CYANOACRYLATE GLUE GREAT SAPHENOUS VEIN ABLATION:

PRELIMINARY 180-Day Follow-UP OF A FIRST-IN-MAN FEASIBILITY STUDY OF A

NO-COMPRESSION-NO-LOCAL-ANESTHESIA TECHNIQUE

Jose Almeida[1], Julian J. Javier[2], Ed Mackay[3], Claudia Bautista[5], Thomas Proebstle[6]

[1] Director Miami Vein Center, Miami, FL, USA,

[2] Physicians Regional Vein Center Naples FL, USA

[3]Mackay Vein Center, St. Petersburg, FL, USA

[5] Canela Clinic, La Romana, Dominican Republic

[6] Dept. of Dermatology, University Clinic of Mainz, Germany

BACKGROUND: Endovenous thermal ablation is a highly effective technology for the treatment of incompetent great saphenous veins (GSVs). However, the treatment requires painful transcutaneous injection of perivenous anesthetic fluids. Graduated compression hose are required post-procedure to help mitigate the inflammatory side-effects of thermal delivery. This study was conducted to demonstrate the safety and efficacy of the Sapheon Closure System for chemical ablation of duplex proven incompetent great saphenous veins.

METHODS: Two series of patients were treated (n=8 and n=30 follow-up of 180 and 30 days, respectively). After venous access and placement of a novel delivery system, the vein was sealed with a proprietary cyanoacrylate (CA) formulation. Perivenous tumescent anesthesia and post-procedure compression stockings were omitted.

RESULTS: Thirty-eight patients (29 female) with a median age of 51 years (range 26-77) and an average VCSS score of 6.0 +/-2.7 (range 2-17) received study treatment. Average maximum saphenofemoral junction (SFJ) diameter was 8.0 +/- 2.2 cm (range 4.1 – 12.0) before treatment. The mean length of ablated GSV segments was 33cm (range 15-52), average treatment duration was 20.3 minutes (range 11 - 33). The mean volume of CA delivered was a total of 1.3 ml (range 0.63 - 2.25). Immediately post-procedure, and at 24-72 hours, 100% (38 of 38) were closed. At 30days follow-up 97% (35 of 36) of treated GSV segments were completely closed; one limb had a 1cm segment of incomplete ablation. VCSS scores improved to a mean of 1.9 +/-2.1 (range 0-11; $p<0.001$ compared to baseline) at 30 days in 37 patients. Of the eight patients followed for 180 days, average VCSS improved to 1.1 +/- 1.0 (range 0 – 3) Thirty-one of 37 patients reported no pain during the 30 days after treatment; the remaining six were successfully treated with NSAIDs. No significant side effects or complications were observed.

CONCLUSION: Endovenous ablation of incompetent GSVs with a CA-based glue is feasible. Procedure times are short, tumescent anesthesia is unnecessary as are post-procedure compression stockings.

Lack of significant side-effects and an initial success rate of 100% with significant, long-standing, improvement of clinical symptoms support further clinical studies.

(422 words, 50 – max 425 words range)