EFFICACY AND OPTIMAL USE OF A PORTABLE ELECTRICAL MUSCLE STIMULATOR (VEINOPLUS®) TO IMPROVE SYMPTOMS OF POST-THROMBOTIC SYNDROME

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Introduction

An estimated 330,000 people in the United States have postthrombotic syndrome (PTS) [1]. Few studies have addressed the treatment of PTS [2]. A 2003 Cochrane Review examined available data regarding treatment of PTS with compression stockings or mechanical devices (intermittent pneumatic compression units) [3]. The authors report that there may be some benefit to the mechanical device at higher pressures in treating PTS though the trialwas too small and of too short a duration to draw strong conclusions. In regards to the ECS, the authors do not support, on basis of available evidence, treatment of PTS with ECS. Recently, a portable mechanical device has been shown to have a beneficial effect on the symptoms of PTS [2]. However, with only 32 patients enrolled, all of them with severe postthrombotic syndrome, and follow-up on treatment only having been 2 months, the study has been interpreted as too small, too short and too patient-selective to warrant advocating large-scale introduction of this device4. With few validated treatment options for PTS, further research and investigation is warranted given its significant morbidity.

Objectives

1. Estimate the *"clinical success"* of the device, defined by moderate improvement of symptoms, and an interest to continue using the device.
2. Estimate improvement in *quality of life* and objective findings of postthrombotic syndrome (villalta scale).
3. Estimate the *optimal electrical stimulation intensity* that has the largest benefit for relief of symptoms.
4. Compute information needed to power a future study.

Design & Methods

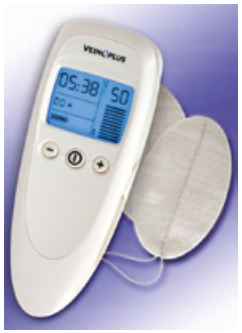
Patient Data Collection
Twelve subjects with postthrombotic syndrome were given a Veinoplusdevice to use for 2 months as they saw fit and record their experience.

Measurements
Villalta scale: : grades severity, from 0 to 3, of each of five symptoms (pain, cramps, heaviness, pruritus, paraesthesia) and six signs (edema, skin induration, hyperpigmentation, venous ectasia, redness, pain during calf compression)
VEINES-QOL/Sym questionnaire: specific for patients with deep vein thrombosis

Design & Methods

Statistical Analysis
Severity of condition was measured by the Villalta scale, where increased scores indicate increased severity. The questionnaire produced two summary scores based on venous symptoms and quality of life. The WilcoxonRank Sum test was used to compare intensity levels.

Device
The Veinoplus device electrically stimulates leg muscles via motor nerves, causing calf muscle contractions which facilitates venous blood return from the legs. The small battery operated device uses two electrode pads that deliver low quantities of electrical energy for 20 minutes per treatment with a user input, variable intensity.



Results

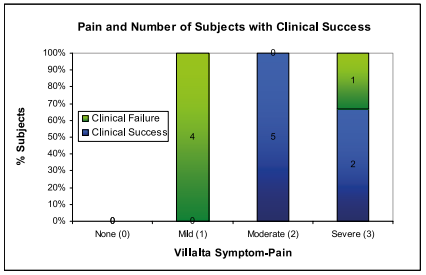
After using the device for eight weeks, 7 out of 12 patients (58%) had clinical success. Eighty-three percent (10) of subjects increased their QOL score, while 75% (9) increased their symptom specific score. The Villalta score improved in 67% of subjects, with a median decrease of two points.

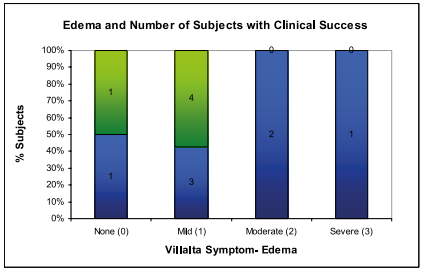
		Villalta Score		VEINES-SYM/QOL Questionnaire		
Subject ID	Clinical Success	Before	After	Before	After	Change
1	no	9	11	50.25	57.05	6.79
2	no	9	7	57.46	67.19	9.74
3	yes	22	15	45.76	50.23	4.47
4	no	14	12	49.66	62.01	12.35
5	no	9	10	51.42	42.5	-8.92
6	yes	14	13	54.1	42.13	-11.97
7	yes	14	15	31.11	32.74	1.63
8	yes	10	12	49.25	54.87	5.61
9	yes	17	14	36.86	47.78	10.92
10	no	15	13	42.49	45.21	2.72
11	yes	6	4	47.35	71.37	24.01
12	yes	12	8	47.31	63.9	16.58
Median		**12.58**	**11.17**	**46.92**	**53.08**	**6.16**

Results

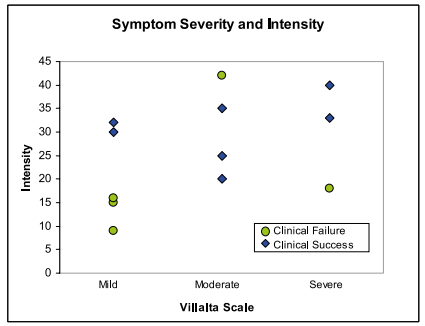
At the end of the study period 4 (33%) subjects had a decreased calf circumference. Optimal intensity was found to be a range, with most of the subjects who had clinical success using an average intensity of 20-40.

Of the five symptoms that make up the baseline Villalta score, only pain appeared to have a significant association with clinical success; all 5 subjects who reported moderate pain had a clinical success, along with 2 of the 3 patients who reported a severe pain level (p=0.02). All 3 subjects with moderate or severe edema had clinical success, along with 5 of 7 subjects with moderate to severe cramps. No significant associations with clinical success were found for other potential predictors of success (symptom severity, body mass index, and calf circumference). However, for all subjects symptom severity was found to be correlated with intensity (Rho=0.5, p=0.095) and calf circumference at baseline was strongly correlated with intensity (Rho=0.7, p=0.07).





Results



Conclusion

The VeinoPlus® electrical stimulation device appears to improve symptoms and QOL for patients with PTS. Although this study did not yield statistically significant results, given its small sample size, it provides the rationale and details needed for a larger trial. These initial findings are of clinical significance, as there are few treatments for patients with PTS. Veinoplus® is easy to use, small and portable, and had minimal disruptions in everyday life for most subjects. Elastic compression stockings and compression pumps could still be used in addition to using the Veinoplus®.

Futurs Directions

With the completion of this pilot study, we will be starting a phase 3 trial of the VeinoPlus® device. This study will have a sample size of 60 subjects. It will be a randomized, placebo controlled, and double-blinded trial. For more information, or if you are interested in becoming a study site, please contact smoll@med.unc.edu.

References

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