

Endovenous radiofrequency ablation vs laser ablation in patients with lower extremity varicose veins: A meta-analysis

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ABSTRACT

Background: Endovenous radiofrequency ablation (RFA) and laser ablation (LA) have been commonly used for treating lower extremity varicose veins (LEVVs). Their therapeutic effects have been widely recognized compared with conventional surgery. However, there have been some controversies regarding the choice between RFA and LA. The objective of our study was to conduct a systematic review and meta-analysis comparing the early and long-term outcomes of RFA and LA.

Methods: A comprehensive search was performed in the PubMed, Embase, and Cochrane databases to identify relevant literature on endovenous thermal ablation for primary LEVV up until June 2023. Randomized controlled trials, cohort studies, and case-control studies involving RFA and LA for LEVV treatment were included. The primary endpoints were the occlusion rate of the great saphenous vein (GSV) and occurrence of venous thrombotic events. Secondary outcomes included nerve injury, hyperpigmentation, burns, recurrence of VVs, postoperative pain, and phlebitis. Data were analyzed using Review Manager 5.3 software.

Results: A total of 29 studies met the inclusion criteria, consisting of 16 randomized controlled trials and 13 cohort studies. At 1 month, the occlusion rates of GSV were 98.35% for RFA and 98.04% for LA, whereas at 1 year, the rates were 93.13% for RFA and 94.18% for LA. Subgroup analyses revealed that RFA had higher GSV occlusion rates at 1 year since 2016 (93.27% vs 91.24%; odds ratio [OR], 1.35; 95% confidence interval [CI], 1.0-1.83; $P = .05$). The incidence of postoperative venous thrombotic events was 0.78% for RFA and 0.87% for LA at 1 month (OR, 1.46; 95% CI, 0.77-2.74; $P = .24$). RFA showed a reduced risk of burns and ecchymosis (OR, 0.65; 95% CI, 0.48-0.87; $P = .005$), postprocedural pain (mean difference, -0.85 ; 95% CI, -1.06 to -0.64 ; $P < .001$), recurrence of VVs (OR, 0.58; 95% CI, 0.36-0.92; $P = .02$), and paresthesia since 2016 (OR, 0.42; 95% CI, 0.19-0.91; $P = .03$), but an increased risk of skin pigmentation (OR, 1.75; 95% CI, 1.06-2.9; $P = .03$) compared with LA therapy. The rate of phlebitis was similar between RFA and LA (OR, 0.87; 95% CI, 0.33-2.27; $P = .78$).

Conclusions: RFA and LA demonstrated similar efficacy in terms of early and long-term occlusion rates of GSV and the incidence of thrombotic and phlebitis complications. However, since 2016, RFA has shown higher GSV occlusion rates compared with LA. Furthermore, RFA was associated with fewer complications such as paresthesia, burns and ecchymosis, and recurrence of VVs when compared with LA. (*J Vasc Surg Venous Lymphat Disord* 2024;12:101842.)

Keywords: Lower extremity varicose veins; Radiofrequency ablation; Laser ablation; complications; prognosis

Primary lower extremity varicose veins (LEVVs) are a common chronic venous disease characterized by venous wall weakness, venous valve defects, and elevated superficial venous pressure, leading to venous reflux. The prevalence rate of LEVV is reported to be 25% in Western countries and 10% to 15% or 20% to 25% in Chinese men or women.¹ LEVVs not only affect the aesthetics of the body, but also significantly

decreases the quality of life, causing pigmentation, dermatitis, eczema, and ulcers.

Over the past few decades, various treatment strategies for LEVVs have been developed, including high ligation and stripping (HL/S) of the great saphenous vein (GSV), compression stockings, and foam sclerosing agents. However, HL/S has several disadvantages, such as trauma, bleeding, and prolonged hospital stays.² With

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the advancement of endovascular technology, endovenous thermal ablation (ETA) has emerged as the first-line therapy for LEVV. ETA includes radiofrequency ablation (RFA) and laser ablation (LA), which are minimally invasive procedures.³ ETA occludes VVs by generating thermal energy to burn the endovenous membrane, leading to fibrotic occlusion.^{4,5} Compared with HL/S, ETA has demonstrated similar or even superior efficacy and safety. Several studies have reported comparable or better results for RFA and LA in terms of technical success, recanalization, clinical recurrence, and reoperation, as well as improved return to routine activities, postoperative pain, and quality of life.⁶⁻⁹

Both RFA and LA are ETA methods with distinct ablation mechanisms. RFA uses a radiofrequency generator to produce energy through an electrode catheter, which contacts the endothelium directly and heats the local venous tissues near the catheter, causing endothelial injury. In contrast, LA uses laser energy transmitted via an optical fiber, which is absorbed by blood components, generating steam bubbles at the tip of the fiber and resulting in thermal damage to the endothelium.^{4,5} Despite both RFA and LA being considered first-line treatments for LEVVs, their therapeutic effects may vary. Several studies have reported conflicting results between RFA and LA. Yoon et al, Aurshina et al, and Wozniak et al found higher recanalization rates in the RFA group compared with the LA group in both early and long-term outcomes. However, El Kilic et al discovered the opposite result, with lower recanalization rates in the RFA group compared with the LA group at 3 and 5 years of follow-up.¹⁰⁻¹⁴ Another study demonstrated similar recanalization rates between the RFA and LA groups after 1 year of postoperative follow-up. Other complications, such as postoperative pain scores, time to return to normal activity, and ecchymosis, were more severe or more frequent in the RFA group compared with the LA group. However, the results from Helin et al, Shepherd et al, and Sydnor et al contradicted these findings.¹⁴⁻¹⁷ Despite RFA and LA being recommended as first-line treatments for LEVV in domestic and foreign guidelines, it remains unclear which method is more efficient. A meta-analysis comparing the efficacy between RFA and LA has been conducted, but it only included literature published before January 5, 2016, in the PubMed database, and limited the inclusion criteria to studies with 4 to 5 years of follow-up. Furthermore, they only focused on long-term technical success rates and recanalization rates.¹ Therefore, a systematic review and comprehensive meta-analysis are necessary to compare the early and long-term efficacy of RFA and LA.

The objective of this study was to conduct a comprehensive meta-analysis of all relevant publications on the treatment of LEVV using RFA and LA. We aim to compare the short-term and long-term outcomes of these treatments and determine which ETA is more effective for

LEVVs. The primary outcomes of interest include occlusion rates and recurrence of VVs, which will be assessed at the 1-month and 1-year follow-ups. Additionally, we will analyze the occurrence of thrombotic events (TEs), burns, ecchymosis, paresthesia, postprocedural pain, and phlebitis as the main short-term results at the 1-month follow-up.

METHODS

This study was approved by the Ethics Committee of the First Affiliated Hospital of Guangxi Medical University. The systematic review and comprehensive meta-analysis were conducted in accordance with the PRISMA guidelines.¹⁸

Search strategy and selection criteria. In June 2023, the PubMed, Embase, and Cochrane databases were selected as the primary databases to search for relevant literature. The search terms used for LEVV included "great saphenous vein," "chronic venous disorder," "lower extremity vein," "superficial venous disease," "varicose veins," and "lower limb varicosity." The second search term focused on "radiofrequency" and included related terms such as "ablation, radiofrequency," and "radio frequency ablation." The third search term was "laser" and included terms like "lasers, Q-switched" and "pulsed lasers." [Supplementary Table 1](#) (online only) provides the detailed retrieval strategies used in the PubMed, Embase, and Cochrane databases.

All retrieved articles were imported into EndNote software, and any duplicate literature was removed. Two different authors independently screened the remaining studies by reviewing titles, abstracts, and full texts. The eligible literature had to meet several criteria: (1) it had to focus on GSV trunk varicosity; (2) it had to be a comparative study comparing at least RFA vs LA; (3) the articles needed to provide relevant results and have full-text availability; and (4) the articles had to be published in English. Case reports, abstracts, reviews, conference records, comments, animal studies, and recurrent varicosity of GSV were all excluded from the analysis.

Data extraction and outcome measures. Data extraction was conducted by two independent authors. In case of any discrepancies or disagreements regarding the data, a consensus was reached through discussion among all reviewers. The relevant information from the eligible studies was extracted and recorded, including study type, authors, publication year, sample size (number of patients and limbs), population characteristics, intervention type, duration of follow-up, and the outcomes of interest. The primary outcomes of interest were the occlusion rate and the occurrence of VTEs. Secondary outcomes included nerve injury, recurrence of VVs, postoperative pain, and other postoperative adverse complications.

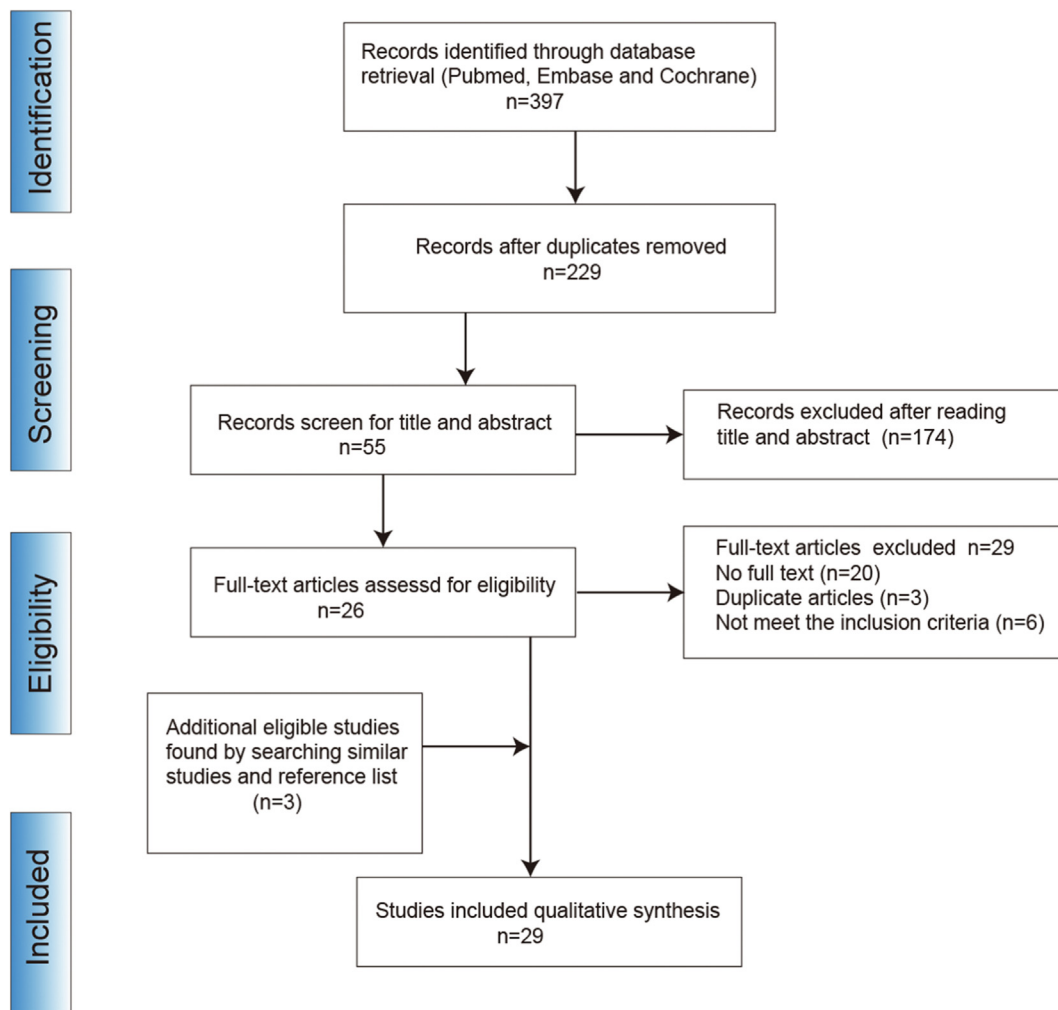


Fig 1. PRISMA flow diagram of the literature screened in the study.

Quality assessment for risk of bias. The Cochrane risk of bias tool (www.cochrane.org/resources/handbook) and the Newcastle-Ottawa Scale (NOS) were used to assess the risk of bias and quality of each included randomized controlled trials (RCTs) and cohort studies, respectively. For RCTs, all potential sources of bias were evaluated, such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, attrition, reporting, and other sources of bias. For cohort studies, the quality was assessed based on the selection of subjects, comparability between groups, and the assessment of exposure or outcome. The NOS ranking system used a semi-quantitative approach using a star system, with scores ranging from 0 to 9. A study with a score of ≥ 7 was considered to be of high quality.

Statistical analysis. The collected data were analyzed using Review Manager 5.3 software. For categorical data, the random-effects model was used to calculate the odds ratio (OR) and 95% confidence intervals (CIs).

For measurement data, the random effects model was used to calculate the mean and standard deviation (SD) with 95% CI. Heterogeneity was assessed using the Cochran Q statistic (χ^2 test) and the I^2 statistic.^{19,20} A Q value of <0.1 indicated the presence of heterogeneity. The I^2 values ranged from 0% to 100% and were categorized into four levels to evaluate the degree of heterogeneity: 0% to 25% (no heterogeneity), 25% to 50% (low heterogeneity), 50% to 75% (moderate heterogeneity), and 75% to 100% (substantial heterogeneity). Subgroup and sensitivity analyses were performed based on study type or publication time. Additionally, funnel plots were used to assess publication bias. Statistical significance was defined as a P value of $<.05$.

RESULTS

Study selection and characteristics

The detailed process of literature screening is presented in Fig 1. Initially, a total of 397 studies were retrieved from the PubMed, Embase, and Cochrane databases using

Table I. Characteristics of the included studies

First author	Year	Design	Modality	No. of patients	No. of limbs Treated	Male/female	Age, years, mean/range	CEAP clinical classification
Vähäaho	2019	RCT	RFA EVLA MOCA	125	125	Not reported	RFA: 50.3 EVLA: 49.5 MOCA: 50.9	C2-C4
Vähäaho	2020	RCT	RFA EVLA MOCA	106	106	Not reported	RFA: 50.6 EVLA: 49.9 MOCA: 50.5	C2-C4
Lawaetz	2017	RCT	RFA EVLA UGFS HL/S	499	577	132/367	RFA: 51 EVLA: 52 UGFS: 51 HL/S: 50	C2-C6
Rasmussen	2011	RCT	RFA EVLA UGFS HL/S	498	578	131/367	RFA: 51 EVLA: 52 UGFS: 51 HL/S: 50	C2-C6
Rasmussen	2013	RCT	RFA EVLA UGFS HL/S	499	578	132/367	RFA: 51 EVLA: 52 UGFS: 51 HL/S: 50	C2-C6
Almeida	2009	RCT	RFA EVLA	69	87	9/60	RFA: 51.6 EVLA: 52.4	C2-C6
Shepherd	2010	RCT	RFA EVLA (980)	131	131	42/89	RFA: 49 EVLA: 48	C1-C6
Hamann	2019	RCT	iRFA dRFA EVLA	450	450	145/305	iRFA: 49.3 dRFA: 52.6 EVLA: 51.1	C2-C6
Gale	2010	RCT	RFA EVLA (810)	118	141	33/85	RFA: 46 EVLA: 49	Not reported
Goode	2010	RCT	RFA EVLA (810)	66	87	17/45	RFA: 45.9 EVLA: 47.6	Not reported
Tofigh	2020	RCT	RFA EVLA (980)	1090	1090	280/810	RFA: 37.26 EVLA: 36.9	C2-C4
Mese	2015	RCT	RFA EVLA (1470)	120	120	Not reported	Not reported	Not reported
Nordon	2011	RCT	RFA EVLA (810)	159	159	60/99	RFA: 46.9 EVLA: 46.7	C2-C6
Kempeeneers	2022	RCT	RFA EVLA (1470)	280	280	103/177	RFA: 51.54 EVLA: 51.48	C2-C6
Sydnor	2016	RCT	RFA EVLA (980)	200	200	43/157	RFA: 47 EVLA: 48.5	Not reported
Woz'niak	2016	RCT	RFA EVLA (980)	110	110	20/90	RFA: 57.9 EVLA: 52.09	C2-C6
Karathanos	2020	PCS	RFA EVLA (1470-R) EVLA (1470-J)	153	160	60/93	RFA: 53.9 EVLA-R: 51 EVLA-J: 49.8	C2-C6
Lawson	2017	PCS	RFA EVLA (1470)	311	346	81/230	RFA: 49.9 EVLA: 50	C1-C6
Yoon	2017	RCS	RFA EVLA (810)	270	343	81/189	RFA: 59.8 EVLA: 56.6	C2-C6
Kubat	2019	RCS	RFA EVLA (980) EVLA (1470) HL/S CAC	671	697	305/366	RFA: 49.5 EVLA (980): 48.8 EVLA (1470): 47.4 HL/S: 49.6 CAC: 50.6	C2-C5

Table I. Continued.

First author	Year	Design	Modality	No. of patients	No. of limbs Treated	Male/female	Age, years, mean/range	CEAP clinical classification
Gianesini	2020	RCS	RFA EVLA	79	85	30/49	RFA: 56 EVLA: 54	C3
Öntas	2019	RCS	RFA EVLA (1470)	50	50	25/25	RFA: 28-65 EVLA: 28-65	C2-C4
Izzo	2020	RCS	RFA EVLA (980)	95	95	22/73		Not reported
Sanioglu	2017	RCS	RFA EVLA (1470)	96	96	31/65	RFA: 46 EVLA: 45	C1-C4
Almeida	2006	RCS	RFA EVLA	694	899	Not reported	Not reported	Not reported
Puggioni	2005	RCS	RFA EVLA	92	130	15/77	RFA: 50.28 EVLA: 52.2	C2-C6
Ravi	2006	RCS	RFA EVLA	981	1149	211/770	51 (15-90)	C2-C6
Bozoglan	2016	RCS	RFA EVLA (1470)	60	120	28/32	RFA: 42.2 EVLA: 42.2	Not reported
Park	2020	RCS	RFA EVLA	80	147	25/55	RFA: 40.4 EVLA: 47.4	C1-C5

CAC, Cyanoacrylate closure; CEAP, Clinical Etiologic Anatomic Pathophysiologic; dRFA, directly endovenous radiofrequency ablation; HL/S, high ligation and stripping; iRFA, indirectly endovenous radiofrequency ablation; LA, laser ablation; MOCA, mechanochemical ablation; PCS, prospective comparative study; RCS, retrospective comparative study; RCT, randomized clinical trial; RFA, endovenous radiofrequency ablation; UGFS, ultrasound-guided foam sclerotherapy.

the specified keywords. Among these, 168 duplicate papers were identified and removed using EndNote software. The remaining 229 articles underwent title and abstract screening, leading to the exclusion of 174 articles. Subsequently, full-text evaluation was performed on the remaining 55 articles. During this process, an additional 16 articles were identified through a thorough examination of similar articles and references. Ultimately, 29 studies met the inclusion criteria, comprising 16 RCTs,^{8,13,15-17,21-31} 2 prospective cohort studies,^{32,33} and 11 retrospective studies,^{10,34-43} which reported comparisons between RFA and LA.

The characteristics of the included studies are summarized in Table. These studies collectively involved a total of 7303 patients and 7877 legs. However, it should be noted that six studies reported multiple treatment methods in addition to RFA and LA.^{8,21,22,30,31} Moreover, Vähäaho et al^{21,22} published two papers based on the same patients but at different follow-up times. Similarly, Lawaetz et al and Rasmussen et al described three articles that contained data from the same individuals at 1, 3, and 5 years after the operation.^{8,30,31} Duplicate data were removed during the final analysis, ensuring that each cohort was included only once. Therefore, a total of approximately 2634 patients and 2458 limbs were investigated in the RFA group, and 4053 patients and 4405 limbs were investigated in the LA group. Among the included studies, 23 specifically compared RFA and

LA in terms of outcomes. One study reported two different types of LA using a 1470-nm dual radial fiber or a 1470-nm jacket-tip fiber for the treatment of LEVVs.³² Another study also reported two different RFAs, namely, direct RFA (radiofrequency-induced thermotherapy) and indirect RFA (the VNUS ClosureFast system) for the treatment of LEVVs.²⁴ In our review, both the LA with a 1470-nm dual radial fiber and indirect RFA were included. Quality assessment indicated that 16 RCTs had a low risk of bias based on Cochrane criteria, whereas the other 13 studies were deemed to be of high quality according to the NOS standard (Fig 2 and Supplementary Table II, online only).

Primary outcomes

The occlusion rate of the treated GSV at 1 month after surgery was reported and collected from 16 of the 29 included studies.^{13,16,17,21,23,25,26,28,29,30,35,36,40,41,42,43} In the RFA group, the occlusion rate ranged from 90.9% to 100%, whereas in the LA group, it ranged from 94.4% to 100%. Specifically, 10 studies reported a 100% occlusion rate for RFA, whereas 12 studies reported the same rate for LA. The overall pooled results from these 16 studies indicated that the occlusion rate of the treated GSV was similar for both procedures. Furthermore, neither RFA nor LA increased the risk of recanalization at 1 month (OR, 0.68; 95% CI, 0.34-1.36; $I^2 = 0\%$; $P = .28$) (Fig 3, A). In addition, we performed a subgroup analysis based on the research

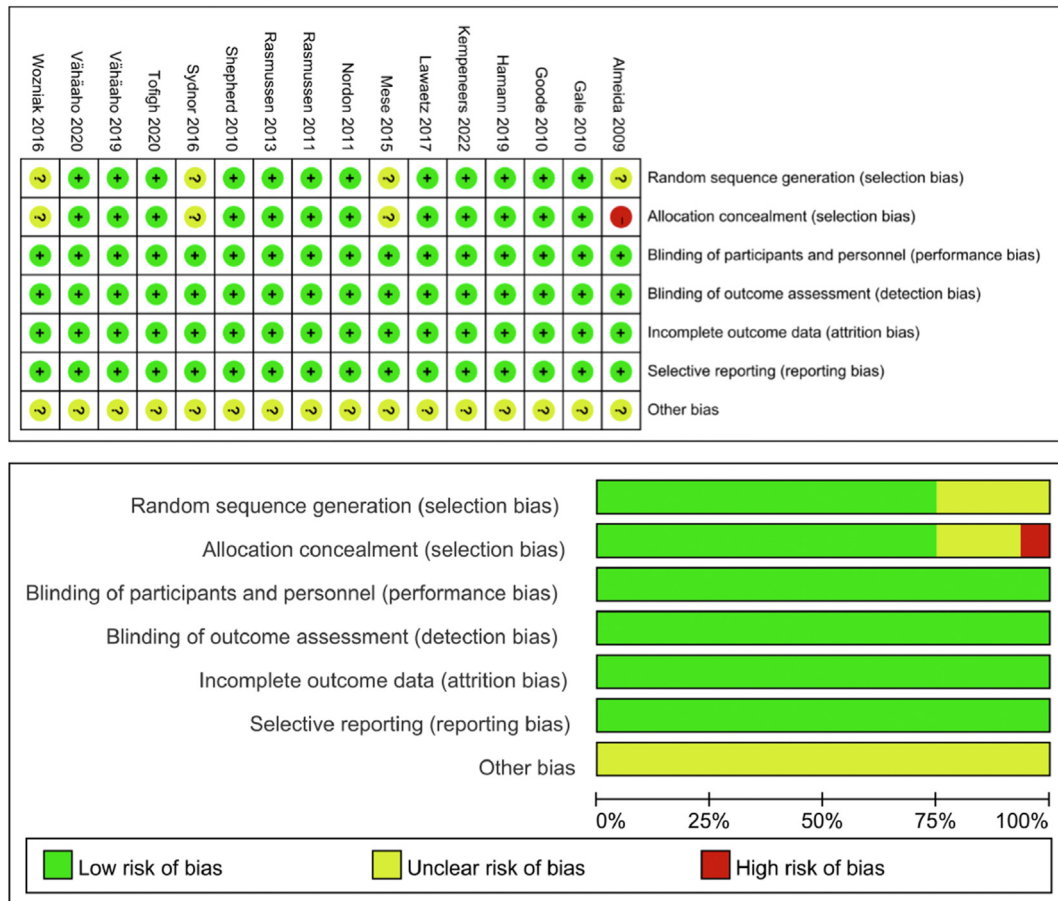


Fig 2. The assessment of biased risk of the 16 included randomized controlled trials (RCTs) in this study.

type in all included studies. There were 10 RCTs and 6 cohort studies reporting the data of the occlusion rate of the treated GSV at 1 month after surgery. Our meta-analysis showed the effect of RFA and LA was similar (OR, 0.6; 95% CI, 0.16-2.26; $I^2 = 0\%$; $P = .45$), (OR, 0.72; 95% CI, 0.32-1.6; $I^2 = 0\%$; $P = .42$) (Supplementary Fig 1, A and B) both in RCTs and cohort studies, which supported our original results.

Fifteen of the 26 eligible studies described the occlusion rate of the treated GSV at 1 year after surgery.^{13,17,23-30,32,34-36,39} The closure rate ranged from 73.5% to 100% for RFA and from 75% to 100% for LA. A comprehensive analysis showed that the efficiency of RFA and LA was similar in terms of closure rate at the 1-year follow-up (OR, 0.94; 95% CI, 0.62-1.42; $P = .76$), but there was significant heterogeneity ($P = .03$; $I^2 = 47\%$) (Fig 3, B). To analyze this heterogeneity, we first checked all included studies. There were no problems in data extraction and no significant change in the pooled results was found for any one study. In view of technological progress in RFA or LA system, we decided to perform a subgroup analysis based on the publication date of the study. These included studies were bundled based on the

chronological order of publication and we found when comparing between those published before 2016 with those after 2016 had statistical significance without heterogeneity. Furthermore, the numbers of included studies in the two group were similar. Therefore, we chose 2016 as the dividing point. The subgroup analysis based on the publication year revealed that seven studies were published before 2016, and their closure rates were similar for RFA and LA (OR, 0.58; 95% CI, 0.28-1.19; $P = .14$) (Fig 3, C).^{13,17,25,26,28,30,39} In contrast, eight included studies were published after 2016, showing that RFA increased the closure rate of the treated GSV compared with LA (OR, 1.35; 95% CI, 1.0-1.83; $P = .05$) without any heterogeneity ($P = .56$; $I^2 = 0\%$) (Fig 3, C).^{21,24,27,29,32,34-36} In addition, we also performed a subgroup analysis separately based on the RCTs and cohort studies. There were 10 RCTs and 5 cohort studies reporting the data of the occlusion rate of the treated GSV at 1-year follow-up. The effect of RFA and LA on occlusion of the treated GSV was also similar (OR, 1.02; 95% CI, 0.69-1.51; $I^2 = 19\%$; $P = .91$), (OR, 0.92; 95% CI, 0.29-2.93; $I^2 = 77\%$; $P = .89$) (Supplementary Fig 1, C and D) both in RCTs and cohort studies, but there was significant heterogeneity ($P = .005$; $I^2 = 77\%$) in cohort studies, which

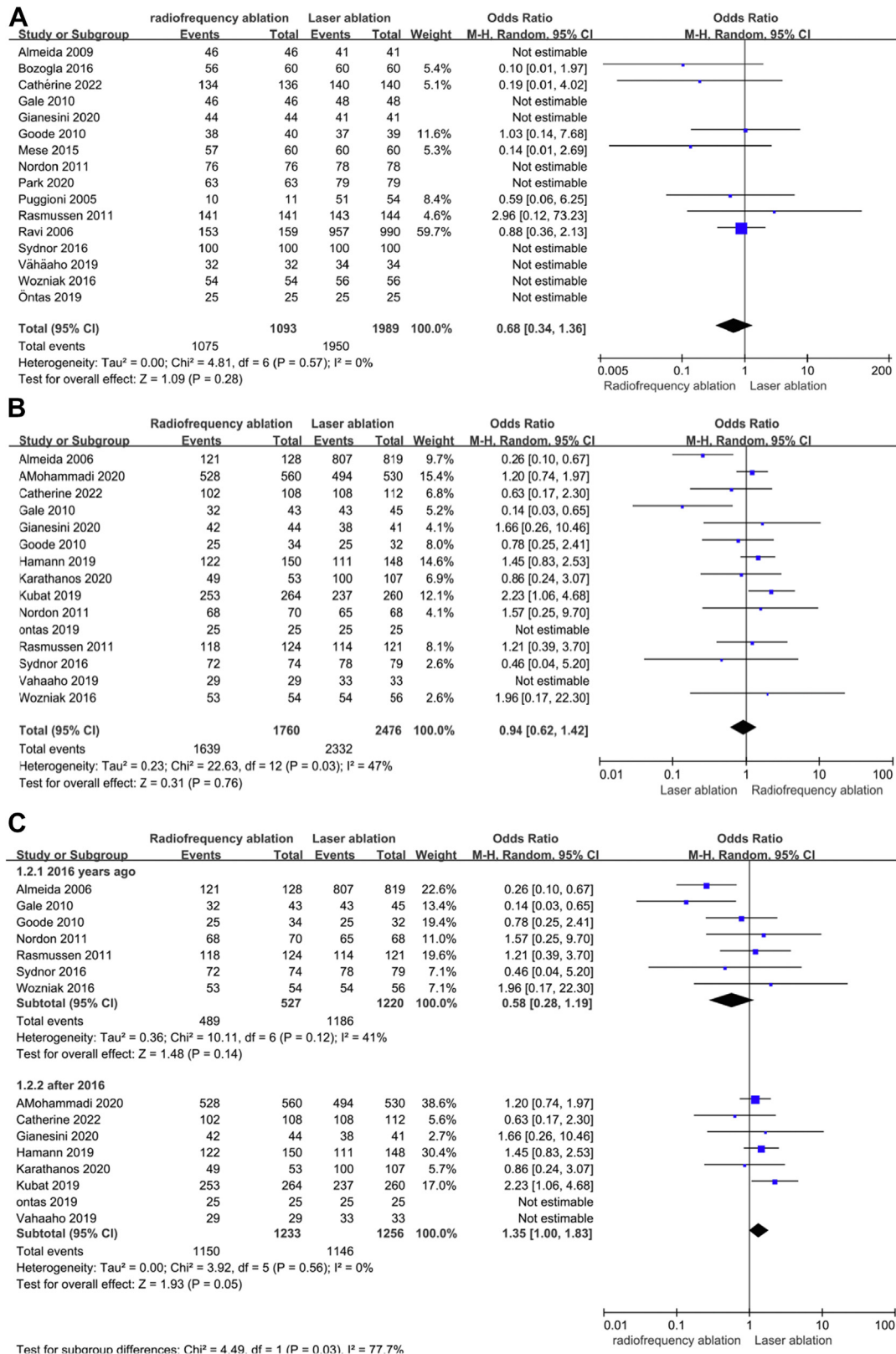


Fig 3. Forest plots showing the odds ratios (ORs) for occlusion rate of the treated great saphenous vein (GSV) with radiofrequency ablation (RFA) vs laser ablation (LA). **(A)** OR for occlusion rate at 1 month postoperative. **(B)** OR for occlusion rate at 1 year postoperative. **(C)** Subgroup analysis of OR for occlusion rate at 1 year postoperative. *CI*, confidence interval; *M-H*, Manzel-Heinz.

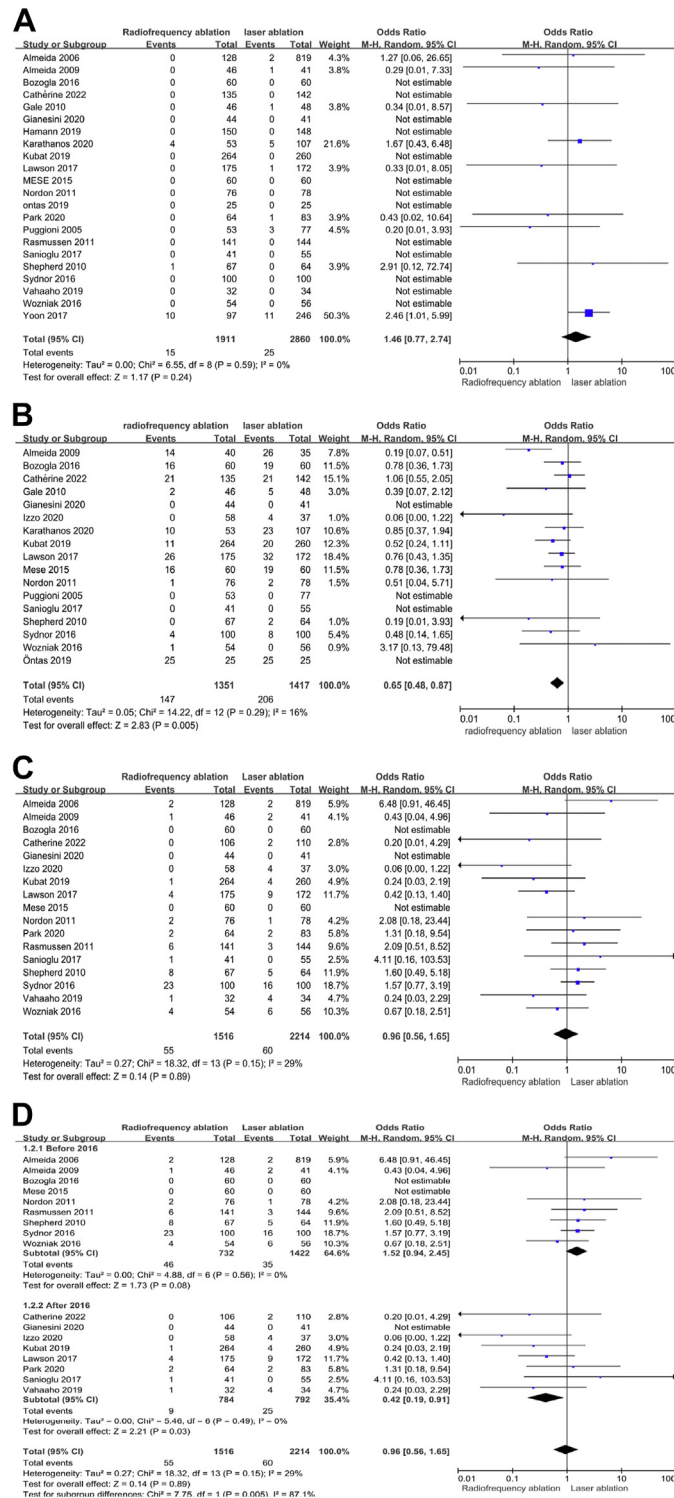


Fig 4. Forest plots showing the odds ratio (OR) for venous thrombotic event (VTE), burns and ecchymosis, and paresthesia in all included patients underwent radiofrequency ablation (RFA) vs laser ablation (LA) at 1 month postoperative. **(A)** OR for VTE. **(B)** OR for burns and ecchymosis. **(C)** OR for paresthesia. **(D)** Subgroup analysis of OR for paresthesia at 1 month postoperative. *CI*, confidence interval; *M-H*, Manzel-Heinz.

also was similar to our original results. We did not observe significant publication bias in funnel plot (Supplementary Fig 2, A).

Venous TEs (VTEs) refer to deep venous thrombosis, pulmonary embolism, and endothelial heat-induced thrombosis (EHIT) in our study, which occurring 1 month

after surgery were another primary outcome assessed in our review. Of the 29 studies included, 22 provided information on the occurrence of thrombogenesis.^{10,13,15-17,21,23-25,28-30,32-36,38-40,42,43} Among them, 13 studies reported that no VTE occurred both in the RFA and LA groups, whereas VTE occurred in the RFA or LA groups in the other 9 studies. A total of 15 cases of VTE in the RFA group, including 1 pulmonary embolism, 2 superficial vein thromboses, and 12 EHIT, in contrast with 25 cases of VTE in the LA group, including 8 deep venous thromboses involving the peroneal vein or femoral vein, 2 superficial vein thromboses, and 15 EHIT. The incidence rates of thrombogenesis ranged from 0% to 10.31% in the RFA group and from 0% to 4.67% in the LA group. Our meta-analysis indicated that RFA showed an increased risk of VTEs compared with LA; however, this difference was not statistically significant (OR, 1.46; 95% CI, 0.77-2.74; $P = .24$), and there was no heterogeneity among the studies (Fig 4, A). In addition, we also performed a subgroup analysis separately based on the RCTs and cohort studies. There were 11 RCTs and 11 cohort studies reporting the data of VTEs during the first month after surgery. The effects of RFA and LA were also similar (OR, 0.66; 95% CI, 0.1-4.26; $I^2 = 0\%$; $P = .66$), (OR, 1.61; 95% CI, 0.82-3.16; $I^2 = 0\%$; $P = .16$) (Supplementary Fig 3, A and B) both in RCTs and cohort studies, which was similar to our original results.

Secondary outcomes

Burns and ecchymosis. Seventeen of the 29 included studies reported on burns and ecchymosis during the first postoperative month.^{13,15-17,23,25,28,29,32-38,40,42} The morbidity rates were 10.88% for RFA and 14.54% for LA. The meta-analysis revealed that RFA decreased the risk of burns and ecchymosis compared with LA significantly (OR, 0.65; 95% CI, 0.48-0.87; $P = .005$) without heterogeneity ($I^2 = 16\%$; $P = .29$) (Fig 4, B). In addition, a subgroup analysis was performed based on the RCTs and cohort studies. There were eight RCTs and nine cohort studies reporting data on burns and ecchymosis at 1 month after surgery. RFA had a better effect in decreasing the risk of burns and ecchymosis than LA both in RCTs (OR, 0.56; 95% CI, 0.32-0.98; $I^2 = 34\%$; $P = .04$) (Supplementary Fig 3, C) and cohort studies (OR, 0.7; 95% CI, 0.49-0.99; $I^2 = 0\%$; $P = .04$) (Supplementary Fig 3, D), which supported our original results.

Paresthesia

Similarly, 17 studies also reported data on paresthesia during the first postoperative month.^{10,13,15-17,21,23,28-30,33-35,37-39,42,43} In these studies, 3.63% of patients experienced paresthesia in the RFA group, and 2.71% experienced it in the LA group. The overall pooled OR was 0.96, indicating no significant difference (95% CI, 0.56-1.65; $P = .89$), with mild heterogeneity ($I^2 = 29\%$; $P = .15$) (Fig 4, C). To address the heterogeneity, subgroup analysis based on

publication time was conducted. We chose to split the groups into two subgroups, using 2016 at the dividing point and then analyzed the occlusion of the treated GSV; we also did this for paresthesia. Nine studies published before 2016^{13,15-17,23,28,30,39,42} were grouped together, and eight studies published after 2016^{10,21,29,33-35,37,38,43} were classified into a second group. In studies published before 2016, 83.64% and 58.33% of patients experienced paresthesia in the RFA and LA groups, respectively. The pooled analysis indicated that the risk of paresthesia was similar between RFA and LA without statistical significance or heterogeneity (OR, 1.52; 95% CI, 0.94-2.45; $I^2 = 0\%$; $P = .08$) (Fig 4, D). However, only 16.36% of all patients with paresthesia were from the RFA group, whereas 41.67% were from the LA group in studies published after 2016. Therefore, we observed that RFA was associated with a decreased risk of paresthesia compared with LA with significant difference and no heterogeneity (OR, 0.42; 95% CI, 0.19-0.91; $I^2 = 0\%$; $P = .03$) (Fig 4, D). In addition, a subgroup analysis also was performed based on the RCTs and cohort studies. There were nine RCTs and eight cohort studies reporting data on paresthesia at 1 month after surgery. The effect of RFA and LA was similar (OR, 1.23; 95% CI, 0.76-1.97; $I^2 = 0\%$; $P = .4$), (OR, 0.79, 95%CI:0.22-2.77; $I^2 = 54\%$; $P = .71$) (Supplementary Fig 4, A and B) both in RCTs and cohort studies, but there was significant heterogeneity ($P = .06$; $I^2 = 54\%$) in cohort studies, which also was similar to our original results. No significant publication bias was detected in funnel plots (Supplementary Fig 2, B).

Pigmentation

Eight eligible studies described pigmentation conditions during the first postoperative month. Among these studies, 7.35% of patients in the RFA group and 4.06% in the LA group experienced pigmentation. The pooled outcomes suggested that RFA was associated with an increased risk of pigmentation compared with LA with significant difference and no heterogeneity (OR, 1.75; 95% CI, 1.06-2.90; $I^2 = 0\%$; $P = .03$) (Fig 5, A).

Phlebitis

Seven studies provided data on phlebitis during the first postoperative month.^{15,17,23,28,30,40,43} The incidence rate of phlebitis was 3.86% in the RFA group and 3.95% in the LA group. The location of phlebitis was along with the treated target veins or main trunks. In the meta-analysis, no statistical significance was observed between RFA and LA in all included studies, with mild heterogeneity (OR, 0.87; 95% CI, 0.33-2.27; $I^2 = 39\%$; $P = .78$) (Fig 5, B).

Recurrence of VVs

Five studies reported data on the recurrence of VVs at 1 year after surgery.^{10,13,17,30,34} The incidence rate of recurrence in the RFA group was 4.89% compared

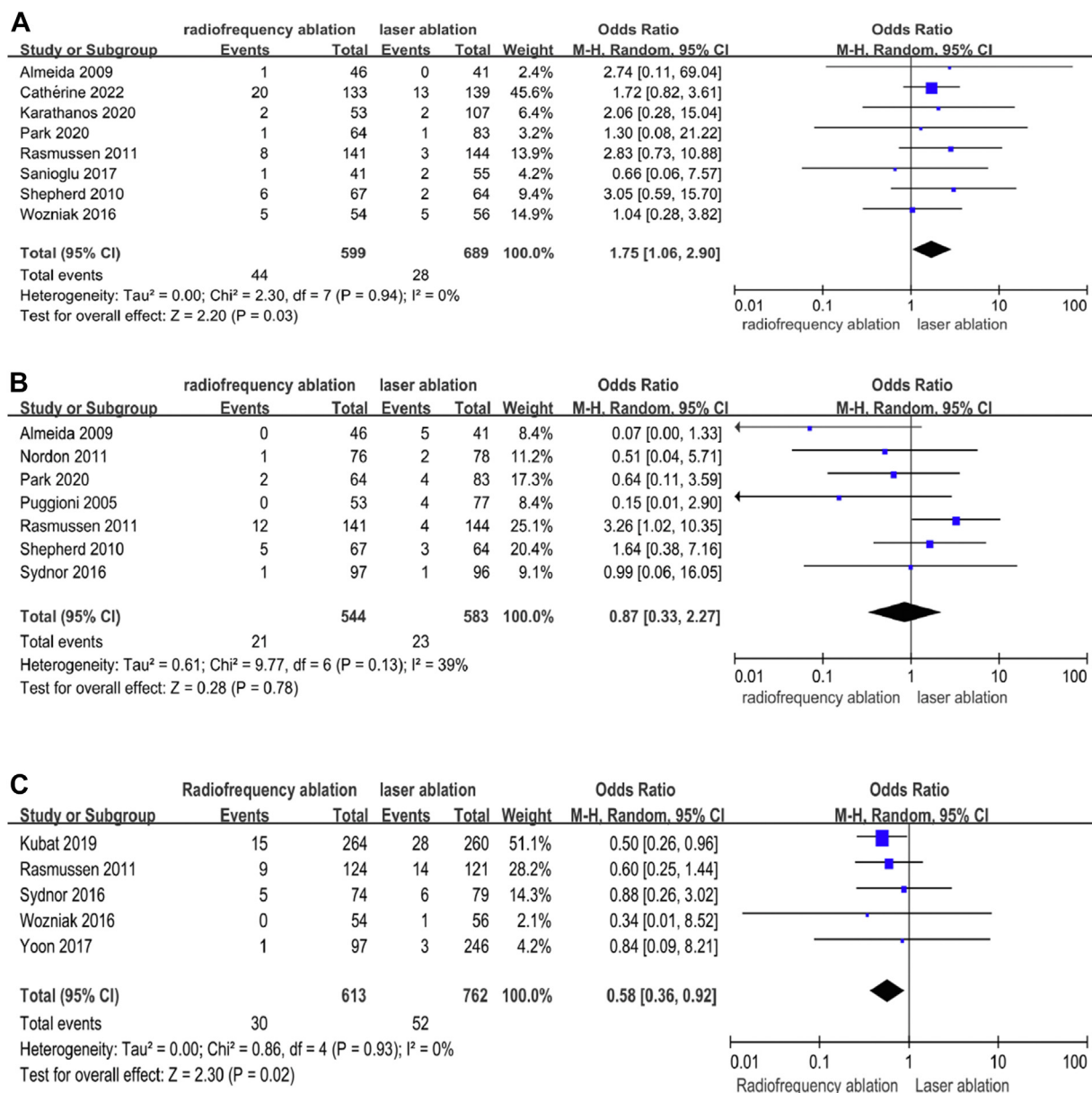


Fig 5. Forest plots showing the odds ratio (OR) for pigmentation, phlebitis, and recurrence of varicose veins (VVs) in all included patients who underwent radiofrequency ablation (RFA) vs laser ablation (LA) at 1 month postoperative and 1 year, respectively. **(A)** OR for pigmentation. **(B)** OR for phlebitis. **(C)** OR for recurrence of VVs. CI, confidence interval; M-H, Manzel-Heinz.

with 6.82% in the LA group. The pooled outcomes indicated that RFA was significantly associated with a decreased risk of VV recurrence without heterogeneity (OR, 0.58; 95% CI, 0.36-0.92; I² = 0%; P = .02) (Fig 5, C).

Postoperative pain scores

Most of the included studies reported postoperative pain scores using the visual analogue scale, which ranged from 0 to 10 during the first month after surgery. However, the time points of postoperative pain score evaluations varied across the different studies.

Additionally, some studies presented postoperative pain scores as means or numerical ranges without SDs, preventing us from conducting a systematic analysis with mean ± SD. We ultimately included and analyzed 12 studies comprising 13 comparisons.^{15,16,23,24,27-30,33-35,38} The pooled results indicated that RFA significantly decreased postoperative pain severity compared with LA, although there was significant heterogeneity (mean difference [MD], -0.57; 95% CI, -0.94 to -0.2; I² = 93%; P = .002) (Fig 6, A). The major source of heterogeneity was the variation in pain score data at different time points. Therefore, a subgroup analysis was performed,

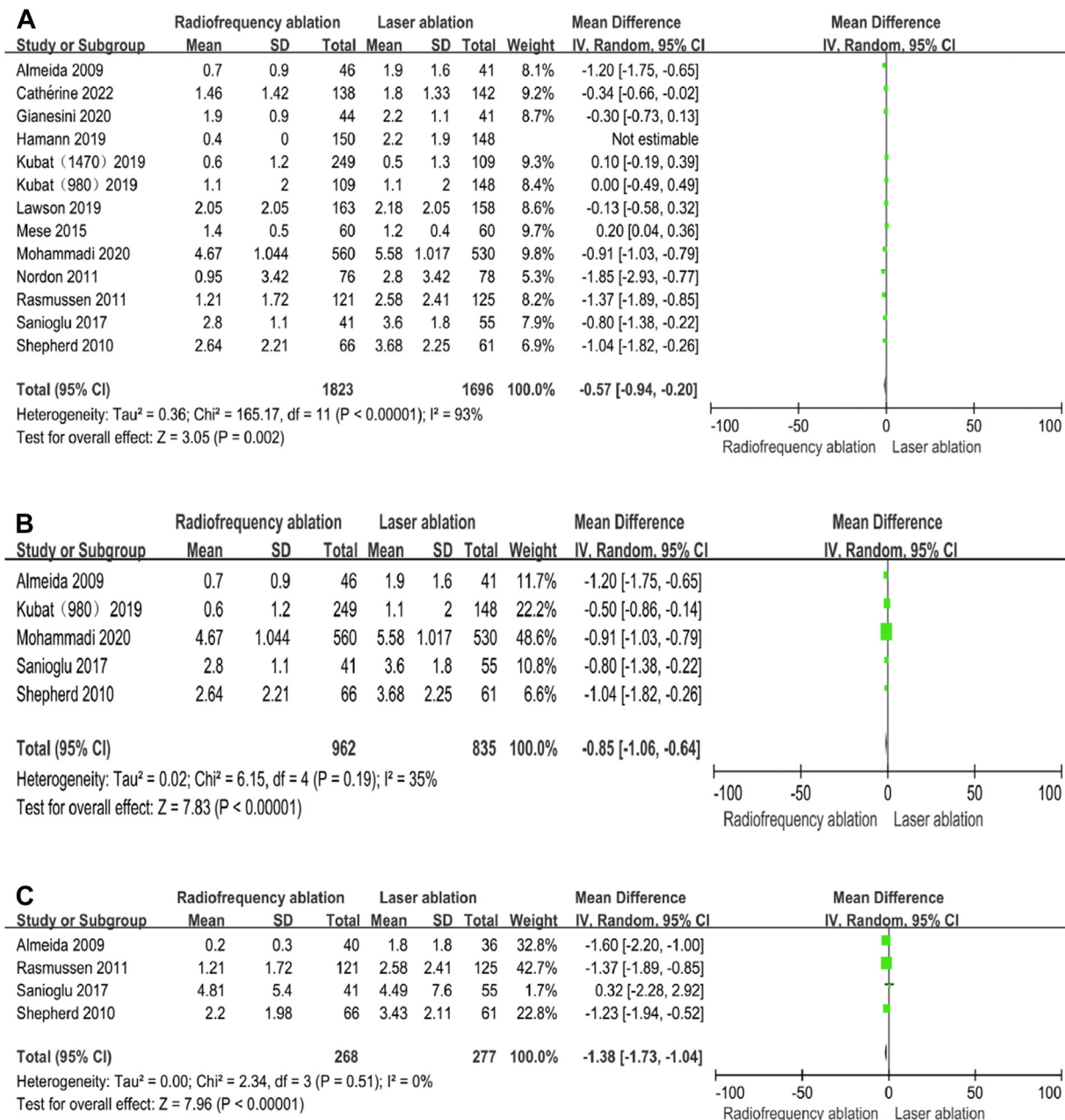


Fig 6. Forest plots showing the mean difference (MD) for postoperative pain scores in all included patients with radiofrequency ablation (RFA) vs laser ablation (LA). **(A)** MD for postoperative pain scores at 1 month postoperative. **(B)** MD for postoperative pain scores at 0 to 3 days. **(C)** MD for postoperative pain scores at 7 to 10 days. CI, confidence interval; SD, standard deviation.

revealing that RFA significantly decreased postoperative pain severity compared with LA with low-grade heterogeneity within the first 3 days after surgery (MD, -0.85; 95% CI, -1.06 to -0.64; I² = 35%; P < .001) (Fig 6, B).^{15,23,27,34,38} Furthermore, pain scores collected between 7 and 10 days postoperatively were grouped separately,^{15,23,30,38} and the meta-analysis demonstrated that RFA still resulted in a significantly decreased risk of pain compared with LA without heterogeneity (MD, -1.38; 95% CI, -1.73 to -1.04; I² = 0%; P < .001)

(Fig 6, C). Therefore, RFA seems to be superior to LA in terms of pain severity during the first 10 days after surgery.

DISCUSSION

Over the past decade, both RFA and LA have been incorporated into guidelines as first-line treatments for LEVVs. However, there remains controversy and contradiction regarding their efficacy and safety. In this meta-analysis, we included 29 studies, comprising 16 RCTs, 2

prospective cohort studies, and 11 retrospective cohort studies, to analyze the early and long-term outcomes of RFA and LA for LEVVs. We found that RFA and LA had similar effects on the occlusion rate of treated GSV, VTE, and phlebitis at the 1-month follow-up. However, RFA was associated with a lower risk of burns, ecchymosis, paresthesia, and pain severity, as well as an increased risk of pigmentation compared with LA in the early postoperative period. For long-term follow-up, RFA decreased the risk of VV recurrence and increased the occlusion rate of treated GSV in studies published after 2016. Therefore, to some extent, RFA may be considered superior to LA for LEVV treatment, but further RCTs are needed to confirm this finding.

The latest Clinical Practice Guidelines of Varicose Veins of the American Venous Forum considers the ETA, including RFA and LA, a preferred option for patients with symptomatic VVs and axial reflux of the GSV.⁴⁴ Even though our results indicated some potential differences between RFA and LA, they had their own advantages and all showed a good therapeutic effect for LEVV, which supported the opinion of the American Venous Forum.

Six years ago, He et al⁴⁵ conducted a similar study comparing RFA with LA for the treatment of LEVVs. Their findings indicated no significant difference in the occlusion rate of GSV at 3 months postoperatively and in postoperative complications, such as pain scores at 3 and 10 days, thrombophlebitis, and so on.⁴⁵ However, our analysis confirmed that the closure rate of GSV, based on data from 13 studies, was similar between RFA and LA at the 1-month and 1-year follow-up. Subgroup analyses revealed that RFA increased the closure rate of GSV based on data from eight studies published after 2016, with a significant difference and no heterogeneity. The contrasting results between He et al's study and our study may be attributed to the fact that He et al only investigated the occlusion rate of GSV based on two articles published before 2016. In addition, the difference between the devices used before and after 2016 may be a major reason leading to different closure rate. Before 2016 in our study, the VNUS ClosureFAST system, the ClosurePLUS system, the Celon RfiTT system, and an 810-nm or a 980-nm laser system were used in RFA group and LA group, respectively, whereas the VNUS ClosureFAST system and a 980-nm or a 1470-nm laser system were the main equipment in RFA and LA groups, respectively, in studies published after 2016. The VNUS ClosureFAST system and 1470-nm laser system had a better effect than the ClosurePLUS system and 980-nm laser system.^{46,47}

Furthermore, our results demonstrated that RFA can decrease pain scores compared with LA within the first 3 days and 7 to 10 days postoperatively, which was not observed in He et al's study. The difference between the two studies might be due to the limited number of

papers reporting pain scores in He et al's study, leading to significant heterogeneity. Only two studies reported postoperative pain scores were higher for LA than for RFA.^{16,34} In another network meta-analysis comparing six interventions for LEVV management, it was found that complete closure of the treated vein within 6 months after intervention was higher with RFA than with LA. Additionally, the frequency of adverse events was higher with LA compared with RFA.⁴⁸

Furthermore, Bontinis et al indirectly demonstrated in their recent network meta-analysis comparing thermal and nonthermal endovenous ablation treatments for LEVV that RFA had a greater odds value for GSV closure compared with LA, and LA at 1470 nm increased the pain profile compared with RFA.⁴⁹ Additionally, Vangelis et al found that LA significantly increased the risk of postoperative paresthesia with a risk ratio of 6.96 when compared with RFA, which supported our findings that RFA decreased the OR of postoperative paresthesia compared with LA. In summary, the aforementioned analysis suggests that RFA is more advantageous than LA for LEVV treatment in terms of the closure rate of the treated GSV, pain scores, and postoperative paresthesia.

Thromboembolic events are serious complications after LEVV surgery, leading to swelling, pain in the affected limb, and even death. Post-thrombotic syndrome significantly impacts survival and quality of life.^{50,51} Fortunately, the incidence rate of venous thromboembolism is low in ETA for LEVV treatment. In our study, both RFA and LA had a low overall morbidity of VTEs, with rates of 0.84%, and the percentage was similar between RFA and LA. Dermody et al's study⁵² was also in agreement with our findings. However, some reports have suggested that the incidence of thromboembolism was higher with LA than with RFA and indicated a positive relationship between LA and the type of vein and increased thrombotic complications. Nonetheless, there were differences between our study and others. For example, in Benarroch-Gampel et al's study,⁵³ there were more older, obese, and diabetic patients in the RFA group compared with the LA group, and multiple veins were treated simultaneously. Aurshina et al's research¹¹ included patients who underwent RFA and LA for GSV, small saphenous vein, anterior accessory saphenous vein, and perforator veins, whereas our study focused only on data from ETA for GSV. These differences may explain the divergent outcomes between our study and others.

Another important factor in evaluating surgical treatment for LEVV is the recurrence of VVs, which can be classified as clinical or anatomical recurrence. Previous studies comparing the incidence of VV recurrence between LA or RFA and HL/S of GSV showed no significant differences, but the reasons for recurrence were significantly different.⁵⁴ In our study, we specifically examined

the clinical recurrence of VVs and found that RFA had a lower recurrence rate (4.89%) compared with LA (6.82%), significantly lowering the odds value compared with LA with notable differences and no heterogeneity at the 1-year follow-up. A 3-year follow-up study by Rasmussen et al³¹ also reported that RFA reduced VV recurrence compared with LA, with rates of 14.9% vs 20.0%. A similar trend was observed in a 5-year follow-up, with recurrence rates of 18.7% for RFA and 38.6% for LA.⁸ However, contrary to these studies, Kheirelseid et al reported no significant difference in VV recurrence between LA and conventional surgery or when comparing LA with RFA at the 5-year follow-up.⁵⁵ It is worth mentioning that the recurrence of VVs in Elrasheid et al's study included both anatomical and clinical recurrence, whereas our study only considered clinical recurrence.

There were several limitations in our study. First, a few of the eligible studies were retrospective cohort studies, which may introduce selection bias. More RCTs comparing RFA and LA for LEVV treatment would be needed to provide level 1 evidence regarding their efficacy and safety. Second, although we included 26 studies, the primary or secondary outcomes were only provided in some of them, resulting in relatively limited data. Third, certain effects, such as quality of life, venous clinical severity score, recovery time to normal activity or work, and hospitalization expenses, were not analyzed owing to insufficient collected data in these aspects. Therefore, a more comprehensive comparison between RFA and LA in terms of their effectiveness would be needed in future research.

CONCLUSIONS

RFA and LA are effective and safe treatments for LEVVs. RFA has shown increased occlusion rates of treated GSV in recent years and has demonstrated a decrease in postoperative complications, such as burns, ecchymosis, paresthesia, postoperative pain scores, and recurrence of VVs compared with LA. RFA seems to be superior to LA in these aspects of LEVV therapy. Further well-matched RCTs are needed to confirm these findings.

AUTHOR CONTRIBUTIONS

Conception and design: WJ, YL, ZL, MH, HY, XQ
Analysis and interpretation: WJ, YL, ZL, MH, HY, XQ
Data collection: WJ, YL, ZL, MH, HY, XQ
Writing the article: WJ, YL, ZL, MH, HY, XQ
Critical revision of the article: WJ, YL, ZL, MH, HY, XQ
Final approval of the article: WJ, YL, ZL, MH, HY, XQ
Statistical analysis: WJ, YL, ZL, MH, HY, XQ
Obtained funding: WJ, XQ
Overall responsibility: XQ

DISCLOSURES

None.

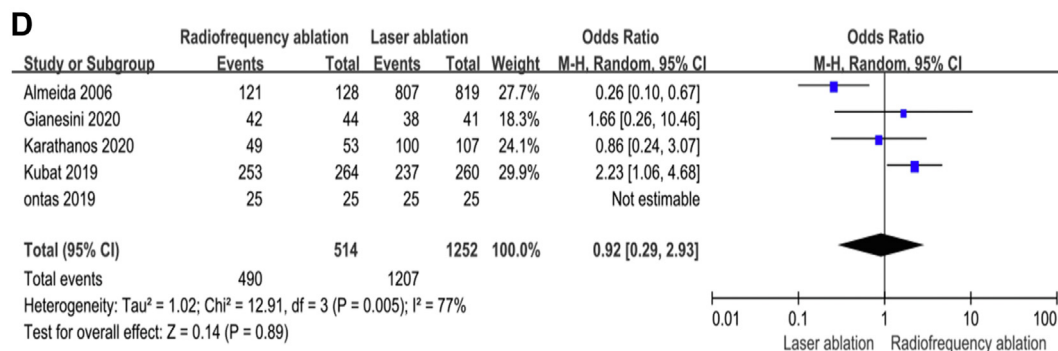
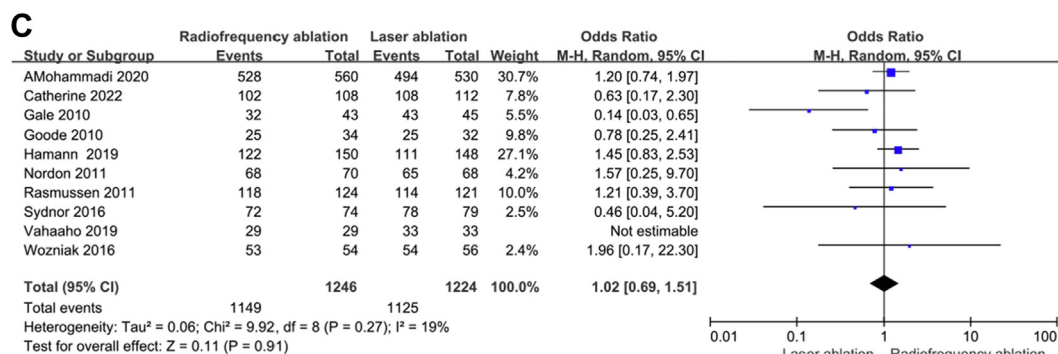
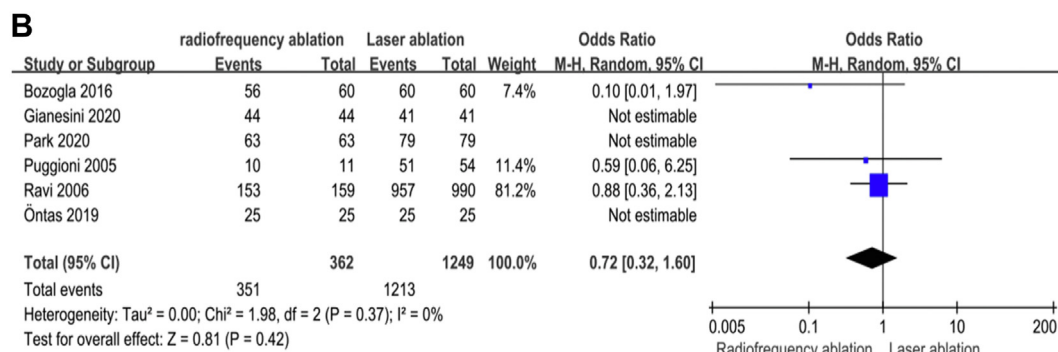
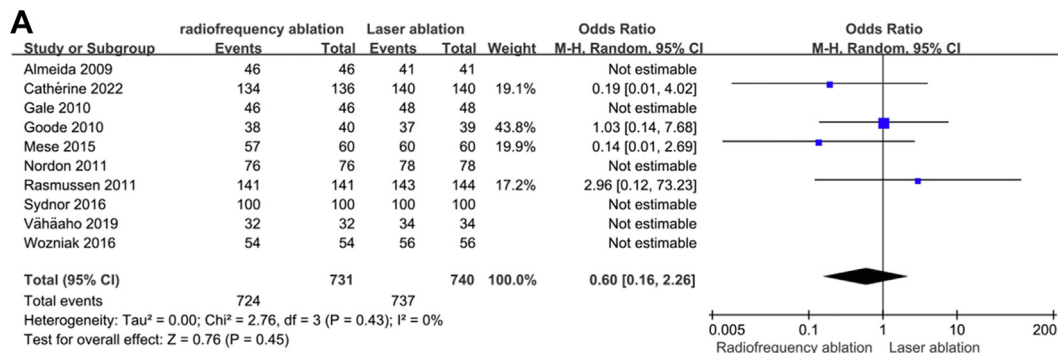
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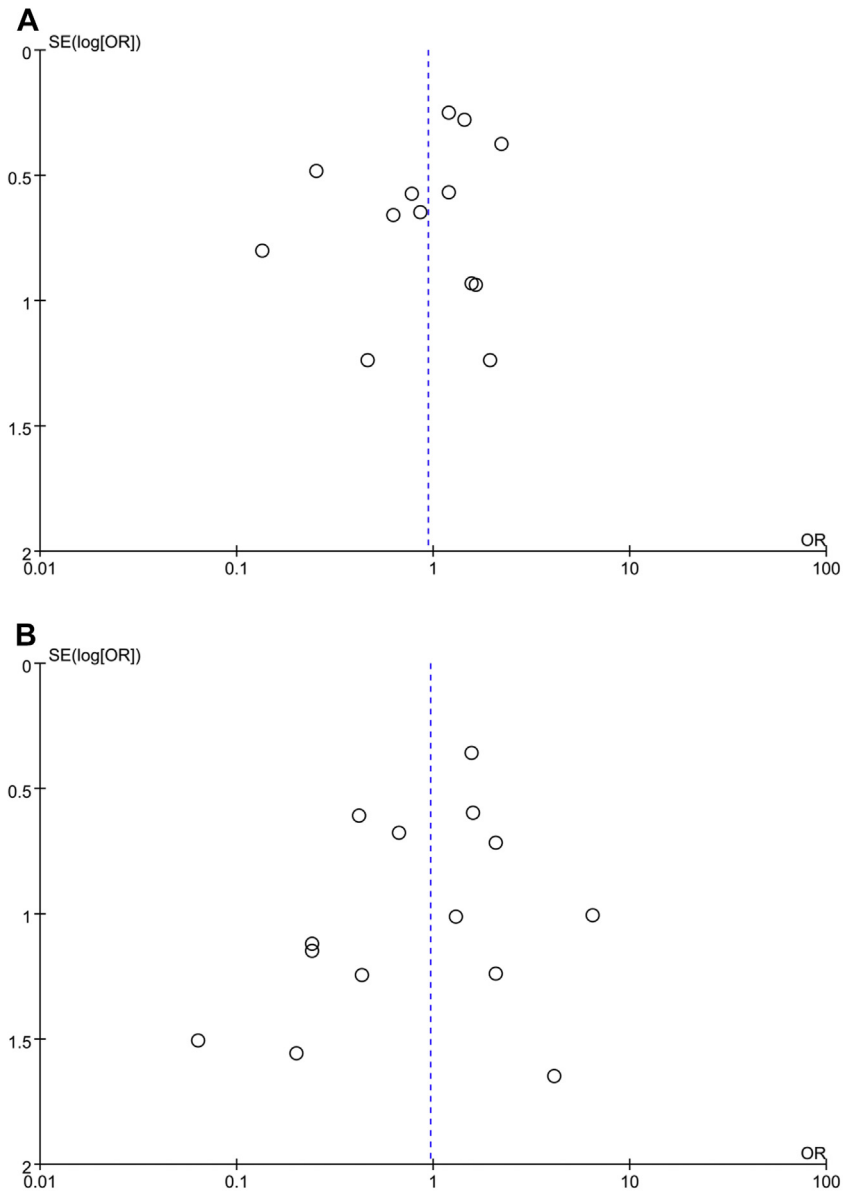
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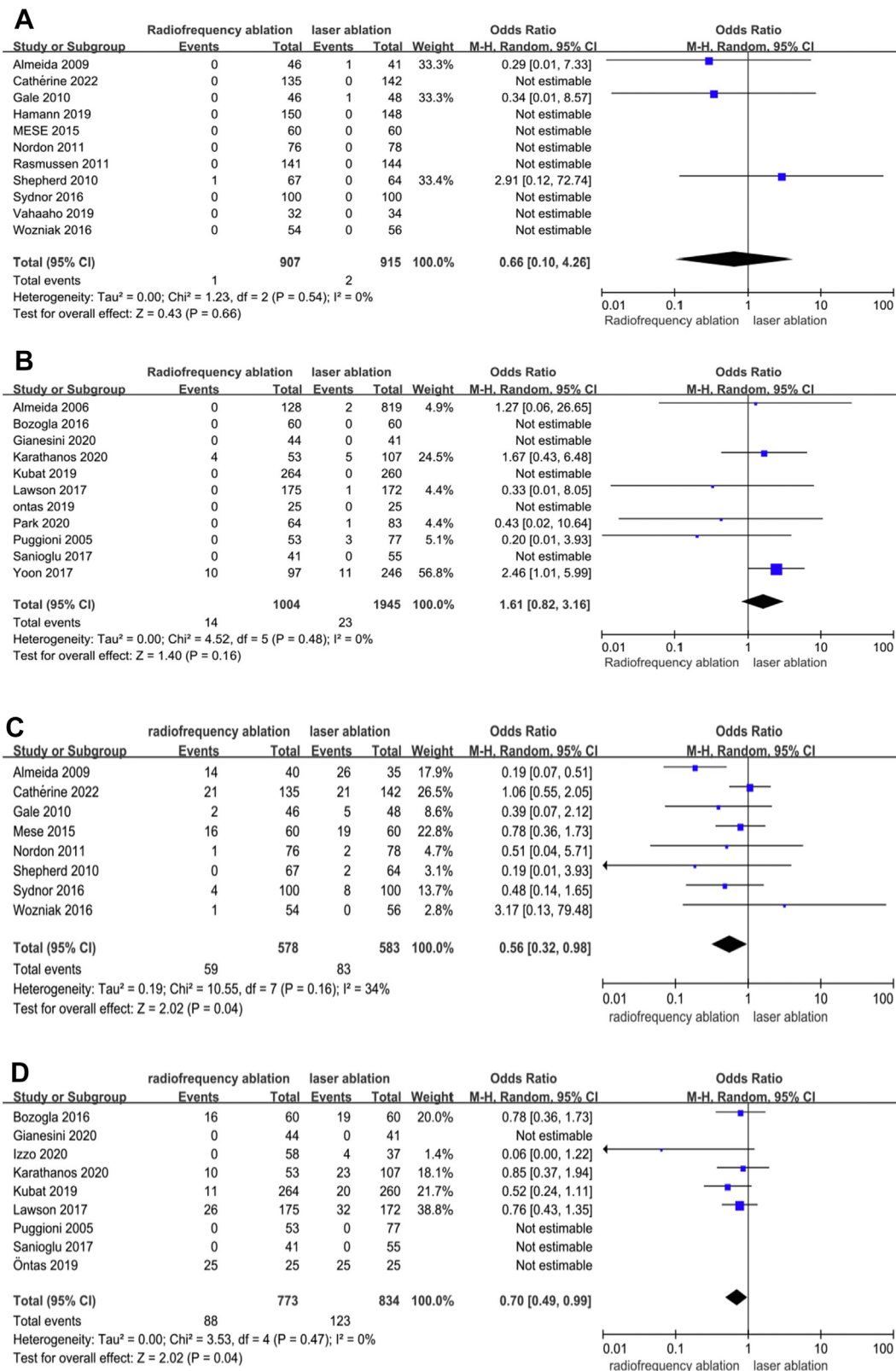
Additional material for this article may be found online at www.jvsvenous.org.



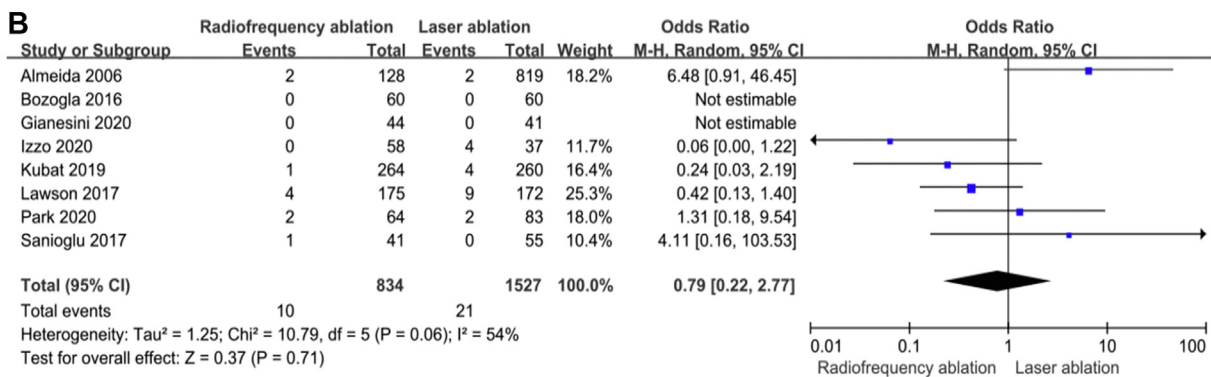
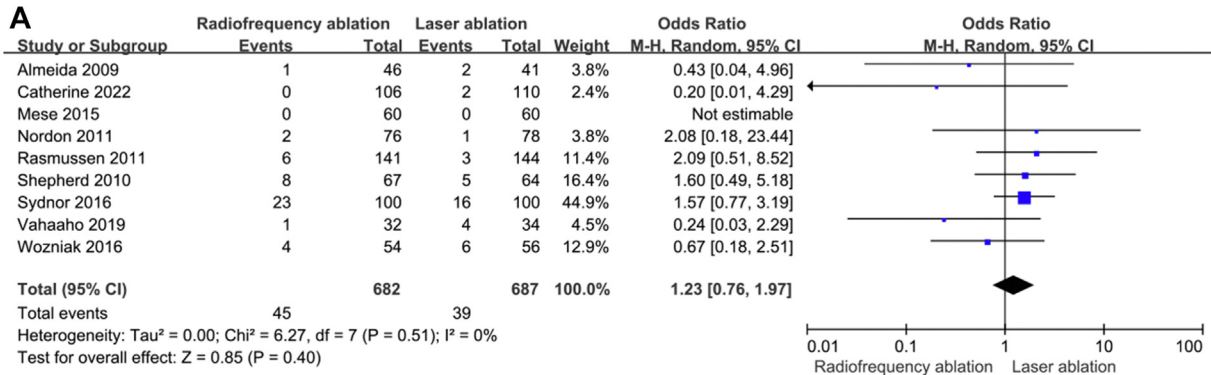
Supplementary Fig 1 (online only). Forest plots showing the odds ratio (OR) for occlusion rate of the treated great saphenous vein (GSV) with radiofrequency ablation (RFA) vs laser ablation (LA) in randomized controlled trials (RCTs) and cohort studies. **(A)** OR for occlusion rate at 1 month postoperative in RCTs. **(B)** OR for occlusion rate at 1 month postoperative in cohort studies. **(C)** OR for occlusion rate at 1 year postoperative in RCTs. **(D)** OR for occlusion rate at 1 year postoperative in cohort studies. *CI*, confidence interval; *M-H*, Manzel-Heinz.



Supplementary Fig 2 (online only). Funnel plots for **(A)** occlusion rate of the treated great saphenous vein (GSV) at 1 year postoperative and **(B)** paresthesia at 1 month postoperative. *OR*, odds ratio; *SE*, standard error.



Supplementary Fig 3 (online only). Forest plots showing the odds ratio (OR) for venous thrombotic event (VTE), burns and ecchymosis with radiofrequency ablation (RFA) vs laser ablation (LA) in randomized controlled trials (RCTs) and cohort studies. **(A)** OR for VTE in RCTs. **(B)** OR for VTE in cohort studies. **(C)** OR for burns and ecchymosis in RCTs. **(D)** OR for burns and ecchymosis in cohort studies. *CI*, confidence interval; *M-H*, Manzel-Heinz.



Supplementary Fig 4 (online only). Forest plots showing the odds ratio (OR) for parasthesia with radiofrequency ablation (RFA) vs laser ablation (LA) in randomized controlled trials (RCTs) and cohort studies. **(A)** OR for parasthesia in RCTs. **(B)** OR for parasthesia in cohort studies. *CI*, confidence interval; *M-H*, Manzel-Heinz.

Supplementary Table I (online only). Detailed search strategies

<p>Pubmed</p> <p>(((((great saphenous vein[Title/Abstract]) OR (chronic venous disorder[Title/Abstract])) OR (lower extremity vein[Title/Abstract]) OR (superficial venous disease[Title/Abstract])) OR (lower limb varicosity[Title/Abstract])) AND (((((Radiofrequency[Title/Abstract]) OR (Ablation, Radiofrequency[Title/Abstract])) OR (Radio Frequency Ablation[Title/Abstract])) OR (Ablation, Radio Frequency[Title/Abstract])) OR (Radio-Frequency Ablation[Title/Abstract])) OR (Ablation, Radio-Frequency[Title/Abstract])) AND ("Laser"[Title/Abstract] OR (((((((((((Q-Switched Lasers[Title/Abstract]) OR (Laser, Q-Switched[Title/Abstract])) OR (Lasers, Q-Switched[Title/Abstract])) OR (Q Switched Lasers[Title/Abstract])) OR (Q-Switched Laser[Title/Abstract])) OR (Pulsed Lasers [Title/Abstract])) OR (Laser, Pulsed[Title/Abstract])) OR (Lasers, Pulsed[Title/Abstract])) OR (Pulsed Laser[Title/Abstract])) OR (Continuous Wave Lasers[Title/Abstract])) OR (Continuous Wave Laser[Title/Abstract])) OR (Laser, Continuous Wave[Title/Abstract])) OR (Lasers, Continuous Wave[Title/Abstract])) OR (Masers[Title/Abstract])) OR (Maser[Title/Abstract]))))</p>
<p>EMBASE</p> <p>('great saphenous vein':ab,ti OR 'chronic venous disorder':ab,ti OR 'lower extremity vein':ab,ti OR 'superficial venous disease':ab,ti OR 'lower limb varicosity':ab,ti) AND (radiofrequency:ab,ti OR 'ablation, radiofrequency':ab,ti OR 'radio frequency ablation':ab,ti OR 'ablation, radio frequency':ab,ti OR 'radio-frequency ablation':ab,ti OR 'ablation, radio-frequency':ab,ti) AND (laser:ab,ti OR 'q-switched lasers':ab,ti OR 'laser, q-switched':ab,ti OR 'lasers, q-switched':ab,ti OR 'q switched lasers':ab,ti OR 'q-switched laser':ab,ti OR 'pulsed lasers':ab,ti OR 'laser, pulsed':ab,ti OR 'lasers, pulsed':ab,ti OR 'pulsed laser':ab,ti OR 'continuous wave lasers':ab,ti OR 'continuous wave laser':ab,ti OR 'laser, continuous wave':ab,ti OR 'lasers, continuous wave':ab,ti OR masers:ab,ti OR maser:ab,ti)</p>
<p>Cochrane Database</p> <p>((great saphenous vein):ti,ab,kw OR (chronic venous disorder):ti,ab,kw OR (lower extremity vein):ti,ab,kw OR (superficial venous disease):ti,ab,kw OR (lower limb varicosity):ti,ab,kw) AND (((Radiofrequency):ti,ab,kw OR (Ablation, Radiofrequency):ti,ab,kw OR (Radio Frequency Ablation):ti,ab,kw OR (Ablation, Radio Frequency):ti,ab,kw OR (Radio-Frequency Ablation):ti,ab,kw OR (Ablation, Radio-Frequency):ti,ab,kw) AND ((Laser):ti,ab,kw OR (Q-Switched Lasers):ti,ab,kw OR (Laser, Q-Switched):ti,ab,kw OR (Lasers, Q-Switched):ti,ab,kw OR (Q Switched Lasers):ti,ab,kw OR (Continuous Wave Lasers):ti,ab,kw OR (Continuous Wave Laser):ti,ab,kw OR (Laser, Continuous Wave):ti,ab,kw OR (Lasers, Continuous Wave):ti,ab,kw OR (Masers):ti,ab,kw OR (Maser):ti,ab,kw)</p>

Supplementary Table II (online only). Quality assessment of the included cohort studies according to the Newcastle-Ottawa scale (NOS)

Study	Selection			Outcome of interest not presented at the start of study	Comparability		Exposure	
	Representativeness of the exposed cohort	Selection of the nonexposed cohort	Ascertainment of exposure		Comparability of cohorts on the basis of the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of the follow-up of cohorts
Karathanos et al, 2020	★	★	★	★	★	★	★	★
Lawson et al, 2017	★	★	★	★	★	★	★	N/A
Yoon et al, 2017	★	★	★	★	★	★	★	N/A
Kubat et al, 2019	N/A	★	★	★	★	★	★	N/A
Gianesini et al, 2020	★	★	★	★	★	★	★	★
Öntas et al 2019	N/A	★	★	★	★	★	N/A	★
Izzo et al 2020	N/A	★	★	★	★	★	N/A	★
Sanioglu et al 2017	★	★	★	★	★	★	★	★
Almeida et al 2006	★	★	★	★	★	★	★	N/A
Puggioni et al 2005	★	★	★	★	★	★	★	N/A
Ravi et al 2006	★	★	★	★	★	★	★	N/A
Bozoglan et al 2016	N/A	★	★	★	★	★	N/A	★
Park et al, 2020	N/A	★	★	★	★	★	N/A	★

★, yes; N/A, not applicable.
This table identifies high-quality choices with a star. A study can be awarded a maximum of 1 star for each numbered item within the selection and exposure categories. A maximum of 2 stars can be given for comparability.