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Evaluation and Management of Patients with Peripheral Vascular Disease Undergoing Endovascular Intervention: A Single Tertiary Center Experience

Mohamed Alshujaa[1], Nabeel Almadwahi[1], Abdulhafeedh Al-Habeet[2,*], Mohammed S Najran[1], Fahd Ali Alfahd[1], Saeed Hadi Al-Bahlooli[3], Abdulfattah Altam[4]

[1]Vascular Surgery Unit, Department of General Surgery, Al-Thawra Modern General Hospital, Sana'a City, Yemen

[2]Master of Epidemiology and Biostatistics, District Sales Manager at Shaphaco Pharmaceutical Industries, Sana'a City, Yemen

[3]Department of Surgery, Faculty of Medicine & Health Sciences, Thamar University, Dhamar, Yemen

[4]Department of General Surgery, School of Medicine, 21 September University, Sana'a City, Yemen

ABSTRACT

Background: Peripheral artery disease (PAD) is a common condition, and its global prevalence is close to 200 million. Percutaneous transluminal angioplasty (PTA) for the treatment of limb ischemia has become the first-line option; however, in Yemen, it is in the embryonic stage due to a dearth of trained surgeons and dedicated centers. Consequently, we aimed to assess the early outcome and procedural success of PTA in the treatment of PAD. **Patients and Methods:** In the period between January 2020 and December 2022, an observational study was conducted at the vascular unit of surgical departments in the Al-Thawra Modern General Hospital (TMGH). We included all patients who were seeking assistance for sever claudication or critical limb ischemia (CLI) symptoms and were still using their limbs. Patients with renal impairment and/or acute limb ischemia, as well as those patients who were missing follow-up within 3 months, were excluded from the final analysis. The main outcomes were immediate success, symptoms, restenosis and amputation of a limb. **Results:** We included an overall of 103 PAD patients in the study. The mean age was 64.6 ± 13.1 years, with mostly male patients (n = 77, 74.8%). Minor tissue loss was the most common clinical presentation in our patients (n= 61, 59.2%). The majority of patients, 55 (53.4%), underwent balloon intervention. The incidence of any complication up to 3 months after the procedure was 15.5% (n = 16). Re-stenosis was the most common complication, occurring in 5 (%) patients. The success rate of the procedure was 79.6% (n = 82). **Conclusion:** Although PTA is in the embryonic stage in Yemen, its immediate outcomes are satisfactory overall. Given that restenosis was the most common complication occurring in our cases, it is still the Achilles' heel of PTA.

Keywords: Peripheral Artery Disease, Percutaneous Transluminal Angioplasty, Endovascular Intervention.

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***Corresponding Author**

Abdulhafeedh Al-Habeet

Master of Epidemiology and Biostatistics, District Sales Manager at Shaphaco Pharmaceutical Industries, Sana'a City, Yemen,
Phone: 0967775586642

E-mail: abdulhafeedh86@gmail.com

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INTRODUCTION

PAD is a major form of cardiovascular disease (CVD) that most frequently affects the lower extremities and is characterized by decreased blood flow in peripheral blood vessels. Despite being caused by thrombosis, vasculitis, or a degenerative disease, PAD is the third most frequent clinical manifestation of atherosclerosis, following coronary artery disease and stroke [1,2]. The global prevalence of PAD is close to 200 million [3]. In addition, within the adult population in the developed world, PAD prevalence is about 12%, which is dependent on age, with men being slightly more affected than women [4].

The clinical manifestations of PAD may vary from asymptomatic to interrupted claudication, atypical leg pain, ischemic rest pain, ulceration, or gangrene. The most common manifestation of PAD is claudication. However, up to 50% of all PAD patients may remain asymptomatic [4]. Patients with advanced PAD experience decreased mobility and a lower quality of life. In their most severe forms, rest pain, tissue necrosis, and CLI are associated with high rates of limb amputation, morbidity, and mortality. Over the past 20 years, the rate of lower-extremity amputations in the United States of America (USA) has increased concurrently with the higher frequency of PAD, going from 19 to 30 amputations per 100,000 person-years [5,6]. In addition, PAD sufferers have a 2-fold higher chance of mortality, even among patients without recognized CVDs [7].

Since the 1960s, there have been advancements in PAD treatment from the traditional open surgical option to one that includes percutaneous minimally invasive methods [8]. PTA has revolutionized the management of PAD. By utilizing minimally invasive techniques, such as angioplasty, stenting, and other specialized procedures, it offers a safer and more effective alternative to traditional open surgeries [9]. The type of endovascular intervention (EVI) that is used depends on the specific location and severity of the blockage [10]. Current professional society guidelines recommend an endovascular-first revascularization strategy in most symptomatic PAD patients with CLI [11]. The benefits of reduced risk, shorter recovery time, and improved patient outcomes make EVI a valuable tool in the treatment of PAD, ultimately improving the quality of life for affected individuals [12,13].

Despite the growth of PTA, optimal postintervention care is not yet well established. Furthermore, it is unclear how surveillance strategies affect the utilization of health resources, whether they can increase the longevity of vascular interventions, and how they can impact the cardiovascular health of the patient. Aging populations and an increasing prevalence of risk factors such as hypertension (HTN), diabetes (DM), dyslipidemia, smoking, and obesity make PAD a major global health burden, and Yemen is no exception. Yemen has been facing a severe health crisis due to years of unrelenting war, economic decline, and institutional collapse [14,15]. The health care system has been decimated, and supplies and medical care are scarce. In addition, foot ulcers are one of the major health problems among Yemeni diabetic patients and cause more than half of limb amputations [16]. To the best of our knowledge, this is the first study to evaluate the procedural success and early outcome of PTA in the treatment of PAD in Yemen. In this study, we aimed to assess the early outcome and procedural success of PTA.

PATIENTS AND METHODS

In the period between January 2020 and December 2022, an observational study was conducted at the vascular unit of surgical departments in the TMGH. We selected all patients prospectively at the outpatient department (OPD) of the hospital. We included all patients who were seeking assistance for sever claudication or CLI and were still using their limbs. By contrast, patients with renal impairment and/or acute limb ischemia, as well as those patients who were missing follow-up within 3 months, were excluded from the final analysis. Doppler scans and computed tomography angiography was performed prior to PTA in all our cases. EVI were characterized as balloon angioplasty alone or balloon angioplasty followed by stenting. For those lesions amenable to management by PTA or bypass, we shared the decision with the patients or their families. For patients who were likely to undergo major amputations (Syme's amputation and up) as a complementary procedure after PTA, they were informed before the operation. Patients with severe foot infections underwent debridement and minor amputations on the same admission for PTA. Lesions were accessed from the femoral, brachial, or axillary arteries. All procedures below the knee were accessed ipsilaterally, while a few superficial femoral artery (SFA) lesions were managed with the crossover technique. The EVI location included common iliac arteries (CIA) up to bifurcation, external iliac artery (EIA) down to 4 cm from the head femur, SFA, popliteal artery (PA), tibial arteries (anterior tibial artery (ATA), posterior tibial artery (PTA), and peroneal artery (PL), and planter arch. All common iliac lesions were stented with retrograde access. All patients were given Clopidogrel for one month and both aspirin and statins for a lifetime. Patients are advised to maintain optimal control of their blood pressure and blood sugar. After the procedure, all cases were referred for rehabilitation in a physiotherapy center in TMGH. Most patients were discharged within 24 hours after the procedure and followed on an OPD for up to 3 months. Complications included cardiac, renal, thromboembolic,

access site complications, and a return to the operating room. The cardiac complications included myocardial infarction, dysrhythmia, and congestive heart failure. The renal complications included an increase in creatinine that persisted for a long time (≥5 days). The thromboembolic complications included thrombosis and embolization of an artery distal to the site of the procedure. The 3-month outcomes included loss of patency and major amputation.

Statistical Analysis

For all analyses, we used the statistical package for the social sciences (SPSS) version 28.0 (SPSS, Inc., Chicago, Illinois, USA). We used the mean ± standard deviation (SD) to describe continuous variables and absolute numbers with percentages in parentheses to describe cohort characteristics.

RESULTS

Baseline characteristics of the patients

Based on the inclusion and exclusion criteria, a total of 103 PAD patients were included in the final analysis. Baseline characteristics of the patients are presented in Table 1. The mean age was 64.6 ± 13.1 years, with mostly male patients (n = 77, 74.8%), and the male-to-female ratio was 3:1, respectively. DM was the most common associated risk factor for PAD in 81 (77.9%) patients, followed by HTN in 47 (45.2%) patients and smoking in 28 (26.9%) patients. The majority of peripheral vascular lesions were in SFA in 44 (42.7%) patients, ATA in 45 (43.7%) patients and PA in 36 (35.0%) patients. Minor tissue loss was the most common clinical presentation in 61 (59.2%), whereas the majority of patients in 88 (85.4%) presented with grade III according to the Rutherford classification.

Table 1. Baseline characteristics of the patients (N=103)

Variables	Frequency (%) or Mean (SD)
Gender	
Males	77 (74.8)
Females	26 (25.2)
Age in Years	
Mean (SD)	64.60 (13.1)
Risk Factors	
Smoking	28 (26.9)
DM	81 (77.9)
HTN	47 (45.2)
Ischemic heart disease	8 (7.7)
Chronic renal failure	12 (11.5)
Cerebral vascular accident	2 (1.9)
Steroid	2 (1.9)
Peripheral Vascular Lesions	
Common iliac artery	12 (11.7)
EIA	3 (2.9)
Common femoral artery	1 (1.0)
SFA	44 (42.7)
PA	36 (35.0)
Anterior tibial artery	45 (43.7)
Tibioperoneal trunk	18 (17.5)
PL	13 (12.6)
Posterior tibial artery	28 (27.2)
Planter arch	1 (1.0)
Clinical presentation	
Sever claudication	5 (4.9)
Rest pain	10 (9.7)
Minor tissue loss	61 (59.2)
Gangrene	27 (26.2)
Grades of Rutherford classification	
I	5 (4.9)
II	10 (9.7)
III	88 (85.4)

Procedural characteristics

The majority of patients, 55 (53.4%), underwent balloon intervention. The CFA was the most common access site for the intervention, with access achieved through it in 84 (81.6%) patients. The access difficulty rate was 7.4% in 8 patients. Ostial obstruction was the most common access difficulty encountered in 5 (4.9%) patients. Regarding access complications, the distribution of both pseudoaneurysm and hematoma complications was equal in 2 (1.9%) patients. (Table 2).

Table 2. Procedural characteristics (N=103).

Variables	Frequency (%)
Type of angioplasty	
Stent	10 (9.7)
Balloon	55 (53.4)
Both	24 (23.3)
None	14 (13.6)
Access	
CFA	84 (81.6)
AXA	18 (17.5)
BA	1 (1.0)
Access difficulties	8 (7.4)
Type of difficulties	
High bifurcation	2 (1.9)
Ostial occlusion	5 (4.9)
Hostile environment	1 (1.0)
Access complications	
Pseudoaneurysm	2 (1.9)
Hematoma	2 (1.9)

Outcome of intervention

As shown in Table 3, the incidence of any complication up to 3 months after the procedure was 15.5% (n = 16). Re-stenosis was the most common complication, occurring in 5 (%) patients, followed by perforation in 4 (%) patients, and then distal embolization in 3 (%) patients. In dealing with complications after PTA, stent implantation was the most common approach, as it was performed in 8 (%) patients. The success rate of the procedure was 79.6% (n = 82). The pain was relieved in the majority of patients (n = 60, 58.3%). The major amputation rate was 8.7% (n = 9). The mortality rate was 4.8% (n = 5).

Table 3. Outcome of intervention after 3 months of follow-up (N=103)

Variables	Frequency (%)
Any complication up to 3 months after procedure	16 (15.5)
Type of post intervention complication	
Re-stenosis	5 (4.9)
Distal embolization	3 (2.9)
Perforation	4 (3.9)
Other complications	4 (3.9)
Dealing with of post intervention complications	
Stent	8 (7.8)
Re-inflation	5 (4.9)
Conversion	3 (2.9)
Technical Outcome	
Success	82 (79.6)
Failed	21 (20.4)
Clinical Outcome	
Satisfactory	
Pain relief	60 (58.3)
Wound healing	12 (41.7)
Total	72 (69.9)
Unsatisfactory	
Persistent of pain	22 (21.4)
Major amputation	9 (8.7)
Total	31 (30)
Mortality following 3 months of follow up	5 (4.8)

DISCUSSION

Charles Dotter was the first to describe PTA, the use of a catheter to re-canalize and dilate occluded arteries, in the 1960s. In the early 1990s, Andreas Gruintzeg was the first to use a balloon catheter to perform PTA [17]. The successful EVI of individuals with symptomatic PAD is challenging, and there is no universal agreement on the relative efficacy of different EVIs. Our study came up with two main findings. First, although the incidence of any complications up to 3 months after the procedure was slightly higher compared to developed countries, PTA is a safe and effective procedure for the treatment of PAD in Yemeni patients. Second, given that restenosis was the most common complication occurring in our cases, it is still the Achilles' heel of PTA.

In recent years, the disease complexity treated with endovascular surgery has improved as a result of advances in intervention techniques [18]. In our study, the technical success rate was 79.6%. There have been reports of a technical success rate of up to 100% and a 1-year primary patency rate of >85% [19]. The success of the intervention is determined by the complexity of the patient's disease overall [20].

On the other hand, the incidence of complications following PTA ranges from 5% to 25% [21,22] and can vary depending on several factors, including the specific procedure performed, patient characteristics, and the experience of the medical team [11,23]. In our cases, the incidence of any complication up to 3 months after the procedure was 15.5%, a figure that is higher in comparison with other findings of 11.9% in the USA [23]. The higher rate of complications in our study can be attributed to several factors. One factor is the longer follow-up period in our study compared to the American study (3 months versus 1 month, respectively). In fact, the duration of follow-up after the intervention can impact the detection and reporting of complications. Longer follow-up periods may reveal complications that were not immediately apparent. Another factor is the variability in techniques and devices between our country and the USA. The variability in techniques and devices used in EVI can contribute to differences in complication rates between

developed and developing countries. However, it is crucial to consider the specific context and resources available in each country when assessing the impact on patient outcomes.

In the last decade, there has been a dramatic change in the management of PAD [24]. Although the durability of aortoiliac interventions rivals that of surgical bypass, restenosis following PTA is still the Achilles' heel of PTA. The 1-year restenosis rates following PTA are unacceptably high (often ≥ 60%) and go worse with lesion complexity [5,25-27]. Some first-generation stents were linked to results resembling PTA [28,29]. Although self-expanding nitinol stents have lately shown improved patency results, restenosis rates ranged between 20% and 37%. The polymer-based sirolimus eluting and everolimus eluting stents showed promising results at six months, but the advantages were not sustained [27]. The 3-month rate of restenosis after the procedure in our cases was not very high, yet restenosis is still a problem [24,27].

According to a recent study published in the journal Vascular Medicine, the mean rate of nontraumatic major amputation within 30 days following EVI for CLI was 2.8%. The study analyzed data from 20,204 peripheral vascular intervention procedures for CLI from 179 healthcare sites. The study also found that the rate of amputation varied across institutions, ranging from 0.0% to 10.0% [30]. Although the majority of our cases presented with advanced stages of PAD, the incidence of major amputation was within the range reported in the previous study [30]. According to Ashraf et al., almost one-fourth of patients who underwent tibioperoneal PTA eventually succumbed to an amputation [24]. Kudo et al. reported that infrapopliteal angioplasty is a first-line therapy for CLI. In spite of the high rates of re-stenosis, re-intervention, or amputation following tibial angioplasty for CLI, they concluded that great limb salvage rates may be achieved with careful follow-up and re-intervention when necessary [31]. These patients are not candidates for surgical bypass.

Performing an EVI as the first-line revascularization intervention is associated with increased survival and limb-salvage when compared with open surgery [18]. In our cohort of cases, the mortality rate was 4.5%. In the largest meta-analysis to date of 4252 limbs, the overall mortality rate was 14% [32]. It is important to note that mortality rates can be influenced by various factors, including the patient's overall health, the presence of other medical conditions, and the complexity of the procedure being performed. Additionally, the experience and skill of the surgeon performing the intervention can also impact outcomes [33].

A crucial aspect of the endovascular management of PAD is health economics [24]. Studies on the cost of treating CLI have been published. A large number of patients were offered PTA in the two-year period. Cost issues were the main reason for patients not attending [34,35]. Depending on whether a basic balloon angioplasty is performed or a stent is used, the cost of PTA in Yemen can range from $3,700 to $4,500. This is significantly cheaper than the cost of PTA in the USA, which is 10,000 US dollars (or 20,000 US dollars if the procedure fails initially or later) [34,35]; however, it is more expensive compared to its cost in Pakistan, which was from 1,500 to 3,000 US dollars [24]. The ongoing war in Yemen has had a profound and devastating impact on the health crisis in the country. The war has also made it difficult for people to access healthcare. During wartime, many people are afraid to travel to hospitals and clinics due to the risk of being caught in crossfire. Others cannot afford to pay for healthcare, as the cost of living has skyrocketed in Yemen. Adding insult to injury, we have observed an alarming prevalence of risk factors like HTN and DM, which is similar to our previous finding in a cohort of CVD patients [36]. All these factors make PAD a major health burden in Yemen. A number of programs to raise awareness of PAD and improve access to PAD prevention and treatment services are necessary.

LIMITATIONS

We would like to acknowledge several potential limitations of this study. The findings of our study may not apply to other healthcare settings because it only included individuals undergoing PTA at a single tertiary center. However, patients in this cohort have sociodemographic characteristics, comorbidities, and levels of vascular disease that are comparable to those of patients in other observational and randomized controlled studies of PTA. Finally, the short duration of follow-up in our study can limit the ability to detect the long-term effects of PTA. Long-term follow-up studies are necessary to gain a more comprehensive understanding of the outcomes and effects of interventions. We are planning to continue and extend the study with a long-term follow-up to achieve this endeavor.

CONCLUSION

PAD is one of the major health burdens in Yemen. Although PTA is in the embryonic stage in Yemen, its immediate outcomes are satisfactory overall. Our experience is comparable to other studies that have been published in which PTA was found to have benefits despite related complications. Given that restenosis was the most common complication occurring in our cases, it is still the Achilles' heel of PTA. A number of programs to raise awareness of PAD and improve access to PAD prevention and treatment services are necessary. Further studies are also needed to elucidate the most effective preventive measures.

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INFORMATION DISCLOSURE

The purpose of the study was explained to the administration staff of TMGH and permission was obtained. We conducted our study in accordance with the Declaration of Helsinki by including basic principles of ensuring the study subject's privacy, risk, and benefit, conducted by trained professionals. Informed consent was obtained verbally from the participants themselves. Furthermore, the confidentiality of the information was assured.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest.

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