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Outpatient Endovascular Tibial Artery Intervention in an Office-Based Setting Is as Safe and Effective as in a Hospital Setting

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Abstract

Purpose: To compare outcomes of outpatient tibial artery procedures between an office endovascular center and a hospital angiography suite. **Methods:** A retrospective review was conducted of 204 outpatient tibial interventions performed on 161 patients (mean age 72±11.5 years; 81 men) in either an office (n=100) or hospital (n=104) angiography suite from April 2011 through September 2013. Patients who had an existing ipsilateral bypass that was completely proximal to the tibial trifurcation were eligible, as were patients with prior proximal endovascular interventions. Exclusion criteria included previous ipsilateral bypass involving the infrapopliteal vessels, in-patient status at the time of the procedure, planned admission after the procedure, and infrapopliteal stenting. Treatment included percutaneous transluminal angioplasty (PTA) or PTA with atherectomy. Primary outcomes were unplanned admission, emergency room visits, acute complications, and patency. **Results:** There were no significant differences in demographics or baseline Rutherford category between patients treated in an office endovascular suite vs a hospital angiography suite. Factors more prevalent in the hospital group included chronic obstructive pulmonary disease (16% vs 8%, p=0.045), renal insufficiency (37% vs 25%, p=0.017), and previous proximal bypass (12% vs 4%, p=0.045). Of the 100 office procedures, 25 involved PTA and 75 were PTA with atherectomy, while in the 104 hospital procedures, PTA was applied in 68 patients and PTA with atherectomy in 36. Thirty-day local complication rates (7% vs 11%, p=0.368), systemic complication rates (4% vs 8%, p=0.263), and mortality (1% vs 2%, p=0.596) in the office vs hospital setting were not statistically different. Unplanned postprocedure hospital admission rates for medical reasons were lower in the office group (2% vs 11%, p=0.01). Kaplan-Meier estimates of the 1-year follow-up data were better in the office group for primary patency (69% vs 53%, p=0.050), assisted primary patency (90% vs 89%, p=0.646), and amputation-free survival (89% vs 83%, p=0.476), but the differences were not statistically significant. **Conclusion:** Efficacy and safety of outpatient endovascular tibial artery interventions between office and hospital settings were similar, with lower unplanned admission rates and better patency. With appropriate patient selection, the office endovascular suite can be a safe alternative to the hospital angiography suite.

Keywords

atherectomy, hospital angiography suite, infrapopliteal interventions, office angiography laboratory, office endovascular suite, outpatient status, patency, percutaneous transluminal angioplasty, peripheral artery disease, tibial artery

Introduction

Peripheral artery disease (PAD) is a relatively common problem, affecting 10% to 20% of the adult population.[1–3] With the advancements in endovascular technology, there has been a shift in the treatment paradigm of PAD from a surgical first approach to endovascular first strategies. Today, an increasing percentage of interventions for PAD are being performed at office endovascular suites. Because of this trend, several studies have looked at the safety of office endovascular procedures. A 2014 study by Jain et al[4] that examined safety and patient satisfaction of office-based procedures noted the lack of comparative research on efficacy between the hospital and the office.

Tibial vessel interventions are typically done for limb salvage, which usually involves patients with a higher percentage of renal failure and diabetes than

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Table 1. Patient Characteristics.[a]

Variable	Office Endovascular Suite (n=84)	Hospital Angiography Suite (n=77)	p
Demographics			
Age, y	70.9±10.4	72.4±12.4	0.286
Men	46 (55)	35 (46)	0.238
Risk factors			
CAD/MI	43 (51)	44 (57)	0.449
Tobacco use	48 (57)	42 (55)	0.740
Diabetes	48 (57)	54 (70)	0.088
Hypertension	76 (91)	67 (87)	0.486
Hyperlipidemia	54 (64)	48 (62)	0.798
COPD	8 (10)	16 (21)	0.045
Stroke/TIA	24 (29)	23 (30)	0.856
RI/ESRD	25 (30)	37 (48)	0.017
Rutherford category (per limb)	(n=100)	(n=104)	
2	8 (8)	8 (8)	
3	15 (15)	13 (13)	
4	20 (20)	35 (34)	
5	56 (56)	46 (44)	0.121[b]
6	1 (1)	2 (2)	
Intervention segment (per limb)			0.621
Infrapopliteal only	33 (33)	39 (38)	
Femoropopliteal, infrapopliteal	63 (63)	59 (57)	
Iliac, femoropopliteal, infrapopliteal	4 (4)	6 (5)	

Abbreviations: CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; ESRD, end-stage renal disease; MI, myocardial infarction; RI, renal insufficiency; TIA, transient ischemic attack.
[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage).
[b]Comparison of tissue loss (categories 5 and 6) between groups.

standard-risk vascular patients. This study sought to fill the gap in knowledge by identifying if the office and hospital are comparable venues by looking at short-term safety and efficacy for percutaneous tibial interventions on these patients with higher risk.

Methods

Study Design and Patient Selection

A retrospective review was conducted of all patients who underwent endovascular infrapopliteal interventions between April 2011 and September 2013 at our office endovascular center and hospital angiography suite. Patients older than 18 years with infrapopliteal PAD of all etiologies who underwent outpatient tibial interventions were eligible for this analysis. Patients with concurrent contralateral or proximal ipsilateral endovascular interventions were eligible. Exclusion criteria included previous ipsilateral bypass involving the infrapopliteal vessels, inpatient status at the time of the procedure, planned admission after the procedure, and infrapopliteal stenting. Patients who had an existing ipsilateral bypass that was completely proximal to the tibial trifurcation were eligible, as were patients with prior proximal endovascular interventions.

During the observation period, 384 patients underwent 508 tibial interventions; of these, 77 patients (mean age 72.4±12.4 years; 35 men) had 104 hospital outpatient infrapopliteal interventions and 84 patients (mean age 70.9±10.4 years; 46 men) had 100 office interventions (Table 1). Patient data were collected from the electronic medical record and de-identified in accordance with the Health Insurance Portability and Accountability Act Privacy Rule. Demographics, risk factors, intervention history, periprocedural data, outcomes, and follow-up to August 2015 were collected for analysis. The Eastern Virginia School of Medicine's Institutional Review Board approved this study; the need for patient consent to participate in the study was waived (approval number 10-11-WC-0248).

Treatment and Follow-up

Interventions included percutaneous transluminal angioplasty (PTA) with or without atherectomy (orbital, laser, or directional) at the discretion of the individual physician. Surgeons involved in the care of these patients included

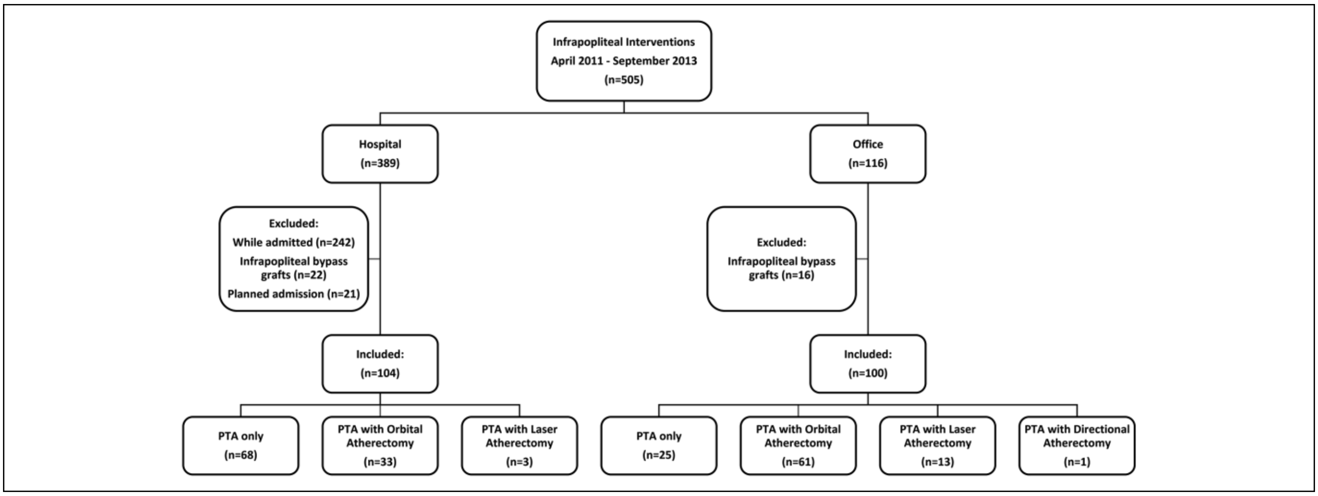

Figure 1. Distribution of outpatient tibial interventions by location and procedure.

those who perform procedures primarily at the hospital, those who perform procedures primarily at the clinic, and surgeons who divide their time at both locations. No comparison among surgeons was feasible due to low numbers. According to the department's standard of care for critical limb ischemia (CLI) patients, follow-up was scheduled at 1, 3, 6, and 12 months with ankle-brachial index (ABI) measurement and duplex ultrasound. Persistent or worsening clinical symptoms or the presence of high-risk lesions were triggers for repeat angiography.

Definitions and Endpoints

In this study, symptomatic improvement was defined as an increase of 1 or more clinical categories according to the Rutherford scale. Patency was defined per the Society for Vascular Surgery (SVS) reporting standards[5] criteria for patency using ABI, duplex ultrasound, and subsequent angiography. Local and systemic complications were also defined per SVS criteria.[5]

Primary outcomes were (1) unplanned admission to the hospital or an emergency department (ED) after the procedure, (2) acute local and systemic complications, and (3) primary patency of native vessels. Secondary outcomes were primary and assisted primary patency, amputation-free survival, and symptomatic improvement. Secondary patency data were collected, but these interventions were rare, so the data were not analyzed.

Statistical Analysis

Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage). Categorical variables were assessed using Pearson chi-square test and multivariate analysis. The Kaplan-Meier method was used to assess patency and amputation-free survival; groups were compared using the log-rank test. Multivariate regression analysis was performed to examine the effect of risk factors on primary patency. The threshold of statistical significance was $p<0.05$. Statistical analysis was performed using IBM SPSS Statistics (IBM Corporation, Armonk, NY, USA).

Results

Group Differences

The hospital group had a larger proportion of patients with chronic obstructive pulmonary disease, renal insufficiency, and a previous proximal ipsilateral bypass compared with the office-based group (Table 1). There were no other significant differences in patient demographics or risk factors. The majority of the procedures were performed for CLI (77% office vs 80% hospital, p=0.626) with multilevel disease (75% vs 68%, p=0.287). The number of patients with tissue loss was not significantly different (57% vs 46%, p=0.121).

The majority of interventions were multilevel (Table 1), with interventions on both the infrapopliteal arteries and more proximal vessels, and there was no significant difference between the office and hospital setting (p=0.621). Of the 100 office procedures, 25 were PTA, 61 were PTA with orbital atherectomy, 13 were PTA with laser atherectomy, and 1 was PTA with directional atherectomy. Of the 104 hospital procedures, 68 were PTA, 33 were PTA with orbital atherectomy, and 3 were PTA with laser atherectomy (Figure 1). The proportion of atherectomies was higher in the office (75% vs 35%, $p<0.001$). By study design, no infrapopliteal stents were placed; drug-coated balloons were not used.

Table 2. Thirty-Day Morbidity and Mortality and Same-Day Admission.[a]

Variable	Office Endovascular Suite (n=100)	Hospital Angiography Suite (n=104)	p
30-day complications			
Local	7 (7)	11 (11)	0.368
Systemic	4 (4)	8 (8)	0.263
30-day mortality	1 (1)	2 (2)	0.596
Same-day admission to hospital or ED			
Overall admission	2 (2)	27 (26)	<0.001
Admission for medical reasons[b]	2 (2)	11 (11)	<0.001

Abbreviation: ED, emergency department.
[a]Data are given as the number (percentage).
[b]For example, bleeding, medical management of pain or other condition, or surgery.

Table 3. Kaplan-Meier Estimates of Amputation-Free Survival and Patency.

Variable	Office Endovascular Suite, %	Hospital Angiography Suite, %	p[a]
Amputation-free survival			0.476
1-year	89.1	82.6	
2-year	85.0	81.2	
3-year	79.4	78.4	
Primary patency			0.050
1-year	68.9	52.6	
2-year	62.7	43.4	
3-year	51.0	39.6	
Assisted primary patency			0.646
1-year	90.3	89.4	
2-year	83.9	80.0	
3-year	77.9	76.9	

[a]Log-rank.

Outcomes

There was no significant difference in 30-day local complications (7% vs 11%, p=0.368), 30-day systemic complications (4% vs 8%, p=0.263), or 30-day mortality (1% vs 2%, p=0.596) between the office and hospital patients (Table 2).

The mean follow-up was 25 months (range 0–52). Fifteen patients were lost to follow-up: 10 of the 100 office procedures and 5 of the 104 hospital cases (p=0.16). Overall unplanned same-day hospital or ED admission rates (Table 2) were lower in the office (2% vs 26%, p<0.001). In the office group, 2 patients required evaluation in the ED following their procedure; one was seen for bleeding from the access site, the other was evaluated for visual changes. Both were discharged from the ED the same day without additional intervention.

The 27 patients who required postprocedure hospitalization after outpatient treatment in the hospital angiography suite were categorized into 2 categories: medical and predictable. There were 11 patients who were hospitalized for medical reasons. Five patients had access-site bleeding, 3 had problems requiring medical management, 1 patient was admitted overnight for anticoagulation to address a distal embolism, another patient was admitted for postprocedure pain, and 1 patient underwent surgical bypass. There were 16 patients who were hospitalized for predictable or avoidable reasons. Twelve patients were admitted overnight for prolonged bed rest until late in the evening, 2 patients required postprocedure dialysis, and 2 had social reasons that delayed discharge.

Kaplan-Meier estimates at 1 year (Table 3) were better in the office group for primary patency (69% vs 53%, p=0.050; Figure 2A), assisted primary patency (90% vs 89%, p=0.646; Figure 2B), and amputation-free survival (89% vs 83%, p=0.476; Figure 3), but the differences were not statistically significant. The trend continued through 3 years. Multivariate analysis of the effect of risk factors on primary patency yielded no significant differences, so the Kaplan-Meier method was used to examine the impact of renal status on outcomes. Patients with vs without renal insufficiency demonstrated primary patency estimates of 50% vs 67% at 1 year and 45% vs 58% at 2 years, respectively (p=0.023). Kaplan-Meier analyses comparing primary patency in the hospital and office settings based on renal insufficiency status showed no statistically significant differences.

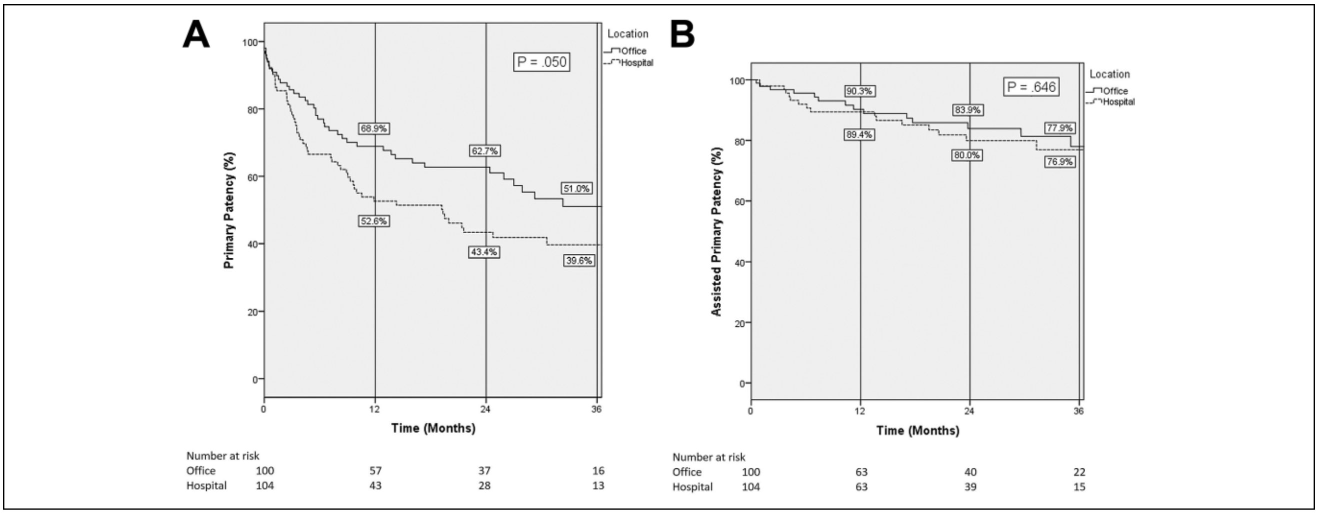

Figure 2. (A) Primary and (B) assisted primary patency for procedures done in the office setting (solid line) vs the hospital setting (dashed line).

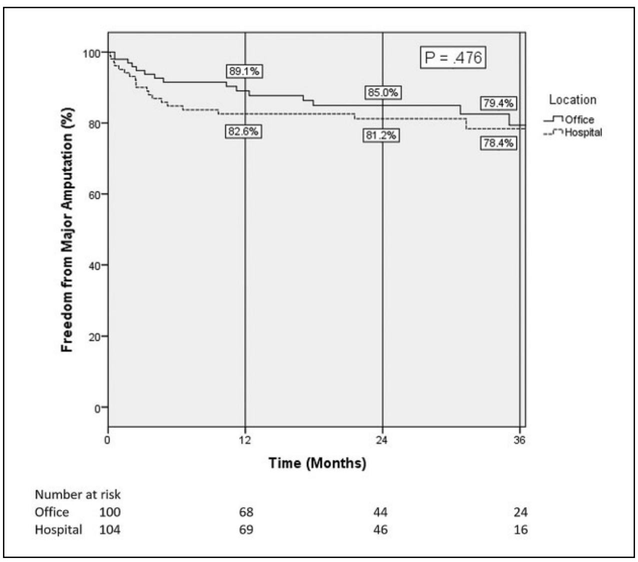

Figure 3. Freedom from major amputation for procedures done in the office setting (solid line) vs the hospital setting (dashed line).

Endovascular reintervention rates (31% vs 35%, p=0.583) and bypass rates (8% vs 14%, p=0.147) for revascularization were not significantly different between the office and hospital groups. Symptomatic improvement at the first follow-up visit was 73% in the office cohort vs 66% among the hospital patients (p=0.25).

Discussion

The aging of the world population and the rising prevalence of comorbidities have led to an increase in the incidence of PAD.[6] The impact of this escalation is evident in the growth of revascularization attempts to treat infrapopliteal disease. Though these procedures have become more common, there is still a lack of data focused on below-the-knee interventions. The TransAtlantic Inter-Society Consensus II guidelines[7] were only recently updated in 2015[8] to classify infrapopliteal disease. Despite the lack of trials dedicated to tibial disease, it is likely that patients with distal disease have worse outcomes compared to the overall population of PAD patients.

In concordance with the national trend toward increased numbers of office interventions, our practice has been performing more endovascular procedures in the office setting. While patient satisfaction and cost data were not collected for this study, both factors bear significant implications for the future use of office centers for endovascular procedures. Several trials have found improvement in both cost and patient satisfaction in the office setting. Jain and colleagues reported high patient satisfaction with office interventions in studies done in 2010[9] and 2014,[4] with rates of 98% and 99% of patients, respectively, who would prefer to come back to the office for future procedures. Their finding of high patient satisfaction has been consistent with our experience (unpublished data). In their 2010 study,[9] Jain and colleagues published the cost implications of performing percutaneous procedures in the office, calculating the savings to Medicare with office-based procedures at $824,059. Their data suggested that their endovascular aortic procedures alone resulted in a savings of $90,545. Similar factors, such as decreased need for an anesthesiologist, evident in our practice as well, indicate that there is a potential for savings to all parties. Both patient satisfaction and savings were major factors in our decision to perform a greater proportion of our procedures in the office.

While both cost and patient preference tend to favor the office setting, there is concern about variation in clinical outcomes within the existing literature on office-based interventions.[10] Our study sought to address this concern by collecting data from hospital suite procedures for comparison. Patients who had their procedures in the office had complication and patency rates that were similar to those patients who had hospital procedures. In general, complication rates in previous studies of endovascular interventions have been low. In their 2014 study of office endovascular procedures, Jain et al[4] reported complication rates of 2.7% among their 368 arterial interventions. Similarly, Mesbah Oskui et al[11] documented an adverse event rate of 1.9% within 108 PAD-related interventions.

Patient selection is critical to achieving high-quality outcomes in any outpatient setting. Patients treated in the office were selected based on their low risk for complications, and our data reflect this position. Our goal of care is to provide similar outcomes for safety and efficacy at all of our venues. This is accomplished by prioritizing the hospital suite for patients with renal disease because these patients are at higher risk for postprocedure complications. It is also more convenient for renal patients to have their procedure done in the hospital as this facilitates scheduling and access to dialysis.

In addition to complication rates, patency outcomes are an important factor in determining suitability of office-based procedures. In 2008, Romiti et al[12] performed a meta-analysis of 30 trials focused on infrapopliteal angioplasty procedures and calculated pooled patency rates of 58.1% at 1 year and 51.3% at 2 years. These rates were similar to our findings, with office patients having slightly better patency outcomes than outpatient hospital patients.

While the significantly greater proportion of atherectomy performed in the office is a possible explanation for the patency difference, Todd et al[13] compared PTA to atherectomy and PTA and found no difference in outcomes. It is our belief that the difference in patency is likely due to patient risk profiles, such as renal insufficiency and severity of underlying PAD, rather than the increased use of atherectomy in the office. Indeed, Kaplan-Meier analysis of patients with renal insufficiency found lower primary patency whether the procedure was performed at the office or the hospital. Patient renal status was likely a factor in the decision to perform the procedure in the hospital setting and is a source of selection bias. Comparing primary patency between patients treated in the hospital vs office setting based on renal insufficiency status yielded no statistically significant difference, which further supports the similarity between the 2 intervention settings.

Limitations

The study was limited by the selection bias between the 2 groups of patients. Additionally, there is a likelihood of type II error in the evaluation of complication rates, especially for systemic sequelae. Understandably, selecting appropriate patients for the appropriate venue likely tilts the safety and outcomes balance in favor of the office-based suite. Additionally, there were significantly more atherectomy procedures performed at the office, even though atherectomy devices were equally available at the hospital and office locations. It is plausible that the surgeons who perform more procedures at the office tend to personally favor atherectomy. While it is hoped that financial incentive would not be a factor in the decision to perform procedures that might require atherectomy in the office, it is impossible to ignore this potential explanation. It is also important to mention the overall potential for conflict of interest due to the increased revenue when an outpatient procedure is performed at an office endovascular suite that is owned by a physician group compared with a hospital suite. Despite this, the addition of the outpatient suite in our diverse practice provides a safe and effective treatment location for select patients requiring tibial interventions.

Conclusion

Efficacy, primary patency, and complication rates of outpatient endovascular tibial artery interventions were comparable between office and hospital settings. Unplanned postprocedural admission rates were lower in the office. These results show that the office endovascular suite can be a safe alternative to the hospital angiography suite for tibial interventions.

Authors' Note

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Declaration of Conflicting Interests

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