

Original Paper

Endovascular Intervention for Critical Lower Limb Ischemia; a Review of Outcomes after Percutaneous Transluminal Angioplasty using Balloon Catheter

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Received: November 26, 2018 Accepted: December 13, 2018 Online Published: December 26, 2018

doi:10.22158/mshp.v3n1p1

URL: <http://dx.doi.org/10.22158/mshp.v3n1p1>

Abstract

Peripheral Arterial Disease (PAD) of lower limb with variable morbidity can be manifested as an asymptomatic, sever or life threatening disease. It is also a major cause of disability in many cases.

The management of patients with PAD can be defined from a number of different treatment options in the terms of conservative-, interventional- and surgical therapies.

Percutaneous Transluminal Angioplasty (PTA) using balloon catheter as a revascularization procedure has been used with acceptable outcomes. The method results are highlighted with comparable success—and patency rates, low complications, improving the quality of life and survival. We reviewed published studies and found that PTA is an appropriate alternative in the management of patient with Critical Limb Ischemia (CLI). Better outcomes have been achieved using Drug Coated Balloons (DCB) as well as Drug Eluting Stents (DES). Atherectomy remains with controversial results. Patient characteristics, the presence of associated risk factors, characteristics of lesions and accompanied cardiopulmonary disease may be the main challenges to use of these treatment options in the future.

Keywords

percutaneous transluminal angioplasty, success-and patency rates, quality of life and survival

1. Review Design

This article was formulated with the aim of literature review on treated patient with CLI using PTA. Searches were conducted via the following databases, covering the period from their commencement to 01/10/2018: Medline, Pre MEDLINE, EMBASE, Cochrane Library and other databases. In this review, are outlined the outcome of this technique and the authors' views on the current status of treatments.

2. Definition of Procedure

Percutaneous Transluminal Angioplasty (PTA) of lower limb using balloon catheter has evolved since the 1960s (Becker & Dake, 2013). This procedure is a well-established treatment for Critical Limb Ischemia (CLI). It is indicated for documented stenosis > 50% of the vessel diameter, single stenosis and occlusions lesser than 10 cm in length, short consecutive multiple stenosis and also calcified occlusions (Pentecost et al., 1994; Athanasoulis, 1980).

It should be not offered in active inflammation of a luminal stricture, sepsis, severe coagulopathy and recent surgical anastomotic stricture (Athanasoulis, 1980).

Standard angiography and Magnetic Resonance Angiography (MRA) can provide a definition of occlusion anatomically and preoperative planning of revascularization but MRA could be considerable in patient with previously operation clips or endovascular stent and other MR imaging contraindications. Under local anesthesia and an antegrade puncture of the common femoral artery, a five or six French gauge sheath is positioned to perform a preliminary angiographic study using diluted (50%) non-ionic contrast medium (Gates et al., 2000).

A guide wire and a French balloon catheter are used for the dilatation of 2-8 mm diameter arteries. Due to increase the risk of thrombosis especially in the infra popliteal arteries, stents are employed if dissection or suboptimal results occurred. During the procedure, 5000-7000 IU of sodium heparin is infused into the arterial lumen. If vessel spasm occurred, 0.1-0.2 mg of nitroglycerine is infused as an intra-arterial bolus. Intra-arterial thrombus is managed by catheter aspiration and/or urokinase and heparin infusion (Papavassiliou et al., 2003).

A nephroprotection protocol is used in all non-dialyzed patients: 1500 ml salin is infused the day before and the day after the procedure. Creatinine value is determined the day before and after the PTA. In subjects with creatinine > 110 mg/dl, dopamine 2 mg/Kg/min is infused 24 h before and after the procedure. In patients with an ejection fraction < 40%, 20 mg of furosemide are injected intravenously at the beginning and the end of the daily hydration. Hospital stay can be 3 days. All the patients are prescribed either ticlopidine 500 mg/day or clopidogrel 75 mg/day for 30 days and subsequently acetyl salicylic acid 100 mg/day or ticlopidine 250 mg/day (Papavassiliou et al., 2003).

This method offers faster recovery and requires shorter hospital stay. It requires no general anesthesia and maintains all option for extremity revascularization. PTA may be repeated if necessary and may be combined with surgery improving inflow or outflow of surgically placed graft. This method also may be considerable due to lower primary patency rate, multiple stenosis and may be limited due to

cost-benefit ration and necessary to reintervention (Mazari et al., 2012).

3. Evaluation Parameters

In the current review, success- and patency rates, complications, quality of life and survival rate were as the available evaluation parameters.

Two forms of success rates include technical and clinical success. Technical success is defined as the substantial relief of stenosis or occlusion with residual narrowing of 20% or less, significant hemodynamic improvement, and no major morbidity (Society of Interventional Radiology Standards of Practice Committee, Guidelines for Percutaneous Transluminal Angioplasty, 2003).

Clinical success in the femoropopliteal segment is defined as relief of or substantial improvement in symptoms, increase in the ankle-brachial index of at least 0.15 (Thom et al., 2011) and/or normalization of the popliteal pulse, thigh/calf pulse volume recording, or Doppler pressure (Society of Interventional Radiology Standards of Practice Committee, Guidelines for Percutaneous Transluminal Angioplasty, 2003). The patency rate is the percentage of patients who have undergone an initially successful procedure for whom flow at the treatment site and symptomatic improvements are uninterrupted in any specified time period (Guidelines for Percutaneous Transluminal Angioplasty, 2003).

Primary patency implies uninterrupted patency following the revascularization procedure being evaluated. Assisted primary patency expresses cases in which a revision of the revascularization method is applied to prevent impending occlusion or progression of stenosis. Secondary patency refers to patency of the initially treated vessel following a re-intervention to restore patency after occlusion (Dormandy et al., 2000).

Complications parameters include; the amputation of treated limb with assessment of yearly evaluation of patient charts, surgical bypass of the trial leg, peri-procedural (within 30 days) complications, endovascular or surgical re-intervention of target lesion and death. Quality of life can be defined as an emotional well-being of satisfaction with a multidimensional construct comprising physical, psychological, social, and functional domains (Korolija et al., 2004). It can be measured by some methods such as McGill quality of life measurement questionnaire (McGill, 2004).

Intermittent claudication is associated with a significant reduction in quality of life. Treatment of claudicants aims to reduce mortality from cardio-and cerebrovascular events and to improve quality of life. PTA is now widely used in the treatment of intermittent claudication (Cassar et al., 2003).

To consider 1-, 2- and 3-years survival rates in patients with PAD using PTA versus stent or surgical treatment methods can clarify the role of PTA as an alternative therapy in the management of these patients.

4. Outcomes

4.1 Technical Success Rate

Table 1 illustrates the reported technical success rate of femoropopliteal PTA in patients with PAD. More than any other vascular segment, technical success and patency in the femoropopliteal artery depend on the characteristics of the lesion treated. Lesion classification has been defined by Society of Interventional Radiology Standards of Practice Committee according to the length, location of stenosis or occlusion and single or multiple lesions. The mean of technical success in reviewed studies was noted for 90.42% with sample Standard Deviation (SD) for 7.43% and Confidence Interval (CI) Approximations in level of 95% between 57.56% and 93.27% of patients with PAD (range 77-100%)

Table 1. The Technical Success Rate of Femoropopliteal PTA in Patients with PAD

Author	Year	No. of Patient	PAT	Limb	Technical success rate
Arfvidsson, B. et al	1983		54		79.62
Jørgensen, B. et al.	1988		86		82
Bakal, C. W. et al.	1990	53	57		97
London, N. J. et al.	1995			54	91
Söder, H. K. et al.	2000	60		72	84
Cejna, M. et al.	2001	77			84
Krankenber, H. et al.	2005	78	104		89.4
Kudo, T. et al.	2005	111			96.4
Krankenber, H. et al.	2007	121			79
Giles, K. A. et al.	2008	163		176	93
Romiti, M. et al.	2008				89
Airoldi, F. et al.	2012	64	45		84
Scatena, A. et al.	2012	245	189		77
Micari et al.	2013	105			100
Yang, et al.	2013	3789			92.29
Joh, J. H.	2014	76			90.5
Thiny, P. O.	2015	53			96
Jang, S. J.	2015	87			100
Tnishibe, T.	2016	65			94
Ming, Z.	2016	183			80.4
Chang, Z.	2016	147			93
Korkmaz, K.	2017	755			84
Davis, T.	2017	123			100
Gray, W. A.	2017	241			98.3

Deloge, C.	2018	53	100
Brodmann, M.	2018	35	97.1

4.2 Clinical Success Rate

Reviewed studies (Table 2) demonstrated the clinical success at 6 months of 73% and 92.7% of treated patients. The mean of clinical success was 68.1% with SD for 13.45% and CI- 95%; 60.14-76.05% of patients at 1- after PTA. This parameter was for at 2 years 77 and 65% of patients.

Clock et al. in a study on 21 patients and 33 performed PTA reported clinical success at 3 years for 72% of patients after PTA. Loeffberg et al. in 2011 performed 121 PTAs on 92 patients and reported 5 years clinical success of 27%.

Table 2. The Clinical Success Rate after Femoropopliteal PTA in Patients with PAD

Author	year	No. Patient	PAT	Limb	Clininical Success (CS) at 6 months	CS at 1 year	CS at 2 years	CS at 3 years	CS at 5 years
Arfvidsson, B. et al.	1983		54		77.4				
Glock, et al.	1984	21	33		72		92		
Fletcher, J. P. et al.	1986	63	91		73	58			
London, N. J. et al.	1995			54			77		
Söder, H. K. et al.	2000	60		72		63			
Cejna, M. et al.	2001					72	65		
Kudo, T. et al.	2005	111			92.7				
Clock, et al.	2007	21					72		
Loeffberg, A. M. et al.	2011	92	121			40			27
Brodmann, M. et al.	2011	33							
Scatena, A. et al.	2012	245	189			60.4			
Sadaghianloo, N. et al.	2013	34				65			
Jang, S. J. et al.	2015	87				77.5			
Ming, Z. et al.	2016	183				92.8			
Liu, X. et al.	2018	100				71			

4.3 Patency Rates

Table 3 shows the primary- and secondary patency rates and details using femoropopliteal PTA. Mean of reported primary patency rate at 1- and 2- years patient's follow-up were 67.43 (SD, 19.7% and CI-95%, 60.00-74.87%) of treated. and 49 (SD for 5.29% and CI-95%; 43.01-54.98%) of patients

respectively.

The mean of secondary patency rate at 1 year patient follow-up was achieved for 73.53 (SD; 18.42% and CI-95; 62.65-84.42%) of patients.

Secondary patency rate at 1 year patient follow-up was achieved for 74 and 50.1% of patients.

Table 3. The Primary and Secondary Patency Rate after Femoropopliteal PTA in Patients with PAD

Author	year	No. Patient	PAT	Limb	Primary patency rate (PPR) at 1 year	PPR at 2 years	Secondary Patency (SPR) rate at 1 year	SPR at 2 years
Engel, A. et al.	1982	192			83			
Arfvidsson, B. et al.	1983		54		45			
Gallino, A. et al.	1984	482	411		58			
Jørgensen, B. et al.	1988		86		85			
London, N. J. et al.	1995			54	78			
Söder, H. K. et al.	2000	60		72	48		56	
Cejna, M. et al.	2001				63	53	84	74
Jämsén, T. S. et al.	2002	178		218	46		63	
Krankenbergh, H. et al.	2005	78	104		81.9		91.5	
Kudo, T. et al.	2005	111			31.4		79	
DeRubertis, B. G. et al.	2007	184			54	43		
Kristina, A. G. et al.	2008	163		176	53			
Romiti, M. et al.	2008				77.4		83.3	
Giles, K. A. et al.	2008	176			53	51		
Casella, I. B. et al.	2010		48				63.7	
Brodmann, M. et al.	2011	33			70.4		76.7	
Micari, et al.	2013	105			72.4		84.7	
Sadaghianloo, N. et al.	2013	34			13		32	
Yang, et al.	2013	3789			57-65			
Joh, J. H. et al.	2014	76			90.9			
Laird, J. R. et al.	2015	331						50.1
Tnishibe, T. et al.	2016	65			81			
De Athayde Soares, R.	2016	92			59.9			
Chang, Z. et al.	2016	147			78		95	
Deloge, C. et al.	2018	53			92			

Lucatelli, P. et al.	2018	31	88.9
Brodmann, M. et al.	2018	35	78.4
Kim, K. et al.	2018	244	67.5
Liu, X. et al.	2018	29	82.7
Lida, O. et al.	2018	100	89

4.4 Complications

Table 4 demonstrates the complication rate and details using femoropopliteal PTA. Reviewed studies showed the mean of complication rate of 8.38 (SD; 4.73% and CI-95%; 4.87-11.89%) of performed femoropopliteal PTA. The reported complications of the patients in whom PTA was attempted, included local hemorrhage, dissection, embolism, and spasm necessitating surgical intervention.

The amputation of treated limb with assessment of yearly evaluation of patient charts was noted for 5.68 (SD for 3.99% and CI-95%; 2.92-8.45% of cases).

The mean of death which was a direct consequence of PTA reported for 3.88 (SD; 4.12% and CI-95%; 0.58-7.18%) of treated patients.

The mean of restenosis were reported for 35.8 with sample standard deviation for 26.73% and CI-Approximations in level of 95% between 21.67% and 50.01% of patients with PAD.

Reintervention was performed for 34.81 (SD; 26.73% and CI-95%; 17.34-52.27%) of patients.

The surgery at the time of angioplasty was reported in Glock's study after 5.6% performed PTAs while in a study of Scatena A et al. in 2012, 1.5% patients needed to surgery.

Table 4. The Complication Rate of Femoropopliteal PTA in Patients with PAD

Author	year	No. Patient	PAT	Limb	Amputation	Death	Re-stenoses	Reintervention	Complication
Engel A et al.	1982	192			9				
Glock et al.	1984	21	33				49	7	
Fletcher JP et al.	1986	63	91		9				
Jørgensen B et al.	1988		86						10.9
Bakal CW et al.	1990	53	57			1.8			
Hasson JE et al.	1990		202		10.9	5.9			
Gapek P et al.	1991		217					32.7	
H K Söder et al.	2000	60		72			32		
Cejna M et al.	2001								5.2
Nasr M K et al.	2002	526		608				87.5	
Jämsén TS et al.	2002	178		218				32.6	
Becquemin JP et al.	2003	115							3.3

Krankenber H et al.	2005	78	104					5.8
Schillinger M et al.	2006	104	53			43		
Bai-xi Zhuang et al.	2007	150		176		13.7	7.2	
Krankenber H et al.	2007	121					18.3	
DeRubertis BG et al.	2007	184		1.9				
Kristina A Giles et al.	2008	163		176	3.4	5	63	61
Campbell W. B. et al.	2009	33		37			21.2	15.2
Faglia E et al.	2009	554	420		8.2		22.4	
Brodmann M et al.	2011	33					39.4	
Faglia E et al.	2012		308		2.6			
Scatena A et al.	2012	245	189		0.5	10.6		
Micari et al.	2013	105						17.5
Thiny PO	2015	53					75	
Mostapha JA	2016	407				0		
Lucatelli P	2018	31					12.9	
Janco PJ et al.	2018	69				0		9.8

4.5 Quality of Life

Keeling AN et al. in 2007 assessed the impact of 86 PTAs on Auality Of Life (QOL) in 72 patients with intermittent claudication or Critical Limb Ischemia (CLI).

PTA results in improved QOL in patients with intermittent claudication and CLI as early as 1 month, which was shown to be maintained at 6 months in this small series.

Cassar K et al. in 2003 examined the effect of PTA on Quality Of Life (QOL) in patients with intermittent claudication. The findings suggest that PTA may result in some improvement in QOL in these patients.

Whyman MR et al. in a randomized controlled clinical trial determined in patients with mild and moderate intermittent claudication differences in outcome between PTA and conventional medical treatment after 2 years. They suggested that two years after PTA, patients had less extensive disease than medically treated patients, but this did not translate into a significant advantage in terms of improved walking or quality of life. There are important implications for patient management and future clinical research.

4.6 Survival Rate

The mean of survival rate at 1 year (Table 5) was calculated of 83.47 (SD; 12.78% and CI-95%; 75.12%-91.82%) of patients.

2- and 3-years survival rates were 71.66 with sample standard deviation for 15.14% and CI-Approximations (95%); 54.52%-88.8% of patients and 62.88 (SD for 12.25% and CI-95%; 52.13%-73.62%) of patients with respectively (Table 5).

Table 5. Survival Rates in Patient with PAD Using PTA

Author	year	No. Pat.	PAT	Limb	Survival at 1 year	Survival at 2 years	Survival at 3 years
Gapek, P. et al.	1991		217		81	61	56
Becquemin, J. P. et al.	2003	115			92	89	82
Laird, J. R. et al.	2006	155			82		
Kristina, A. G. et al.	2008	163		176	81	65	54
Romiti, M. et al.	2008				98.3		68.4
Bosiers, M. et al.	2008	51			79		
Giles, K. A. et al.	2008	176			81		54
Arvela et al.	2011		274		57		
Lucatelli, P. et al.	2018	31			100		

5. Developed Endovascular Techniques

In recently years many different endovascular techniques have been used for the management of peripheral artery diseases such as Drug-Coated Balloons (DCB), Bare Metal Stents (BMS) and Drug-Eluting Stents (DES) as well as numerous atherectomy devices.

5.1 Drug Coated Balloon (DCB)

The DCB delivers an anti-proliferative drug to the arterial wall during balloon angioplasty, 6-month primary patency of PTA in femoropopliteal disease with Drug-Coated (DCB) and Uncoated Balloons has been reviewed by Zhen Y et al. in 2018. They reported that DCB may improve early primary patency by inhibiting inflammation. A higher postoperative Neutrophil-Lymphocyte Ratio (NLR) was associated with early restenosis. Through a randomized trials in 2018 Chou HH et al. suggested that superior 2-year outcomes using DCB compared with uncoated balloon angioplasty and similar safety profiles in dialysis patients with femoropopliteal disease.

5.2 Bare-Metal Stent (BMS) and Drug Eluting Stent (DES)

Bare-metal stent is a stent with or without covering. Stent placement has been used with an acceptable success rate. Yang X et al. suggested that primary stent implantation had no advantage over balloon angioplasty in reducing restenosis or revascularization for infrapopliteal disease. Primary stent implantation seems to be a promising treatment for focal infrapopliteal lesions. Publication bias could not be ruled out, and the results should be treated with caution (Yang et al., 2014).

Cejna M et al. reported that after stent placement, the primary success rate was significantly higher than after PTA. However, 1-year angiographic and clinical/hemodynamic success was not improved.

An extensive review of the literature was carried out over the last 15 years by Caradu et al. (2016) on the use of BMSs in lower limb revascularization based on a PubMed (Medline). They reported that primary BMS implantation showed no advantage over PTA and as of today DES trials have not shown

enough clinical or economic benefit. Thus, BMSs are recommended over DESs, and only as a bailout strategy in case of flow limiting dissection or recoil. Quality trials assessing long-term clinically relevant outcomes, evolution in stents designs and vessel preparation could lead to a change in those recommendations.

Liistro F et al. in 2009 reported that repeat balloon angioplasty for DES restenosis showed similar clinical outcome compared to re-DES (homo- or hetero-) implantation and could be considered as first treatment strategy in this setting.

Torii S et al. in 2018 reported that in the treated arteries, irrespective of preceding DCB treatment or PTA, DES treatment showed maximum drug effects vs DCB alone or in combination with BMS placement, and there was no detrimental toxic effect in DCB-treated iliofemoral arteries before DES treatment compared with PTA before DES treatment. Downstream vascular changes were exclusively seen in groups treated with DCBs.

5.3 Atherectomy

Abdollah O et al. in 2018 reported that PTA alone and atherectomy-PTA was associated with similar outcomes in terms of vessel dissection and residual stenosis, mortality at 12months, and limb amputation at 1 or 12months. But Janas et al. in 2017 compared long-term outcomes after percutaneous PTA and atherectomy in patients requiring endovascular revascularization and showed that atherectomy was associated with lower risk of Target Lesion Revascularization (TLR).

Shammas et al. (2018) in a single center cohort of Jetstream Atherectomy (JA) followed 311 procedures and reported that JA with DCB had a superior TLR rate up to 16-month follow-up when compared to JA with PTA in treating all comers' femoropopliteal artery disease.

6. Discussion

Percutaneous transluminal angioplasty using balloon catheter can be performed as the first choice in treatment of the CLI with high success- and patency rates, low complication rate, increase the quality of life and providing an acceptable survival.

The outcomes of PTA have been evaluated comparatively with other treatment options. Romiti M et al. in a meta-analysis of 30 related studies presented that the technical success and subsequent durability of angioplasty are limited compared with bypass surgery, but the clinical benefit is acceptable because limb salvage rates are equivalent to bypass surgery. Limb salvage was noted for 95.4% patients at 1 year and 82.4% at 3 years.

Janczak, D. et al. in 2017 suggested that the endovascular method results in a similar re-operation rate and number of complications as open surgery.

Reasons for unsuccessful PTA are mainly difficulties in passing the stenosis/occlusion with the guide wire or that dilation cannot be completed because of extensive calcification in the arterial wall.

Many reports suggest that PTA is a satisfactory alternative to surgical treatment of occlusion of the infrapopliteal arteries. Nasr, M. K. et al. demonstrated that PTA is increasingly replacing bypass

surgery in the treatment of CLI, without compromising patient survival or limb salvage rates. They achieved the limb salvage in 89% patient at 1 year and 87% at 5 years. Giles KA et al. showed that the excellent limb salvage rates may be obtained with careful follow-up and reinterventions when necessary.

Retrograde tibiopedal access and interventions have contributed to advance of endovascular techniques to treat Critical Limb Ischemia (CLI) patients. Mustapha JA in a review of infrapopliteal angioplasty in 2017 showed that retrograde pedal access has emerged as an important tool to facilitate successfully percutaneous revascularization and limb salvage in patients with CLI. Retrograde tibial-pedal access has shown improvement in the rate of successful revascularizations (Mustapha et al., 2017).

Subintimal recanalization is one of treatment options with this technique; a channel is deliberately created by dissecting the vessel wall in order to replace the native occluded lumen. This is opposed to intraluminal recanalization, where passage of an arterial obstructive lesion is performed by central luminal navigation. Bosiers et al. in 2012 presented that in lower extremity PTAs intraluminal is better than subintimal.

Kim K et al. in 2018 suggested that in long femoropopliteal occlusions, the subintimal approach achieved a higher technical success rate and similar mid-term primary patency and TLR-free survival compared with intraluminal approach.

Jaemsen TS et al. reported that although the long-term patency rates of femoropopliteal PTA in claudicant patients were poor, the acceptable number of reinterventions and the low frequency of development of CLI imply the long-term benefits achievable with this treatment.

Hunink et al. evaluated the cost-effectiveness of PTA and bypass surgery in patient with stenotic or occlusive PAD and suggested that PTA is the preferred initial treatment in patients with disabling claudication and a femoropopliteal stenosis or occlusion and in those with chronic critical ischemia and a stenosis. Bypass surgery is the preferred initial treatment in patients with chronic critical ischemia and a femoropopliteal occlusion.

Age may be as an important factor in the treatment of patients with PAD. Arvela et al. in 2011 reported that when feasible, a strategy of PTA first appears to achieve better results than infrainguinal bypass surgery in patients aged 80 years and older.

Associated risk factors such as diabetes mellitus can change the outcome of treatment options. Fagila E et al. evaluated the long-term prognosis of Critical Limb Ischemia (CLI) in diabetic patients. They reported that diabetic patients with CLI have high risks of amputation and death. In a dedicated diabetic foot center, the major amputation, ulcer recurrence, and major contralateral limb amputation rates were low. Coronary Artery Disease (CAD) is the leading cause of death and in patients with CAD history the impaired ejection fraction is the major independent prognostic factor.

Fagila et al. in 2009 also evaluated the feasibility of peripheral revascularization by PTA or By Pass Grafting (BPG) in diabetic patients with Critical Limb Ischemia (CLI). They presented that revascularization by PTA is highly feasible in diabetics with CLI. The feasibility of revascularization

by BPG is lower but nonetheless consistent. Darling et al. in 2018 reported that a bypass-first strategy is associated with similar 30-day outcomes and lower restenosis and reintervention rates. These data suggest that a bypass-first approach may best serve appropriately selected, anatomically suitable patients with diabetes mellitus and pedal ischemia that requires revascularization.

In conclusion, PTA is an appropriate method with comparable outcomes in patients with critical limb ischemia. Better outcomes have been achieved using drug coated balloon as well as drug eluting stent. Atherectomy remains with controversial results. Patient characteristics such as gender, age and life style, characteristics of lesions, presence of associated risk factors and accompanied cardiopulmonary disease may be the major future challenges of treating PAD using PTA.

7. Conflict of Interest Statement

The authors declare no conflict of interest associated with this manuscript.

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