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**Effectiveness of Endovenous Laser, Radiofrequency, Endovenous Steam Ablation, and Surgery for Great Saphenous Vein Incompetence: A Comprehensive Systematic Review with Meta-Analysis of Randomized Controlled Trials**

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**ADMINISTRATIVE INFORMATION**

**Support** - N/A.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202590092

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 September 2025 and was last updated on 23 September 2025.

**INTRODUCTION**

**Review question / Objective** To compare the efficacy, safety, and patient-reported outcomes of endovenous laser ablation (EVLA), radiofrequency ablation (RFA), endovenous steam ablation (EVSA), and conventional surgery for great saphenous vein (GSV) incompetence in randomized controlled trials (RCTs), and to quantify between-technique differences in anatomic success and key complications.

**Condition being studied** Primary truncal venous reflux—predominantly GSV incompetence ( $\pm$  small saphenous vein, SSV) manifesting as symptomatic varicose veins (CEAP C2–C6).

**METHODS**

**Search strategy** Systematic search of MEDLINE/ PubMed, Embase, Web of Science, Scopus, and Cochrane CENTRAL from inception to September 2025; backward/forward citation chasing; trial

registries (ClinicalTrials.gov, WHO ICTRP); conference abstracts where RCTs are reported; no study design filters; detailed Boolean blocks for condition AND intervention terms; de-duplication prior to screening; full strategies to be provided as an appendix.

**Participant or population** Adults with duplex-confirmed primary truncal reflux (GSV $\pm$ SSV), eligible for endovenous or surgical intervention; outpatient or inpatient settings; primary interventions (not exclusively recurrent disease cohorts).

**Intervention** Endovenous thermal/non-thermal modalities, surgery: EVLA (all wavelengths/fiber types), RFA (all catheter generations), EVSA. (Exploratory: mechanochemical ablation, cyanoacrylate, and ultrasound-guided foam sclerotherapy when included as randomized arms.).

**Comparator** Conventional surgery (high ligation with stripping) and/or active endovenous comparators (EVLA vs RFA; surgery vs EVLA; RFA vs surgery; EVLA vs surgery); foam as a comparator when randomized.

**Study designs to be included** Parallel-group RCTs (including multicenter) with individual randomization; quasi-randomized and cluster trials excluded unless true randomization is verified.

**Eligibility criteria** Inclusion: RCTs; adults; primary truncal reflux; at least one prespecified outcome; minimum post-procedure follow-up of  $\geq 4$  weeks. Exclusion: Non-randomized studies; pediatric cohorts; case series; studies limited to tributary veins only; perioperative technique papers without outcomes; duplicate/overlapping cohorts (most complete/longest follow-up retained).

**Information sources** Databases listed above; trial registries; grey literature (conference proceedings where RCT data are presented); reference lists of included studies and relevant reviews; contact authors for missing data where feasible.

**Main outcome(s)** Primary: Anatomic success (complete occlusion and/or reflux-free truncal segment on duplex at prespecified time points, prioritizing longest available follow-up). Secondary: nerve injury/sensory disturbance; clinical severity (VCSS/AVVSS); disease-specific QoL (AVVQ).

**Data management** Two independent reviewers will screen titles/abstracts/full texts in duplicate, extract data with piloted forms, and manage records in Covidence (or equivalent) with citation software for de-duplication; discrepancies resolved by a third reviewer (MEA). Authors will be contacted for clarification/missing data; numerical extraction from figures via validated tools if necessary.

**Quality assessment / Risk of bias analysis** Cochrane RoB 2 across domains (randomization, deviations from intended interventions, missing outcome data, outcome measurement, selection of reported results); outcome-level judgments; consensus resolution with MEA arbitration.

**Strategy of data synthesis** Random-effects meta-analysis (DerSimonian-Laird with Hartung-Knapp adjustment; REML for  $\tau^2$  in sensitivity checks). Dichotomous outcomes summarized as risk ratios (RR); continuous outcomes as mean differences (MD) or standardized MD where scales differ. Heterogeneity assessed by  $I^2$ ,  $\tau^2$ , and Q; 95%

prediction intervals reported where  $\geq 3$  studies. Small-study effects assessed by funnel plots/Egger's test (when  $\geq 10$  studies) and trim-and-fill as exploratory.

**Subgroup analysis** Exclude high RoB studies; exclude studies with cross-over or major protocol deviations; leave-one-out influence analysis; meta-analysis using alternative estimators (Paule-Mandel, Sidik-Jonkman); fixed-effect as comparator model; limb-level vs patient-level reporting harmonization.

**Sensitivity analysis** Exclude high RoB studies; exclude studies with cross-over or major protocol deviations; leave-one-out influence analysis; meta-analysis using alternative estimators (Paule-Mandel, Sidik-Jonkman); fixed-effect as comparator model; limb-level vs patient-level reporting harmonization.

**Language restriction** No language restrictions; non-English full texts will be translated (professional or validated machine-assisted translation) before eligibility assessment and extraction.

**Country(ies) involved** Turkey.

**Keywords** Varicose veins; Great saphenous vein incompetence; Endovenous laser ablation (EVLA); Radiofrequency ablation (RFA); Radiofrequency ablation (RFA); meta-analysis.

#### Contributions of each author

Author 1 - Ceren Sayarer - CS: Conceptualization; Literature search; Study selection; Data extraction; Quality appraisal; Validation; Writing—original draft; Writing—review & editing; Final approval of the manuscript.

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Author 2 - Mehmet Emin Arayici - MEA: Conceptualization; Methodology; Formal analysis and meta-analysis; Investigation; Data curation oversight; Sensitivity and heterogeneity analyses; Interpretation of results; Supervision; Project administration; Writing—review & editing; Guarantor of the work and corresponding author; Final approval of the manuscript.

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Author 3 - Tugra Gencpinar - Conceptualization; Literature search; Study selection; Data extraction; Risk-of-bias assessment; Visualization; Writing—original draft; Writing—review & editing; Final approval of the manuscript. SB: Conceptualization; Literature search; Study selection; Data extraction; Risk-of-bias assessment; Visualization; Writing—

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