Neurostimulation treatment in 'End Stage Peripheral Vascular Disease' with no revascularization option can achieve limb salvage and treat disabling claudication by improving blood flow into the affected limb: Review of cases

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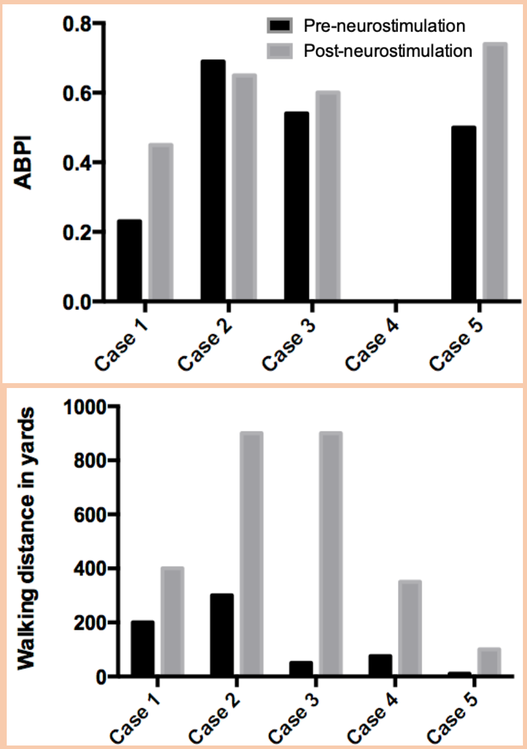
INTRODUCTION:

End stage Peripheral Arterial Disease (PAD) with no option of further revascularization may result in disabling claudication, rest pain and limb loss. The patient may have had multiple interventions in the past exhausting all revascularization options or have severe disease with no target vessel or not fit for an endovascular or open surgical intervention. Treating those patients with Neurostimulation improves peripheral blood flow by parasympathetic mediat ed arterial dilatation, achieving symptom improvement and limb salvage.

METHODS:

A total of 117 patients have been treated between September 2018 and September 2022. In this presentation, we will review 5 cases (age 40-75) of severe/end-stage symptomatic PAD who were offered Neurostimulation treatment as they have exhausted all revascularization options. In all patients, pre-neurostimulation arterial duplex scan to measure tibial artery diameter, tibial blood flow volume, ABPI, pain score, claudication distance and impact on quality-of-life were recorded. A Ducest* Neurostimulator device was implanted in fossa triangularis in the ear for two consecutive sessions of 3 weeks each. Post-neurostimulation arterial duplex scan repeated to compare vessel diameter, flow volume and ABPI. Post-treatment clinical parameters were recorded.

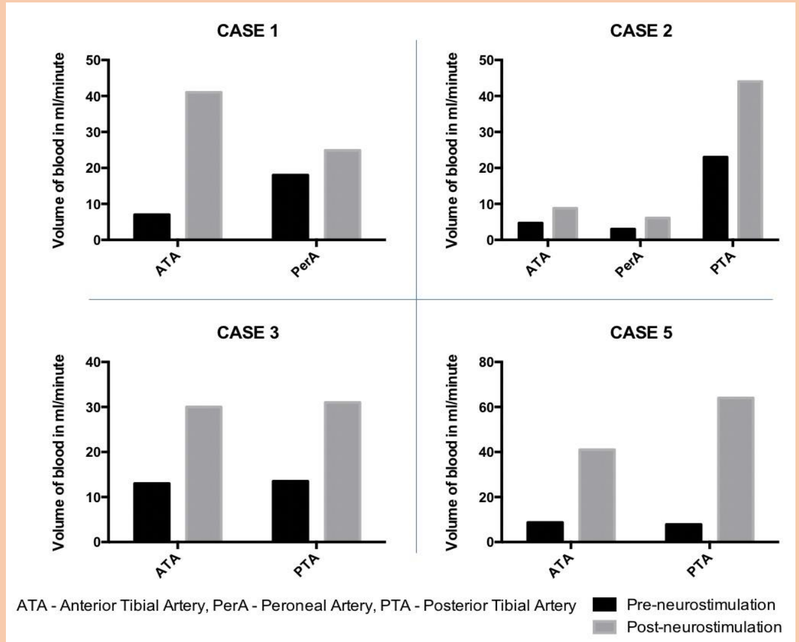
Figure 1: Comparison of ABPI (top panel) and walking distance(bottom panel) before and after treatment with neurostimulation in Cases 1-5



Top panel: ABPI increased to double in case 1, ~1.5 times in case 5 and slightly in case 3. However, case 2 showed a slight decrease. Case 4 had falsely elevated ABPI due to calcified tibial artery disease.

Bottom panel: A 2-fold increase in walking distance is reported by patient 1. An incredible difference is noted by case 3 with an almost 10-time increment in his walking distance. Furthermore, cases 2, 4 and 5 also experienced a 3-fold increase in the distance they could walk post-NS treatment. Symptomatic and pain relief was reported by each patient which was evident by the significant improvement in their walking distance.

Figure 2: Comparison of blood flow through Anterior tibial (ATA), Posterior tibial (PTA) and Peroneal (PerA) arteries before and after treatment with neurostimulation (NS)



Top left panel shows greater that 4-fold increase in flow of blood through ATA in Case 1. **Top right panel** depicts an increase in blood flow through ATA, PTA and PerA in case 2. The increase in PTA is particularly remarkable. A greater than 2-fold increment in both the ATA and PTA (**bottom left panel**) are noted in case 3 post-NS treatment. **Bottom right panel** illustrates a huge increase in blood flow through both the PTA and ATA in Case 5.
(Case 4 did not have measurements. However, hand-held doppler revealed good biphasic signals over PTAs and good monophasic signals over ATAs, suggesting that the NS treatment has had a positive outcome on the blood flow to his calves. Pre-NS doppler had revealed monophasic tibial signals and were falsely elevated due to vessel calcification)

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Table 1: Demographics of Cases 1-5

Case	Age	Sex	Diabetic	Smoking status	Relevant medical history
1	73	Female	No	Yes	Medications include- statin, clopidogrel and Enalapril.
2	41	Male	No	Yes. Quit before NS	Buerger's disease. Medications include - Aspirin, Statin, clopidogrel and Naftidrofuryl.
3	45	Male	No	No	Factor V Leiden deficiency, Atrial septal defect repaired, hypertension, obesity, multiple DVTs. Warfarin.
4	76	Male	No	Ex-smoker	Previous vascular interventions for claudication, atrial fibrillation. Medications include Apixaban and a statin.
5	70	Male	yes	Ex-smoker	Popliteal artery aneurysm, atrial fibrillation, ischaemic cardiomyopathy, Asthma, COPD, ectatic aorta, spinal disc herniation. Medication includes Aspirin, metformin, ramipril, simvastatin, lansoprazole and Naftidrofuryl.

Table 1: Summarising the demographics of Cases 1-5 including their age; sex; risk factors – diabetes and smoking status; and any relevant past medical history including their current medication.

Table 2: Arterial site of occlusion of blood flow and comparison of diameter of arteries pre- and post- neurostimulation (NS) treatment for Cases 1-5

Case	Site of occlusion	ATA diam (in cm)		PTA diam (in cm)		PerA diam (in cm)	
		Pre-NS	Post-NS	Pre-NS	Post-NS	Pre-NS	Post-NS
1	SFA, proximal popliteal artery, PTA	TS: 0.11 LS: 0.11	TS: 0.16 LS: 0.19	NA	NA	TS: 0.21 LS: 0.19	TS: 0.21 LS: 0.23
2	Distal popliteal artery, tibio-peroneal trunk, ATA and proximal PTA	TS: 0.12 LS: 0.10	TS: 0.19 LS: 0.17	TS: 0.14 LS: 0.15	TS: 0.18 LS: 0.18	TS: 0.14 LS: 0.13	TS: 0.15 LS: 0.17
3	SFA (with slight flow in knee region), distal popliteal artery, tibio-peroneal trunk, ATA, PTA and PerA	TS: 0.18 LS: 0.17	TS: 0.18 LS: 0.17	TS: 0.14 LS: 0.14	TS: 0.22 LS: 0.23	NA	NA
4	Bilateral SFA, proximal popliteal artery with calcified tibial artery disease.	NA	NA	NA	NA	NA	NA
5	Occluded popliteal artery aneurysm; proximal PTA and ATA; PerA.	TS: 0.22 LS: 0.21	TS: 0.26 LS: 0.25	TS: 0.15 LS: 0.14	TS: 0.30 LS: 0.30	NA	NA

Table 2: Summarising the site of arterial occlusion and changes in [transverse section (TS) and longitudinal section (LS)] diameter (diam) of anterior tibial artery (ATA), posterior tibial Artery (PTA) and Peroneal Artery (PerA) pre- and post- treatment with NS. [SFA is superficial femoral artery]

RESULT:

Major Improvement in symptoms were noted in all cases. Post-treatment, patients had a 2-16-fold increase in their walking distance, pain score reduced significantly (0 in 2 cases), improved quality of life. Profound (2-8 times) improvement of blood flow in tibial arteries, increase in tibial artery diameter and an increase in ABPI were also noted.

CONCLUSION:

This series strongly suggests a beneficial role of neurostimulation in the symptomatic treatment of PAD in selective cases of end stage or severe peripheral vascular disease.