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Sequential Contraction Compression has a Positive Effect on Patients with Peripheral Arterial Disease

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Abstract

PAD is increasing in incidence with the rise in obesity, Diabetes and smoking. The author sets out to evaluate a new technology, Sequential Contraction Compression Therapy, in patients with PAD. On an open label prospective analysis of 18 patients with moderate PAD and claudication SCCD was found to be effective in lowering their complaints of pain and in increasing the distance walked before claudication. The results of this study show that this technology warrants a further evaluation as a possible adjunct therapy in the treatment of PAD.

Keywords Peripheral arterial disease; Vascular disease; Electric muscle stimulation; Compression therapy

Introduction

PAD affects >8 million adults in the United States and is strongly associated with high mortality risk, deteriorated exercise capacity, and poor quality of life [1]. Supervised exercise training remains the most effective option for claudicant patients, with improvements in maximal walking distances approaching 150% in some trials [2]. However, because most patients experience pain during exercise and require direct supervision from a health care professional, this strategy remains poorly accessible, costly, and adherence is low [3].

Externally applied rhythmic limb compressions to improve the outcomes of patients with peripheral artery disease have been utilized as a treatment modality for nearly a century. Traditional thinking has suggested that Intermittent Pneumatic Compression (IPC) transiently elevates blood flow, which is purported to relieve ischemia, improve vascular function, and promote vascular remodeling. Recent evidence challenges the physiologic basis on which current IPC systems were designed, and further research to elucidate the basic and clinical outcomes of alternate stimulation characteristics is necessary [4]. In fact, Sheldon et al. [4] have shown that other stimulation characteristics may provide superior clinical utility [5,6].

Sequential Contraction Compression Devices (SCCD) has a similar mode of action to IPC but a different mechanism. Where IPC compresses the legs and the blood vessels with an external source, the SCCD generates the vascular compression by initiating a muscular contraction. The SCCD generates a series of electric impulses causing a peristaltic series of contractions in the leg. The contractions are timed so that they maximize the vascular response. SCCD like IPC has been shown to elevate blood flow during application both in healthy volunteers and in patients across a spectrum of PAD severity [7].

Methods and Materials

Patients were included in this study if they were males or females between 18 to 90 years of age. Patients had to have a proven diagnosis of Peripheral Arterial Disease (PAD) in Doppler Ultrasound and Ankle-Brachial Pressure Index (ABPI ≤ 0.8 in one leg) and with stable (>3 month) PAD Fontaine Stage II. Patients had to have stable intermittent claudication and claudication pain of the calf (>3 month and not more than one year) with initial claudication distance not more than 250 meters, as determined by treadmill test (3.2 km/h, 10% grade) Patients had to be with current treatment with Aspirin or Clopidogrel for at least 7 days. Patients were excluded if they were morbidly obese (BMI>35), or if they had an orthopedic or vascular surgery or procedure in the 6 months prior to the study, or if they were scheduled for a vascular procedure during the study or in the 6 weeks after completion of the study.

18 patients were recruited for this study. 12 were male and 6 females. The average age was 61 (range 55-67). All patients were smokers of between 0.5 and 2 pack per day and less. All patients who had diagnosed Type 2 Diabetes Mellitus did not have a diagnosis of Diabetic Peripheral Neuropathy. Table 1 shows the gender and age distribution as well as the initial distance able to be walked before onset of initial claudication. This was measured by a treadmill test (3.2 km/h at 10% incline). Patients were asked to complete a Visual Analog Scale (VAS) reflecting their current level of pain as well as a SF-36 to evaluate the effect of their condition on their quality of life.

Patients were given the FA100 SCCD device, which was programmed to the AA (arterial disease) mode, and were instructed to use the SCCD for one hour on each leg twice daily for a period of 90 days. As part of their evaluation they were asked to complete a VAS of their average pain at the end of each week. A member of the study staff evaluated the patients at the end of each month and for complications, adverse reactions, and to ensure completion of their logs. Table 1 also shows the reported levels of pain and diatance walked before onset of initial claudication.

After 90 days of treatment with the SCCD, the patients were evaluated for adverse events or complications, and for collection of their pain logs. Patients were also put on a treadmill test (3.2 km/h at 10% incline) and distance to initial claudication was recorded.

Results

Table 2 shows the VAS, and maximum distance walked before claudication at the 90 -day visit. All patients showed improvement in both their subjective and objective responses. The average reported VAS was decreased by 37%. The average recorded distance walked prior to claudication increased by 65%. Because the sample size was small adequate statistical analysis could not be performed. However, in the statistical analysis performed there was significance shown. These results are also clinically significant and are similar if not better than results published in the literature for other modalities. The results were also independent of gender or age bias. No adverse events were reported during the course of the study.

Patient #	Gender	Age	Smokes (ppd)	Diabetes	VAS	Distance (m)
1	M	67	1	Y	8	125
2	M	55	1	Y	7	110
3	F	67	.5	Y	9	90
4	M	55	1.5	N	6	80
5	M	58	2	Y	7	60
6	M	58	.5	Y	8	70
7	F	58	.5	Y	6	100
8	F	62	.5	N	7	90
9	M	61	1	N	8	80
10	M	63	1	Y	8	60
11	M	60	1.5	N	6	105
12	F	60	2	N	7	90
13	M	64	1	Y	5	150
14	M	65	1.5	Y	7	110
15	F	63	.5	Y	8	80
16	F	60	1	N	7	100
17	M	59	1.5	Y	9	70
18	F	61	.5	N	7	105

Table 1: Gender and Age distribution

Discussion

IPC is an effective treatment for treating PAD with a history of more than 50 years. While a lot of its effects are understood, little has been done to maximize the method of action for best results [4]. In addition patient compliance to usage is variable for numerous reasons [8]. SCCD takes the benefits of IPC technology and alters its delivery. While maintaining the mechanism of sequential compression, SCCD provides other actions and benefits as well. Because IPC is an external mechanism, there is no intrinsic strengthening of the musculature as no physiologic changes are occurring. In contrast SCCD stimulates the muscle to contract by itself, thereby providing physiologic scaffolding for growth and strengthening and a potential for sustained response even while not being treated. In addition these contractions cause an oxygen request sending stimuli that further force an increase in circulation.

Patient #	VAS	% change in VAS	Distance (m)	% change in Distance
1	5	38	200	60
2	5	28	160	45
3	4	56	190	111
4	5	17	110	38
5	4	43	120	100
6	5	38	120	71
7	3	50	200	100
8	4	43	170	89
9	5	38	130	63
10	6	25	90	50
11	3	50	170	62
12	4	43	140	56
13	4	20	170	13
14	5	29	160	45
15	4	50	150	88
16	5	29	160	60
17	6	33	125	79
18	5	29	140	33
Average		37%		65%

Table 2: VAS and maximum distance walked before claudication.

The results of this study compare favorably with others reported in the literature for the use of IPC in treating PAD. Kakkos et al. demonstrated an increase of 33% at 6 weeks of treatment and approximately 50% at 6 months with IPC [9]. Use of the SCCD increased walking distance by an average of 65% over 3 months. Our feeling is that some of this significant difference can be attributed to patient compliance. Another possible reason for the increase would be the physiological effects of the SCCD on the muscles themselves which is not part of the mechanism of traditional IPC.

SCCD is a small, portable, quiet apparatus with no tubes that get kinked. Patient compliance is significantly increased especially because SCCD can be used during activities of daily living and does not require dedicated time for use, or rest. With better compliance, efficacy is further improved.

While no ideal IPC device has been found, SCCD has taken the more positive aspects of the modality while removing some of the hurdles to its efficacy.

Conclusion

SCCD has a similar physiologic effect as IPC. Clinically it is effective in treating PAD through its method of action of electrically stimulating muscular contractions to compress the veins in the leg. A randomized controlled trial is recommended to attain the evidence necessary to back up the clinical results initially found.

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