Comparable Effectiveness of Endovenous Laser Ablation and High Ligation With Stripping of the Great Saphenous Vein

Two-Year Results of a Randomized Clinical Trial (RELACS Study)

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Objective To compare the clinical efficacy and safety of endovenous laser treatment (EVLT) with high ligation and stripping (HLS) as standard treatment for great saphenous vein (GSV) insufficiency.

Design Two-center randomized controlled trial with 2-year follow-up.

Setting Interventions were performed on ambulatory and hospitalized patients at 2 vein centers, a university dermatology department (EVLT-treated group), and a specialized vein clinic (HLS-treated group).

Patients Random sample of 400 patients with GSV insufficiency.

Interventions Patients were assigned (1:1) to EVLT or HLS of the GSV from September 2004 through March 2007; 185 and 161 patients (limbs), respectively, were treated per protocol.

Main Outcome Measures Clinically recurrent varicose veins after surgery (REVAS classification, primary study objective), duplex-detected saphenofemoral recurrence, clinical venous severity scoring (Homburg Varicose Vein Severity Score), hemodynamics (venous refilling time), quality of life (Chronic Venous Insufficiency Questionnaire 2), adverse effects, and visual analog scale–based evaluations of patients' satisfaction.

Results Clinically recurrent varicose veins after surgery were similarly observed in both groups: 16.2% (EVLT-treated group) vs 23.1% (HLS-treated group); P = .15. Duplex-detected saphenofemoral refluxes occurred significantly more frequently after EVLT (17.8% vs 1.3%; P < .001). Both treatments equally improved medical condition (Homburg Varicose Vein Severity Score) and disease-related quality of life. Endovenous laser treatment caused more adverse effects (phlebitic reaction, tightness, dyspigmentation) but revealed advantages concerning hemodynamics, recovery, and cosmetic outcome.

Conclusions Both EVLT and HLS are comparably safe and effective procedures to treat GSV incompetence. The significantly higher rate and the course of duplex-detected saphenofemoral recurrences after EVLT remain a matter of further investigations.

Trial Registration isrctn.org Identifier: ISRCTN18322872

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