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Case Report

Case Report - Enhanced External Counterpulsation in the Management of Diabetic Peripheral Neuropathy

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Abstract

A patient with intermittent claudication, evening leg pain, and unsteady gait secondary to peripheral artery disease and diabetic peripheral neuropathy were treated by enhanced external counterpulsation (EECP).

The case arose three years before the consultation. Conventional medical treatments involve controlling hyperglycemia, cholesterol levels, blood pressure, and physiotherapy. Opioids and NSAIDs were prescribed. These approaches reduced the pain from 10/10 to 7/10 in one year but did not improve the paresthesia and hyperesthesia of the feet and the walking distance. Frustrated by the lack of significant improvement after visiting multiple medical establishments and receiving over 100 various physiotherapy treatments, he reluctantly discontinued further physiotherapy treatments.

The laboratory tests since 2022 showed that the patient had diabetes. The glycemic parameters were all elevated. Examination using Tensiomed revealed an increased augmentation index and pulse wave velocity. A low nerve score, a measure of the sudomotor response, was also found, suggesting small fibres neuropathy. The findings indicated that the patient had peripheral artery disease (PAD) and early manifestation of diabetic peripheral neuropathy.

With his consent, he tried EECP treatment and nutraceuticals on him. His glycemic parameters improved after 19 sessions. After 35 sessions, which spanned over 7 weeks, he could walk for 500 metres, whereas before the intervention, he could only walk 100 metres. Also, the area of the left calf cramp during ambulation was reduced. More importantly, perhaps, the sensation in the sole improved, and he could walk more steadily. His gait was more balanced. Yet, the evening pain still persisted.

As we did not only use EECP for treatment, we cannot determine if the benefits derive entirely from the EECP. Further studies are required to elucidate whether EECP intervention improves peripheral artery disease (PAD) or diabetic peripheral neuropathy.

Keywords: *External Counterpulsation; Peripheral Artery Disease; Intermittent Claudication; Diabetic Peripheral Neuropathy*

Abbreviations

Aix: Augmentation Index; EECP: Enhanced External Counterpulsation; PAD: Peripheral Artery Disease; PEA: Palmitoylethanolamine; PPao: Pulse Pressure (Aorta); PWVao: Pulse Wave Velocity (Aorta); SBPao: Systolic Blood Pressure (Aorta); T2DM: Type II Diabetes Mellitus

Introduction

Diabetic peripheral neuropathy is a common complication of diabetes mellitus. Patients generally present with paresthesia, hyperesthesia, or hypothesia of the feet and calves, and less commonly in the hands. The tingling, burning, and stabbing pain are usually symmetrical and present in a sock-like distribution. Pain is generally worse in the evening and frequently disturbs sleep, lowering patients' quality of life. More importantly, perhaps, the condition is associated with higher cardiovascular and all-cause mortality [1].

Of significance is that the prevalence of type II diabetes (T2DM) is increasing worldwide. The increase is particularly significant in countries with improving economies, from low- to middle-income [2]. In China, the prevalence of T2DM increases significantly from 1994 to 2010, from 2.5% to 11.6%, respectively [3], parallel to the improving economies. The study estimated that 15.5% of the population are pre-diabetic [3]. With the escalating prevalence of T2DM, it is expected that the number of people afflicted with diabetic peripheral neuropathy will increase. A recent cross-sectional study in China in 14,908 T2DM patients, using the Toronto Clinical Scoring System, found that 67.6% of the cohort had diabetic peripheral neuropathy of varying severity, with 33.0% and 19.3% present with moderate and severe diabetes peripheral neuropathy, respectively [4].

Currently, the standard medical treatment for diabetic peripheral neuropathy involves a combination of antidepressants, anticonvulsants, opioid medications for pain management, and drugs to control hyperglycemia and metabolic syndrome. However, these treatments do not effectively address peripheral artery disease and nerve damage, which are complications of diabetes. Thus, suboptimal outcomes are not unexpected.

We report below a case of diabetic peripheral neuropathy and peripheral artery disease treated by enhanced external counterpulsation (EECP) after failing to respond to standard medical treatments. Studies have shown that EECP is safe in managing PAD [5,6]. As the patient did not have any signs of critical limb ischemia, we treated him with EECP, with his consent.

Case Description

A male, aged 59, complained of tingling and pain in the left foot in the sock distribution. The pain was particularly severe in the evening, disrupting his sleep. Even a short walk of 100 metres would trigger pain in the calf, and he found it challenging to ascend even a gentle slope. His wife noted his deteriorating mood and increasing signs of depression. His leg pain remained unaltered despite seeking treatment in multiple medical establishments and consulting physicians of different specialties.

The complaint arose three years ago, in February 2022. In November 2021, before taking the second COVID-19 vaccination, he was medically checked for vaccine suitability. Incidentally, he was found to be hypertensive, with a blood pressure of 182/103 mm Hg. He was thus referred for laboratory tests. Results in February 2022 showed that he had diabetes, with a serum fasting glucose of 15.69 mmol/L and HbA1c of 11.2%. Also, the total and LDL cholesterol levels were marginally high. Physical examination using 10 gm monofilament showed that he lost protective sensation in both feet. Also, the vibration threshold was elevated. He was treated by antihypertensives, cholesterol-lowering agents, and hypoglycemic drugs.

Soon after, the patient developed left leg pain with marked hyperesthesia in a sock-like distribution. He graded the pain as 10/10 on the visual analogue scale. The pain generally commenced around 6:00 pm and continued until the following morning. His walking distance was reduced to around 100 metres when he needed to rest for a minute before he could resume ambulation. The physician diagnosed the condition as diabetes feet and lumbar spondylosis. He was treated by Celebrex and tramadol and was referred for physiotherapy, which included lumbar traction, extracorporeal shockwave therapy, ultrasound, mobilization of the feet, moxibustion, stretching and strengthening exercises, and various home exercises.

The treatments reduced the pain from 10/10 to 7/10 in one year. As the pain persisted, the patient sought treatments from different private physiotherapists. A lumbar MRI in July 2022 showed nothing of significance. After over 100 sessions of physiotherapy with no improvement and being told nothing could be done, he decided to discontinue further conventional therapy at the end of 2023.

He smoked from a young age, and he disliked and did not take many vegetables and fruits. He had a history of fatty liver, cholelithiasis, prostate hypertrophy, right ear hearing loss, and Meniere disease and had been taking different medications to address these conditions. His wife noted a gradual decrease in weight loss from 63.5 kgs in 2021 to 54.4 kgs in 2024. He had no history of surgery

Despite the medication, the blood tests in the hospital on 13th June 2024 still showed deranged glycemic parameters. The fasting glucose was elevated at 8.29 mmol/L, and the HbA1c was 6.7%. Also increased was the fructosamine serum level; it was at 329 µmol/L. Glucose was detected in urine, measuring 500 mg/dL, while urinary ketones were negative, suggesting that his diabetes was poorly controlled. Cholesterol levels, however, were adequately controlled.

When he first visited us on 2nd September 2024, he hunched over when walking, constantly checking where he placed his feet during ambulation. He described his sensation as akin to stepping on a cloud. The gait was unsteady. Physical examination showed brownish discoloration on the inside of the left distal leg, and the left leg muscles were atrophic compared to the right. The skin was very dry; the couch was covered with skin flakes after the examination. He rated his pain 7/10 on a visual analogue scale of 0-10.

He was assessed on 12th September 2024 for arterial stiffness using a Tensiomed device. Aortic systolic blood pressure (SBPao) was 130.2 mmHg, and the aortic pulse pressure (Ppao) was 62.2 mm Hg. The aortic augmentation index (Aix aortic) was elevated at 60.4%. In systole, blood flows along the aorta distally and is reflected at its bifurcation into the common iliac arteries. In healthy arteries, the reflected wave returns in the aorta during diastole, facilitating blood flow without increasing the cardiac workload. In arteriosclerosis, the reflected wave returns faster as the artery is stiffer; blood arrives during cardiac systole, thus increasing the heart's workload. The augmentation index measures the extra pressure exerted by the reflected wave. It should generally be below 33%. Therefore, a 60.4% measurement signifies significant arterial stiffness. The arteriosclerosis is further confirmed by the high pulse wave velocity (PWVao) of 12.6 m/sec, as opposed to the normal 10 m/sec for his age.

Examination on the same date, using Withings Health Hub, a device similar to the Body Scan [7], showed a nerve score of 37. The findings suggested the patient had a C fibres dysfunction [7], which represents the earliest manifestation of diabetic peripheral neuropathy. His left leg was seen to be atrophic in comparison with the right. The observation was consistent with the findings using the Charder Body Composition Analyzer, which showed that the muscle lean mass of the right lower extremity was 7.2 kgs, compared to the left, which was 6.8 kgs. The laboratory findings, together with the vascular parameters and nerve score, suggested the patient had left PAD and diabetic peripheral neuropathy.

On 12th September 2024, he received enhanced external counterpulsation treatment (EECP) and nutraceuticals. The EECP device consists of three cuffs wrapped around the calves, the thighs, and the hip. The cuffs are pumped sequentially, from distal to proximal. Inflation and deflation of the cuffs are synchronized to the cardiac cycle. During diastole, the pumps are activated, pumping blood retrogradely to the heart. During systole, the pumps rest. Treatment was conducted 5 times every week for seven consecutive weeks. The nutritional supplements include nattokinase, omega-3 fatty acids, vitamins K2 and D3, magnesium, and topical magnesium oil. He was also advised to soak his legs in a carbon dioxide bath for 20 minutes every evening.

After 19 sessions, the glycemic parameters improved. At the end of the intervention, the aortic AIx worsened to 70.8%, but the PWVao fell to 9.4 m/sec, which is within the normal range for his age (Table 1). Nerve score measured 39. The findings suggested an improvement in PAD and neuropathy. Symptom-wise, the intermittent claudication improved, and the area of left calf pain reduced; the patient could

walk for 500 metres but still needed to rest for around one minute before he could resume ambulation. Gait was more steady and balanced. Nocturnal pain remained at 7/10 VAS. The pain still commenced around 6:00 pm and continued until the following morning, requiring opioid medication and NSAID to control. Paresthesia of the legs, however, reduced from 7/10 to 4/10. Also, we noted that his skin conditions improved, as we found significantly fewer skin flakes on the ECP treatment table.

Measurement Methods	Parameters	13/06	12/09	24/10	12/12
Laboratory	Fasting Glucose (mmol/L)	8.29		7.05	
	HbA1c %	6.7		6.0	
	Fructosamine (µmol/L)	329		290	
	Serum Urea (mmol/L)	13.6		11.5	
	Urinary Glucose (mg/dL)	500		1000	
Tensiomed	Augmentation Index aortic (AIx)%		60.4		70.8
	PWVao (m/sec)		12.6		9.4
Health Hub	Nerve Score		37		39

Table 1: *The changes in glycemic and vascular parameters and nerve score before and after ECP treatments. PWVao refers to the pulse wave velocity of the aorta. The dates are significant: 12th September 2024 marks the start of EECP treatment, 24th October is the day after the 19 sessions of EECP intervention, and 12th December 2024 is one week after the last EECP treatment.*

Discussion and Conclusion

The clinical history and the laboratory findings suggested that the patient had left PAD and diabetic peripheral neuropathy. Based on the diagnosis, EECP was tried on the patient, as the treatment is considered safe in the absence of critical limb ischemia [6].

The EECP intervention improved fasting blood glucose, HbA1c, fructosamine, and serum urea levels. Also, the treatment significantly improved the patient's walking distance and sole paresthesia. However, there was no improvement in nocturnal pain intensity, though the nerve score improved marginally from 37 to 39. As the patient has been taking similar medications before the EECP intervention, the improvements are probably related to the EECP treatment and the nutraceuticals rather than the lapse of time.

Our results showed that EECP improves glycemic control, a result which is consistent with the findings that the treatment improves glycemic control in T2DM patients for up to three months [10]. Indeed, the improvement prompted the medical practitioner to reduce the metformin dose from twice to once daily in October 2024.

EECP treatment improves lower limb perfusion [8,9]. During the procedures, there is a decrease in blood flow to the lower extremities. However, after the treatment, arterial reactive hyperemia occurs [9]. Werner., *et al*. (2007) showed that the average blood flow volume of the posterior tibial artery decreased by one-third during EECP treatment but increased to 133% of the baseline one-hour post-procedure [9]. Similarly, Zhang., *et al*. (2021) showed that the conventional EECP increases the blood flow and velocity of the anterior tibial artery [8]. The increased perfusion of the lower extremities may account for the patient's increased walking distance.

The treatment also improves paresthesia on soles and steadiness in gait but not the pain. We speculated that the increased lower extremity perfusion improved the functions of the myelinated nerve fibres (Aα and Aβ fibres) but not the feet' small fibres (C fibres). The recovery of C fibres may take more time.

The present study has limitations. Apart from EECP, the patient was advised to take supplements and a carbon dioxide footbath, which may help PAD. It is thus challenging to identify the benefits derived from the EECP treatments. Future studies are required to elucidate if

EECP does have a role in the management of PAD and diabetic peripheral neuropathy. In the meantime, however, EECP can be considered a complementary treatment in managing diabetic complications involving the feet until proven ineffective.

Patient's Consent

The patient consents to the publication of the case.

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Conflict of Interest

None.

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