

5Table XIII Open surgery versus sclerotherapy,

15 articles, 15 RCTs

Operative procedure	Reference	Summary
Liquid chemical ablation versus Open Surgery	Einarsson E, Eklöf B, Neglén P. Sclerotherapy or surgery as treatment for varicose veins: A prospective randomized study. <i>Phlebology</i> .1993;8:22-26.	<p>Monocenter study 164 patients with symptomatic primary VV located in GSV or/and SSV territory. No data on deep vein or CEAP classification Group I (n=80): OS versus Group II (n=84): Liquid sclerotherapy Post-operative results: <ul style="list-style-type: none"> · Loss of working days: 1 day in group II vs 20 days in group I Results at 5 years of follow-up: <ul style="list-style-type: none"> · Rate of clinical failure: 10% in group I versus 74% in group II · Foot volumetry measurement: in favor of group I. P< 0.01 </p>
Liquid chemical ablation + HL versus Open Surgery	Rutgers PH, Kitslaar PJEHM. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. <i>Am J Surg</i> . 1994;168:311-5.	<p>Monocenter study 156 patients and 181 lower limbs with primary GSV incompetence. No data on SSV, deep vein or CEAP classification Group I (n=78; 89 lower limbs): OS under general anesthesia versus Group II (n=78; 92 lower limbs): HL+ Liquid sclerotherapy Results at 3 years of follow-up: <ul style="list-style-type: none"> · Clinical results: in favor of group I. P<0.05 · Doppler results: in favor of group I. P<0.001 </p>

<p>Liquid chemical ablation <i>versus</i> Open Surgery+ liquid chemical ablation <i>versus</i> Open Surgery</p>	<p>Belcaro G, Nicolaidis AN, Ricci A, Dugall M, Errichi BM, Vasdekis S et al. Endovascular sclerotherapy, surgery and surgery plus sclerotherapy in superficial venous incompetence. A randomized, 10-year follow-up trial-Final results. <i>Angiology</i> 2000 ;51 :529-34</p>	<p>Multi-center study 150 patients with primary GSV incompetence No data on SSV, no deep vein anomaly, no data on CEAP classification Group I: liquid sclerotherapy (polidocanol 3%; 5- 10 ml) + complementary session at 3 months if needed <i>versus</i> Group II: HL + phlebectomy (?) + liquid sclerotherapy <i>versus</i> Group III: HL + phlebectomy (?) Any surgical procedure under spinal or general anesthesia Results at 1,5 and 10 years of follow-up: <ul style="list-style-type: none"> · Reflux at SFJ: 18.8% in group I vs none in groups II and III · Below the knee reflux: 43.8% in group I vs 16.1% in group II and 36% in group III. It's difficult to draw conclusion from this study</p>
<p>Liquid and foam chemical ablation <i>versus</i> various open surgery procedures</p>	<p>Belcaro G, Cesarone NM, Di Renzo A, Bandolini R, Coen L, Acerbi G et al. Foam sclerotherapy, surgery, sclerotherapy and combined treatment for varicose veins. A 10-year, prospective, randomised, controlled trial (VEDICO trial). <i>Angiology</i> 2003; 54:307-15.</p>	<p>Multi-center study 749 patients with primary GSV incompetence. No data on SSV, no deep vein anomaly, CEAP clinical classification C2-C3 Six groups: Group I (n=123): liquid sclerotherapy Group II (n=112): high dose of liquid sclerotherapy Group III (n=132): multiple ligations Group IV (n=122): stab avulsion Group E (N=129): foam + tension-active substance Group V (n=131): surgery (ligation) + sclerotherapy Results at 1, 5 and 10 years of follow-up: all treatments were similarly effective at 10 years. Low-dose sclerotherapy appeared to be less effective than high-dose sclero and foam- sclerotherapy which may obtain, in selected subjects, results comparable to surgery. It's difficult to draw conclusion from this study</p>

<p>Phlebectomy versus liquid chemical ablation</p>	<p>De Roos KP, Nieman FHM, Neumann M. Ambulatory phlebectomy versus compression sclerotherapy: results of a randomized controlled trial. <i>Dermatol Surg.</i> 2003;29:221-226.</p>	<p>Multi-center study 92 patients and 98 lower limbs presenting VV classified C2 Ep A5 Pr: competent GSV, but incompetent lateral accessory veins. No data on SSV, no deep vein anomaly. Group I (n=49 lower limbs): liquid sclerotherapy + 10 day-compression therapy versus Group II (n=49 lower limbs): ambulatory phlebectomy under local anesthesia + 10 day- compression therapy Results at 2 years of follow-up: <ul style="list-style-type: none"> · Complications: more minor complications in group I compared with group II · Recurrence: 18/48 in group I vs 1/48 in groups II. P<0.001 </p>
	<p>Bountouroglou DG, Azzam M, Pathmarajh M, Young P, Geroulakos G. Ultrasound guided foam sclerotherapy combined with sapheno- femoral ligation compared to surgical treatment of varicose veins: early results of a randomised controlled trial. <i>Eur J Vasc Endovasc Surg.</i> 2006;31:93-100.</p>	<p>Monocenter study Patients with primary incompetent GSV No SSV incompetence, no previous DVT. CEAP clinical classification C2-C6 Group I (n=30): HL+ UGFS versus Group II (n=30): HL+S General anesthesia for all procedures Results at 3 months of follow-up: <ul style="list-style-type: none"> · No difference between groups in terms of complication · Less expensive and less loss of working days in group I versus group II. P<0.0001. · Early recanalization in 13% of patients in group I, needing complementary injection that resulted in a short-term closure in 87% · Costs lower in group I compared with group II. </p>
<p>Chemical ablation (UGFS) + HL versus Open Surgery (HL + S)</p>	<p>Abela R, Liamis A, Prionidis I, Mathai J, Gorton L, Browne T, Panayotopoulos Y. Reverse foam sclerotherapy of the great saphenous vein and saphenofemoral ligation compared to standard and invagination stripping: A prospective clinical series. <i>Eur J Vasc endovasc Surg.</i> 2008;36:485-490.</p>	<p>Monocenter study Patients with primary symptomatic incompetent GSV. No data on SSV, and deep vein CEAP clinical classification C2-C3 Group I (n=30): HL+ reverse foam sclerotherapy versus Group II (n=30): HL + invagination Stripping versus Group III (n=30): HL+ standard Stripping. General anesthesia for all procedures Results at 2 weeks of follow-up: Less post-operative complications and better patients' satisfaction in group I</p>

<p>Liu X, Jia X, Guo W, Xiong J, Zhang H, Liu M, Du X, Zhang MH. Ultrasound- guided sclerotherapy of the great saphenous vein with sapheno-femoral ligation compared to standard stripping. <i>Int Angiol.</i> 2011;30 321-6</p>	<p>Monocenter study Patients with primary symptomatic incompetent GSV. No data on SSV, and deep vein. CEAP clinical classification C2-C6 Group S (n=30): HL+ Stripping+/- TP <i>versus</i> Group F (n=30): HL + UFGS of which 5 received complementary foam sclerotherapy General Anesthesia for all procedures Results at 6 months of follow-up: · Shorter operation time, earlier return-to work and less analgesics intake in group F compared with group S (P< 0.01) · Obliteration: 80% in group F vs 89.5% in group S. P=NS</p>
<p>Kalodiki E, Lattimer C R, Azzam M, Shawish E, Bountouroglou D G, Geroulakos G. Long Term Results of a Randomized Controlled Trial on</p>	<p>Monocenter study Seventy-three atients with primary incompetent GSV No SSV incompetence, no previous DVT. CEAP clinical classification C2-C6 Group S (n=39): HL+ S+/- TP of which 25 received complementary foam sclerotherapy <i>versus</i> Group F (n=41): HL + UGFS of which 33 received complementary foam sclerotherapy General anesthesia for all procedures</p>

	<p>Ultrasound Guided Foam Sclerotherapy Combined with Sapheno-femoral Ligation vs Standard Surgery for Varicose Veins. <i>J Vasc Surg.</i> 2012;55:451- 7.</p>	<p>Results at 3 to 5 years of follow-up:</p> <ul style="list-style-type: none"> · VCSS: no difference between groups · VSDS: no difference between groups · HRQoL (with specific AVVQ) better in group S compared with group F. P<0.0005 · HRQoL (with generic SF-36): no difference between groups for the physical component
<p>Chemical ablation (UGFS) versus Open Surgery (HL+S)</p>	<p>Figueiredo M, Araujo Q, Barros Jr N, Miranda Jr F. Results of surgical treatment compared with Ultrasound-guided foam sclerotherapy in patients with varicose veins: a prospective randomised trial. <i>Eur J Vasc Endovasc Surg.</i> 2009;38:758-63.</p>	<p>Multi-center study Patients with incompetent GSV or/and SSV. No PTS CEAP clinical classification C5 Group I (n=27): Foam sclerotherapy, 1–3 sessions, 10 ml/session <i>versus</i> Group II (n=29): HL+ stripping Surgery under local anesthesia Results at 6 months of follow-up:</p> <ul style="list-style-type: none"> · Significant clinical improvement in both groups. · Vein ablation at DS: 78% in group I vs 90% in group II. P=NS related to the small number of included patients.
	<p>Shadid N, Ceulen R, Nelemans P, et al. Randomized clinical trial of ultrasoundguided foam sclerotherapy <i>versus</i> surgery for the incompetent great saphenous vein. <i>Br J Surg.</i> 2012;99:1062-70.</p>	<p>Multi-center study Patients with primary symptomatic incompetent GSV at least 20 cm at the thigh SSV incompetence in association possible, but not treated in the same session. No deep vein anomaly CEAP clinical classification C2-C5 Group I (n=23): UGFS polidocanol 3%; 1ml <i>versus</i> Group II (n=200): HL+S partial GSV stripping+/- tributary phlebectomy under general anesthesia Results at 2 years of follow-up:</p> <ul style="list-style-type: none"> · PREVAIT: similar in both groups · Symptoms persistence: 11.3% in group I vs 9% in group II; P=0.407 (NS) · Reflux (more than 2cm in the length of the treated GSV): 35% in group I vs 21% in group II; P=0.003 · Cost: € 774 in group I vs €1824 in group II

<p>Chemical ablation (liquid or UGFS) <i>versus</i> HL or HL+S or phlebectomy</p>	<p>Wright D, Gobin J-P, Bradbury AW, Coleridge- Smith P, Spooelstra H et al. Varisolve[®] polidocanol microfoam compared with surgery or sclerotherapy in the management of varicose veins in the presence of trunk vein incompetence: European randomized controlled trial. <i>Phlebology</i>. 2006;21:180-90.</p>	<p>Multi-center study Patients with primary, symptomatic incompetent symptomatic GSV and SSV, no deep vein anomaly CEAP clinical classification C2-C6 710 patients randomized to Group I: foam sclerotherapy (Varisolve[®] polidocanol), <i>versus</i> Group II: surgery (HL 92%, stripping 88%, phlebectomies 53%); no information on the type of anesthesia <i>versus</i> Group III: conventional sclerotherapy (92% homemade foam) Endpoint ultrasound determined occlusion of truncal veins and elimination of reflux. Results at 1 year of follow-up:</p> <ul style="list-style-type: none"> · Occlusion of truncal veins and elimination of reflux determined by US: · 63% in group I vs 86% in group II; P=0.06 · 90% in group I vs 76% in group III; P=0.001 · Foam resulted in less pain and earlier return to work than surgery.
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<p>Chemical ablation (UGFS) + HL versus Open Surgery (HL+ S+TP)</p>	<p>Yin H, He H, Wang M, Li Z, Hu Z, Yao C et al. Prospective Randomized Study of Ultrasound-Guided Foam Sclerotherapy Combined with Great Saphenous Vein High Ligation in the Treatment of Severe Lower Extremity Varicosis. Ann Vasc Surg 2017; 39: 256–263 doi.org/10.1016/j.avsg.2016.06.027</p>	<p>Monocenter study 117 patients with primary, symptomatic GSV insufficiency. No data on SSV, no deep vein anomaly CEAP clinical classification C4-C6 Group S (n=90): HL+ S+/- TP+/- SEPS Complementary foam session in 9 patients <i>versus</i> Group F (n=73): HL + UFGS 1% polidocanol +/-SEPS. Complementary foam session in 6 patients Postoperative course No difference between the 2 groups in terms of complications. Group F. The average operating and recovery times were much shorter P<0.001 and the average hospital cost was lower. P<0.001 Results at 1 year of follow-up: Group S (n=74) Group F (n=65) . Occlusion of truncal veins and elimination of reflux determined by US, No difference between the 2 groups . PREVAIT No difference between the 2 groups.</p>
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	<p>Lam YL, Lawson JA, Toonder IM, Shadid NH, Sommer A, Veenstra M, et al. Eight-year follow-up of a randomized clinical trial comparing ultrasound-guided foam sclerotherapy with surgical stripping of the great saphenous vein. Br J Surg. 2018;105:692-8</p>	<p>430 patients presenting primary GSV incompetence were randomized between UGFS and open surgery CEAP clinical class C1(?) -C5. SSV, perforator and deep vein status not documented Group I (n=230): UGFS <i>versus</i> Group II (n=200): OS. Outcome at 8 years Patients available, group I=123, group II=103. . Symptoms free: Group I =72.1% P=0.024 Group I= 55.1% . Absence of GSV reflux Group I =49.7% P=0.0009 Group II= 33.1% . Reflux at SFJ Group I = 65.8 % P=0.001 Group II= 41.7% . Clinical outcomes Long-term follow-up suggests significant clinical progression of venous disease measured by VCSS in both groups, but less after surgery.</p>
<p>Chemical ablation (UGFS) + HL <i>versus</i> Open Surgery (HL+ S+TP+/- SEPS) In C6 patient</p>	<p>Campos, Jr W. Ohashi Torres I, Simão da Silva E, Benaduce Casella I, Puech-Leão, P. A prospective randomised study comparing polidocanol foam sclerotherapy with surgical treatment of patients with primary chronic venous insufficiency and ulcer. Annals of Vascular Surgery 2015, doi: 10.1016/j</p>	<p>Monocenter study 56 patients (58 lower limb) with primary GSV insufficiency. CEAP classification C=6, E=P, A=S, P=R. Most of the ulcer were recurrent Group I (n=28): HL+ S+/- TP+/- SEPS <i>versus</i> Group II (n=23): UFGS 3% polidocanol ,8-10mL Postoperative course No difference between the 2 groups in terms of complications. Mean time for ulcer healing. P=0.008 in favor of group I Results at 1 year of follow-up: Ulcer healing Group I 100% P>0.05 Group II 91.3% There were no significant differences in AVVQ, VCSS and VDS between the two groups after the procedures</p>

Abbreviations:

AVVQ =Aberdeen Varicose Vein Questionnaire; DS= duplex scan; DVT=deep venous thrombosis; EQ-5D[®]= standardized instrument for measuring generic health status; GSV= great saphenous vein; HL=high ligation; HRQoL=health-related quality of life; OS=open surgery; HL=high ligation; PREVAIT= presence of varices after operative treatment; PTS= postthrombotic syndrome; SEPS= subfascial endoscopic perforator surgery; SFJ= saphenofemoral junction; SSV= small saphenous vein; TP= tributary phlebectomy; UGFS= ultrasound foam guided sclerotherapy ;US=ultrasound; VCSS= venous clinical severity score; VDS=venous disability score ; VSDS=venous segmental disease score; VV= varicose vein