibio-peroneal trunk	Posterior tibial	Peroneal	Dorsalis pedis	Femoral-popliteal	Anterior tibial-dorsalis pedis	Tibial-peroneal	Tibial peroneal-posterior tibial
Atherectomy	118	211	83	153	103	6	17	0	10	5
Angioplasty	94	247	42	154	85	15	53	17	56	29
Stent	2	0	0	0	0	0	0	0	0	0

in urban areas with greater healthcare resources. In a study by Stevens *et al.*, it was found that amputation rates are higher in areas of lower average income and higher poverty, both rural and urban.[9] Our study population comes from a region with higher rates of PAD risk factors such as diabetes, smoking, and obesity than the national average, in addition to higher rates of cardiovascular disease.[10,11] On average, heart disease accounted for 17% of all deaths in this region from 2012 to 2014. The area is predominantly Hispanic with almost one-third of inhabitants being foreign born, and 75.7% of inhabitants speaking a language other than English.[12] Residents are more likely to come from disadvantaged socioeconomic classes, with a median household income far below the national average. Providing endovascular interventions serves the purpose of widening healthcare access to a morbid population, achieving high success rates that improve quality of life and enhancing procedural efficiency. Inpatient interventions also require patients to stay overnight, contributing to bourgeoning costs.[7] However, when executed in an outpatient setting, peripheral arterial interventions are more affordable without compromising patient safety. Shorter inpatient admissions will also be more desirable in future as infections such as COVID-19 become a new reality. Moving forward, our center has been involved in piloting a new form of laser atherectomy known as DABRA (destruction of arteriosclerotic blockages by laser radiation ablation). This is a novel approach to laser atherectomy which facilitates a continuous transmission of photons for the removal of heavily calcified plaques. As one of the centers to adopt this technology, we aim to present our findings in due course.

Limitations of this study include the lack of significant follow up 6 months post-procedure and no comment on procedural efficacy. While we aim to comment on this in future following further analyses, there were no adverse outcomes reported at 1 month follow up. In addition, as a single-center, the reproducibility of our results may not be consistent across other regions of the country. Furthermore, we did not undertake a formal cost–benefit analysis which would allow us to fully examine the financial implications of this practice. A more comprehensive examination with follow-up studies is required to fully appreciate the efficacy of this practice; we aim to report on this in due course. However, a randomized controlled trial would be the gold standard methodology for this determination, and would provide information on morbidity, mortality, and procedural success.

Table 5. Complication rates.

Major	**%(*n*/*N*)**
Hemorrhage	(2/609)
Wire retention	(2/609)
Total major complication	**0.66 (4/609)**
Minor	**%(*n*/*N*)**
Distal embolization	3.12 (19/609)
Minor perforation	3.12 (19/609)
Flow limiting dissection	0.33 (2/609)
Allergic reaction	0.16 (1/609)
AV fistula formation	0.16 (1/609)
Other	2.63 (16/609)
Total minor complication	**9.54 (58/609)**

Categorical data are presented %(*n*/*N*).
AV, arteriovenous.

Conclusion

We demonstrate safe practice of outpatient endovascular procedures in a rural, underserved area. With the evidence base for this slowly growing, there is potential for further expansion across the country if investigators can achieve similar rates of same-day discharge. Efficacy will also need to be proven with patients followed up periodically. This may result in increased efficiency and wider access to specialist procedures.

Conflict of interest statement

The authors declare that there is no conflict of interest.

Ethical approval

Ethical approval was not required for this particular study.

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Informed consent

All patients were consented to retrospective analysis of data.

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