

Table VIII. OS versus EVLA.

Operative procedure	Reference <i>Abstracts corresponding to references can be found using the listing "RCTs by alphabetical order" or "RCTs by topic."</i>	Summary
OS versus EVLA for for GSV or SSV incompetence	de Medeiros CA, Luccas GC. Comparison of endovenous treatment with an 810 nm laser versus conventional stripping of the great saphenous vein in patients with primary varicose veins. <i>Dermatol Surg.</i> 2005;31:1685-94.	Patients with GSV incompetence Group I (N=20): 980 nm diode laser, bare fiber, stepwise laser withdrawal <i>versus</i> Group II (N=20): open surgery Spinal anesthesia for both procedures Results at 9 months (mean) of follow-up: <ul style="list-style-type: none"> · No difference between groups regarding postoperative pain · Group I (EVLA) · Fewer swelling and less bruising in group I (EVLA) compared with group II (P not known) · Better outcome in group I (EVLA) compared with group II (P not known)
	Vuylstecke M, Van den Busche D, Audenaert EA, Lissens P. Endovenous laser obliteration for the treatment of primary varicose veins. <i>Phlebology.</i> 2006;21:80-87.	Patients with GSV incompetence Group I (N=118): 980-nm diode laser bare fiber, stepwise laser withdrawal <i>versus</i> Group II (N=124): open surgery General anesthesia for both procedures Results at 1, 8 weeks and 9 months of follow-up: <ul style="list-style-type: none"> · Less postoperative complications in group I (EVLA) compared with group II · Sick leave shorter complications in group I (EVLA) compared with group II (P< 0.001) · Total cost lower complications in group I (EVLA) compared with group II
	Ying L, Sheng Y, Ling H, Lian Y, Hui Y, Ming W. [A random, comparative study on endovenous laser therapy and saphenous veins stripping for the treatment of great saphenous vein incompetence.] <i>Zhonghua-Yi-Xue-Za-Zhi.</i> 2007;87(43):3043-3046.	Patients with GSV incompetence Group I (N=40): 980-nm diode laser, bare fiber pulse mode <i>versus</i> Group II (N=40): OS General anesthesia for both procedures Results at 1 year of follow-up: <ul style="list-style-type: none"> · Less bleeding complications in group I (EVLA) compared with group II (P <0.01) · Less postoperative pain complications in group I (EVLA) compared with group II (P<0.05)

		<ul style="list-style-type: none"> · Hospitalization shorter complications in group I (EVLA) compared with group II (P<0.05) · No difference between groups regarding APG results
	<p>Rasmussen LH, Bjoern L, Lawaetz M, Blemings A, Lawaetz B, Eklof B. Randomized trial comparing endovenous laser ablation of the great saphenous vein with ligation and stripping in patients with varicose veins : short-term results. <i>J Vasc Surg.</i> 2007;46:308-15.</p>	<p>Patients with GSV incompetence Group I (N=62): Diode 980-nm diode laser, bare fiber, stepwise laser withdrawal <i>versus</i> Group II (N=59): OS General anesthesia for both procedures Results at 1, 2 and 6 months of follow-up:</p> <ul style="list-style-type: none"> · No difference between groups in terms of efficacy and safety · Less postoperative pain and bruising in group I (EVLA) compared with group II (P=0.05).
	<p>Darwood RJ, Theivacumar N, Dellagrammaticas D, Mayor AL, Gough MJ. Randomized Clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous veins. <i>Br J Surg.</i> 2008; 95: 294-301.</p>	<p>Patients with GSV incompetence Group I : EVLA with local tumescent anesthesia, 980-nm diode laser, bare fiber, stepwise laser withdrawal (N= 42), continuous laser withdrawal (N= 29) <i>versus</i> Group II (N=32): OS with general anesthesia Results at 3 months of follow-up: No difference between groups (EVLA and OS) in terms of reflux abolition and HRQoL (specific questionnaire) Group I (EVLA) Earlier return to normal activity in group I (EVLA, both laser groups) compared with group II (P=0.005)</p>
	<p>Kalteis M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Pölz W, Hieller F. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: Early results of a randomized controlled study. <i>J Vasc Surg.</i> 2008;47:822-9.</p>	<p>Patients with GSV incompetence Anesthesia : incomplete information Group I (N=47): Diode 810-nm diode laser, bare fiber, stepwise laser withdrawal+ HL <i>versus</i> Group II (N=48): OS Results at 1, 4 and 16 weeks of follow-up:</p> <ul style="list-style-type: none"> · Less bruising in group I (EVLA) compared with group II (P= 0.001) · Longer period of time until return to work in group I (EVLA) compared with group II (P= 0.054) · No difference between groups regarding HRQoL (CIVIQ)

	<p>Pronk P, Gauw SA, Mooij MC, Gaastra MTW, Lawson JA, van Goethem AR, van Vlijmen-van Keulen CJ. Randomised Controlled Trial Comparing Sapheno-Femoral Ligation and Stripping of the Great Saphenous Vein with Endovenous Laser Ablation (980 nm) Using Local Tumescence Anaesthesia: One Year Results. <i>Eur J Vasc Endovasc Surg</i> 2010 ;40 :649-656</p>	<p>Patients with GSV incompetence Local tumescent anesthesia for both procedures Group I (N 62): 980-nm diode laser, bare fiber, continuous laser withdrawal + postoperative sclerotherapy for persistent varices <i>versus</i> Group II OS (N 68): HL +pin-stripping +tributary stab avulsion</p> <p>Results at 1 -14 days of follow-up: After 2 weeks more postoperative pain in group II compared to group I (P<0, 01) After 2 weeks more hindrance in mobility and daily activities in group II compared to group I (P>0,01)</p> <p>Results at 1 year of follow-up: No significant differences between groups in terms of DUS recurrence</p>
	<p>Theivacumar NS, Darwood MJ, Gough MJ. Neovascularization and Recurrence 2 years after treatment for sapheno-femoral and great saphenous reflux : a comparison of surgery and endovenous laser. <i>Eur J Vasc Endovasc Surg.</i> 2009;38:203-207</p>	<p>Patients with GSV incompetence Group I (N= 69 lower limbs): 980-nm diode laser , bare fiber, pulse mode, with local tumescent anesthesia <i>versus</i> Group II (N= 60 lower limbs): OS with general anesthesia</p> <p>Results at 2 years of follow-up:</p> <ul style="list-style-type: none"> · Recurrence rates similar in both groups · Neovascularization less frequent in group I (EVLA) compared with group II (P= 0.001)
	<p>Christenson JT, Gueddi S, Gemayel G, Bounameaux H. Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up. <i>J Vasc Surg.</i> 2010;52:1234-41.</p>	<p>Patients with GSV incompetence Group I (N=100): 980-nm diode laser, bare fiber, stepwise mode <i>versus</i> Group II (N=100): OS General or spinal anesthesia for both procedures</p> <p>Results at 12 days of follow-up:</p> <ul style="list-style-type: none"> · No difference between groups in postoperative pain, use of analgesics and return time to normal activities · More hematoma in group II (OS) compared with group I · More bruising in group I (EVLA) compared with group II <p>Results at 1 and 2 years of follow-up:</p> <ul style="list-style-type: none"> · No difference between groups in terms of symptoms, VCSS or HRQoL · One GSV reopening in group I (EVLA)

		and none in group II (P<0.051)
	Rasmussen LH, Bjoern L, Lawaetz M, Blemings A, Lawaetz B, Eklof B. Randomized trial comparing endovenous laser ablation with stripping of the great saphenous vein: clinical outcome and recurrence after 2 years. <i>Eur J Vasc Endovasc Surg.</i> 2010;39:630-5.	<p>Patients with GSV incompetence</p> <p>Group I (N=62): 980-nm diode laser , bare fiber, pulse mode</p> <p><i>versus</i></p> <p>Group II(N=59): OS</p> <p>Local tumescent anesthesia for both procedures</p> <p>Results at 2 years of follow-up:</p> <p>No significant differences between groups in terms of:</p> <ul style="list-style-type: none"> - Clinical or DUS recurrence - Clinical severity scores (VCSS;AVQQ) - Quality of Life (SF 36)
	Carradice D, Mekako AI, Mazari FAK, Samuel N, Hatfield J, Chetter IC. Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. <i>Br J Surg.</i> 2011;98:501-10.	<p>Patients with GSV incompetence + incompetent saphenofemoral junction</p> <p>Group I (N=140): 810-nm diode, bare fiber, continuous laser withdrawal, continuous power delivery 14W, under local tumescent anesthesia</p> <p><i>versus</i></p> <p>Group II (N=140): HL+ inversion stripping under general anesthesia</p> <p>Tributaries phlebectomy + perforator ligation in both groups</p> <p>Results at 1 week and 1 year of follow-up:</p> <p>Significant improvement after treatment in both groups regarding VCSS & QUALY gain (P < 0.001)</p> <ul style="list-style-type: none"> · Less pain in group I (EVLA) compared with group II (P<0.001) · Better HRQoL improvement (SF-36) in 6 out 8 domains in group I (EVLA) compared with group II (P= 0.004) · Shorter return to work in group I (EVLA) compared with group II (P< 0.001)
	Carradice D, Mekako AI, Mazari FAK, Samuel N, Hatfield J, Chetter IC. Clinical and technical poutcomes from a randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. <i>Br J Sur.</i> 2011;98:1117-23.	<p>Patients with GSV incompetence + incompetent saphenofemoral junction</p> <p>Group I (N=140): 810-nm diode, bare fiber, continuous laser withdrawal, continuous power delivery 14W under local tumescent anesthesia</p> <p><i>versus</i></p> <p>Group II (N=140): HL+ inversion stripping under general anesthesia</p> <p>Tributaries phlebectomy + perforator ligation in both groups</p> <p>Results at 1 week to 1 year of follow-up:</p> <ul style="list-style-type: none"> · Better initial technical results in group I

		<p>(EVLA) compared with group II (93% vs 92.4%; P= 0.005)</p> <p>Results at 1-year of follow-up:</p> <ul style="list-style-type: none"> · Clinical recurrence rate was lower in group I (EVLA) compared with group II (4% vs 20.4%; P< 0.001) · Clinical recurrence was associated with worse AVVQ scores(P < 0.001)
	<p>Rass K, Frings N, Glowack P, Hamsch C, Gräber S, Vogt T, Tilgen W. Comparable Effectiveness of Endovenous Laser Ablation and High Ligation With Stripping of the Great Saphenous Vein. <i>Arch Dermatol</i> 2012;148: 49-58</p>	<p>Patients with GSV incompetence + incompetent saphenofemoral junction + saphenous reflux at least down the knee level</p> <p>Tumescent local anesthesia for both procedures</p> <p>Group I (N=185): 810-nm diode laser, bare fiber, continuous laser withdrawal ,applied energy 20 J/cm2 vein surface</p> <p><i>versus</i></p> <p>Group II (N=161): OS</p> <p>Results at 2 years of follow-up:</p> <ul style="list-style-type: none"> · <u>PREVAIT</u>: Group I,2%; group II, 23.1 % (P= NS) · <u>DUS recurrence: reflux at the SFJ</u>: Group I, 17.8% (clinically silent in 81%); Group II, 1.3% (P<0.001) · <u>Clinical venous severity scoring (HVSS)</u>: no difference between groups · <u>HRQoL (CIVIQ)</u>: no difference between groups · <u>Recovery time, ability to work</u> : no difference between groups
	<p>Samuel N, Carradice D, Wallace T, Mekako A, Hatfield J, Chetter I. Randomized Clinical Trial of Endovenous Laser Ablation Versus Conventional Surgery for Small Saphenous Varicose Veins. <i>Ann Surg.</i> 2013;257(3):419-26. PMID:23160149.</p>	<p>Patients with incompetent SPJ + reflux in SSV</p> <p>Group I (N=53): EVLA</p> <p><i>versus</i></p> <p>Group II (N=53): OS</p> <p>Results at 1 week to 1 year (99 limbs) of follow-up:</p> <ul style="list-style-type: none"> · Better initial technical results in group I (EVLA) compared with group II (96.2% vs 71.7%; P<0.001) · Lower postoperative pain in group I (EVLA) compared with group II (P<0.05) · Earlier return to work and normal function in group I (EVLA) compared with group II (P<0.001) · Minor sensory disturbance in group I (P= 0.009) <p>Results at 1 year of follow-up:</p> <ul style="list-style-type: none"> · No difference between groups regarding VCSS and HRQoL improvement

	<p>Rasmussen LA, Lawaetz M, Serup J, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins with 3 years follow-up. <i>J Vasc Surg & Venous Lym Dis</i> 2013;1:349-56</p>	<p>Patients with GSV incompetence in CEAP C₂₋₄E_pA_sP_r Group I (N=69): Diode 980-nm diode laser, bare fiber, stepwise laser withdrawal <i>versus</i> Group II (N=68): OS Local tumescent anesthesia for both procedures Results at 1, 2 and 6 months, and then 1-5 years of follow-up Results at 5 years of follow-up:</p> <ul style="list-style-type: none"> · <i>GSV persistent reflux at DS examination:</i> no significant difference between groups (P=0.2145) · <i>Clinical recurrence:</i> no significant difference between groups. (P= 0.7209) · <i>Retreatment:</i> no significant difference between groups (P=0.9876) · <i>VCSS improvement:</i> lasted from month 1 month to year 5 without difference between groups. · <i>AVVSS improvement:</i> significant improvement in both groups from 3 month and onwards (P < 0.0001), with no difference between groups at any time point · <i>SF-36 scores:</i> improved in all domains and similarly in both groups

<p>Flessenkämper I, Hartmann M, Stenger D, Roll S. Endovenous laser ablation with and without high ligation compared with high ligation and stripping in the treatment of great saphenous varicose veins: initial results of a multicentre randomized controlled trial. <i>Phlebology</i>. 2013;28:16-23.</p>	<p>Patients with GSV incompetence + incompetent SFJ in CEAP C₂₋₆E_pA_sP_r</p> <p>Group I (N=159): HL+ ST Group II (N=142): EVLA Group III (N=148): EVLA+HL Diode 980-nm diode laser, bare fiber, continuous mode in groups II and III. Anesthesia: unknown in group I; local tumescent anesthesia in groups II and III.</p> <p>Results at day 1 after operation:</p> <ul style="list-style-type: none"> · <i>Post-operative pain</i> was higher in group III compared with groups I and II (P=0.0069) <p>Results at 2 months of follow-up:</p> <ul style="list-style-type: none"> · VCSS scores: no difference between groups · <i>Presence of inguinal reflux in GSV:</i> Group I=0; Group II = 26.7%; Group III=6.7% <ul style="list-style-type: none"> · Group I versus group II; P<0.0001 · Group I versus group III; P< 0009 · Group II versus group III; P<0.0001
<p>Roopram AD, Lind MY, Van Brussel JP, Terloux-Punt LC, Birnie E, De Smet AEA et al. Endovenous laser ablation versus conventional surgery in the treatment of small saphenous vein incompetence. <i>J Vasc Surg: Venous and Lym Dis</i>. 2013;1 357-63.</p>	<p>Patients in CEAP C₂₋₆ SSV diameter <10 mm with incompetent SPJ</p> <p>Group I (N=118): EVLA with 810-nm diode laser, bare fiber, continuous laser withdrawal under local anesthesia <i>versus</i> Group II (N=57): SPJ ligation under general or spinal anesthesia</p> <p>Post-operative results:</p> <ul style="list-style-type: none"> · <i>Easiness of procedure</i> in favor of group I (EVLA ; P<0.001) · Persistent reflux at SPJ in group I: 0.9 % vs group II: 21% · Decrease in pain intensity on VAS in favor of group II (P= 0.03) · AVQQ scores: no difference between groups · Return to work shortened in group I (P<0.05) <p>Results at 6 weeks of follow-up:</p> <ul style="list-style-type: none"> · Less neurologic complications in group I (P<0.001) <ul style="list-style-type: none"> · Less infections in group I (P<0.05)

<p>Nandhra S, El-Sheika J, Carradice D, Wallace T, Souroullas P, Samuel N et al. A Randomized Clinical Trial of Endovenous Laser Ablation Versus Conventional Surgery for Small Saphenous Varicose Veins. <i>J Vasc Surg.</i> 2015; 61:741-6</p>	<p>Patients with incompetent SPJ + reflux in SSV (106 patients included, 88 assessed at 2Y, 9 patients lost to Follow-up in each group Group I (N=44): EVLA <i>versus</i> Group II (N=44): OS Results at 2 Y <i>Eradication of axial reflux assessed by DUS</i> Group I = 36 (81.2%) P=0.002 Group II= 29 (68.9%) PREVAIT, sensory disturbance and QoL: no difference between the 2 groups</p>
<p>Rass K, Frings N, Glowacki P, Tilgen W, Vogt T. Same Site Recurrence is More Frequent After Endovenous Laser Ablation Compared with High Ligation and Stripping of the Great Saphenous Vein: 5 year Results of a Randomized Clinical Trial (RELACS Study). <i>Eur J Vasc Endovasc Surg.</i> 2015;50:648-56</p>	<p>Patients with GSV incompetence + incompetent saphenofemoral junction + saphenous reflux at least down the knee level Tumescent local anesthesia for both procedures Group I (N=185): 810-nm diode laser, bare fiber, continuous laser withdrawal, applied energy 20 J/cm² vein surface <i>versus</i> Group II (N=161): OS Results at 5 years of follow-up: 281 legs evaluated (81% of the study population) · <u>PREVAIT:</u> Group I,45%; group II, 54 % (P= NS) · <u>Recurrence at the same site</u> · Group I 18%: group II 5%. P=0.002 · <u>Recurrence at different site</u> · Group I 31%; group II 50%. P=0.002 · <u>DUS recurrence: reflux at the SFJ:</u> Group I, 28 % Group II, 5 % (P<0.001) · <u>Both treatments improved disease severity and QoL without any difference</u></p>

<p>Flessenkämper I, Hartmann M, Hartmann K, Stenger D, Roll S. Endovenous laser ablation with and without high ligation compared with high ligation and stripping for treatment of great saphenous varicose veins: Results of a multicentre randomised controlled trial with up to 6 years follow-up. <i>Phlebology</i>. 2016;31(1):23-33.</p>	<p>Patients with GSV incompetence + incompetent SFJ in CEAP C₂₋₆E_pA_sP_r Group I (N=159): HL+ ST Group II (N=142): EVLA Group III (N=148): EVLA+HL Diode 980-nm diode laser, bare fiber, continuous mode in groups II and III. Anesthesia: unknown in group I; local tumescent anesthesia in groups II and III. Results at 2 (74%of patients) up to 6 years of follow-up (31% of patients) Clinical recurrence appears with the same frequency in all three treatment groups, but the responsible pathological mechanisms seem to differ. Group I: more recurrence at the SFJ Group II and III: more recurrence into the GVS and tributaries</p>
<p>Gauw SA, Lawson JA, van Vlijmen-van Keulen CJ, Pronk P, MTW Gaastra, Mooij MC. Five-year follow-up of a randomized, controlled trial comparing saphenofemoral ligation and stripping of the great saphenous vein with endovenous laser ablation (980 nm) using local tumescent anesthesia. <i>J Vasc Surg</i>. 2016; 63:420-428</p>	<p>Patients with GSV incompetence Local tumescent anesthesia for both procedures Group I (N 62): 980-nm diode laser, bare fiber, continuous laser withdrawal + postoperative sclerotherapy for persistent varices <i>versus</i> Group II OS (N 68): HL +pin-stripping +tributary stab avulsion Results at 5 years of follow-up: Group I; more PREVAIT originating from the SFJ. P<0.04 There were no differences in the relief of venous symptoms, or general QoL between the 2 groups.</p>

	<p>Kalteis M, Adelsgruber P, Messie-Werndl S, Gangl O, Berger I. Five-year results of a randomized controlled trial comparing high ligation combined with endogenous laser ablation and stripping of the great saphenous vein. <i>Dermal Surg</i> 2015; 41: 579–586.</p>	<p>Patients with GSV incompetence Anesthesia : incomplete information. No tumescence Group I (N=49): Diode 810-nm diode laser, bare fiber, stepwise laser withdrawal+ HL <i>versus</i> Group II (N=50): OS Results at 5-year of follow-up Group I Analysed (N=40); 83% . Group II. Analysed (N=32); 68%</p> <p>There was no difference in terms of patient satisfaction as well as CIVIQ2 global index score, VCSS between the 2 groups after treatment. Conversely a significant benefice was noted in all fields when compared to pre-op status. Clinical and DUS recurrence were also similar in both groups</p>
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Abbreviations

APG = Air Plethysmography; AVVQ : Aberdeen varicose vein questionnaire; AVVSS= Aberdeen varicose vein severity score ; DUS= duplex ultrasound ; EVLA = endovenous laser ablation ; GSV = Great saphenous vein ;HL= high ligation ;HRQoL, health-related quality of life; HVSS= Homburg Varicose Vein Severity Score ; PREVAIT= Presence of varices after operative treatment ; OS= Open surgery: High ligation + Saphenous stripping+/- Perforator ligation +/- tributary phlebectomy ; QALY=quality adjusted life year ; QoL= quality of life ; ST= GSV stripping ; SFJ= saphenofemoral junction ; SFP= saphenopopliteal junction, ; SSV=short saphenous vein ;VCSS = Venous clinical severity scoring