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A multicenter, randomized, placebo-controlled trial of endovenous thermal ablation with or without polidocanol endovenous microfoam treatment in patients with great saphenous vein incompetence and visible varicosities

Michael Vasquez, Antonios P Gasparis, on behalf of the Varithena® 017 Investigator Group*

First Published March 7, 2016

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Abstract
Objectives

*__Varithena 017 Investigator Group:__ Michael Vasquez, MD, Venous Institute of Buffalo, Amherst, NY; Antonios Gasparis, MD, Stony Brook University Medical Center, Stony Brook, NY; Kathleen Gibson, MD, Lake Washington Vascular, Bellevue, WA; James Theodore King, MD, Vein Clinics of America, Oakbrook Terrace, IL; Nick Morrison, MD, Morrison Vein Institute, Scottsdale, AZ; Girish Munavalli, MD, Dermatology, Laser & Vein Specialists of the Carolinas, Charlotte, NC; Eulogio J. Sanchez, MD, Batey Cardiovascular Center, Bradenton, FL. Varithena® is a trademark of Provensis Ltd, a BTG International group company.
To determine the efficacy and safety of polidocanol endovenous microfoam (PEM 0.5%, 1.0%) and placebo each administered with endovenous thermal ablation.

Methods
A multicenter, randomized, placebo-controlled, blinded study was conducted in patients with great saphenous vein incompetence and symptomatic and visible superficial venous disease. Co-primary endpoints were physician-assessed and patient-assessed appearance change from Baseline to Week 8.
Results
A total of 117 patients received treatment (38 placebo, 39 PEM 0.5%, 40 PEM 1%). Physician-rated vein appearance at Week 8 was significantly better with PEM ($p = 0.001$ vs. placebo); patient-assessed appearance trended similarly. Polidocanol endovenous microfoam provided improvements in clinically meaningful change in patient-assessed and physician-assessed appearance ($p < 0.05$), need for additional treatment ($p < 0.05$), saphenofemoral junction reflux elimination, symptoms, and QOL. In PEM recipients, the most

frequent adverse event was superficial thrombophlebitis (35.4%)

Conclusions

Endovenous thermal ablation + PEM significantly improved physician-assessed appearance at Week 8, increased the proportion of patients with a clinically meaningful change in appearance, and reduced need for additional treatment. www.clinicaltrials.gov (NCT01197833)