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ORIGINAL ARTICLE

Comparison of endovenous ablation techniques, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Extended 5-year follow-up of a RCT

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ABSTRACT

BACKGROUND: This study compares the outcome 5 years after treatment of varicose veins with endovenous radiofrequency ablation (RFA), endovenous laser ablation (EVLA), ultrasound guided foam sclerotherapy (UGFS) or high ligation and stripping (HL/S) by assessing technical efficacy, clinical recurrence and the rate of reoperations.

METHODS: Five hundred patients (580 legs) with Great Saphenous Vein (GSV) reflux and varicose veins were randomized to one of the 4 treatments. Follow-up included clinical and duplex ultrasound examinations.

RESULTS: During 5 years there was a difference in the rate of GSV recanalization, recurrence and reoperations across the groups, KM P<0.001, P<0.01, P<0.001 respectively. Thus 8 in the RFA group (Kaplan Meier [KM] estimate 5.8%), 8 in the EVLA group (KM estimate 6.8%), 37 (KM estimate 31.5%) in the UGFS group and 8 in the HL/S group (KM estimate 6.3%) of GSVs recanalized or had a failed stripping procedure. Nineteen (RFA) (KM estimate 18.7%), 42 (EVLA) (KM estimate 38.6%), 28 (UGFS) (KM estimate 31.7%) and 38 (HL/S) (KM estimate 34.6%) legs developed recurrent varicose veins. Within 5 years after treatment, 19 (RFA) (KM estimate 17%), 19 (EVLA) (KM estimate 18.7%), 43 (UGFS) (KM estimate 37.7%) and 25 (HL/S) (KM estimate 23.4%) legs were retreated.

CONCLUSIONS: More recanalization's of the GSV occurred after UGFS and no difference in the technical efficacy was found between the other modalities during 5-year follow-up. The higher frequency of clinical recurrence after EVLA and HL/S cannot be explained and requires confirmation in other studies.

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Key words: Varicose veins - Endovascular procedures - Saphenous vein - Therapeutics - Ablation techniques - Surgery.

Varicose veins are common and most often associated with reflux in the great saphenous vein (GSV).[1] Previously, the standard treatment has been high ligation and stripping (HL/S) of the GSV combined with phlebectomies, and several studies have shown improvement of symptoms and quality of life following such treatment.[2, 3] However, complications such as postoperative pain, wound infections and nerve damage has been reported frequently.[4] In addition, a high rate of recurrence is also a problem.[5] In recent years, endovenous ablation of the GSV with radiofrequency (RFA), laser (EVLA) or ultrasound guided foam sclerotherapy

(UGFS) has been widely accepted as alternatives to surgical stripping. Thus, in the USA guidelines as well as in the recommendations from the National Institute of Health and Excellence in Great Britain (NICE), thermo ablation is considered the preferred treatment, while ultrasound guided foam sclerotherapy is considered a second choice but is rated before surgery.[6, 7] The preference is primarily based on the patients recovery which, in some studies, appears to be easier following endovenous treatment.[8] Furthermore, several studies have reported excellent efficacy of endovenous treatments in the short and medium term, and in a few reports of longer-term follow-up that are beginning to emerge.[9-11] The present study was initiated in 2007 and compares RFA, EVLA, UGFS and HL/S. Short- and medium term results have been published previously.[12, 13] This publication reports the long-term (5-year) results with regards to technical efficacy and clinical recurrence based on ultrasound and clinical findings respectively.

Materials and methods

The study was conducted in two private surgical centers, which work under contract with the National Health Insurance in Denmark. The primary endpoint was closed or absent GSV. An open refluxing segment of the treated part of the GSV of 10 cm or more at follow-up was considered a failure to strip or ablate the vein (technical failure).[13] The GSV below the knee level was not treated or assessed at follow-up. Secondary endpoints were the presence of varicose veins during follow-up according to the REVAS classification and the frequency of reoperations. The REVAS classification is a clinical and ultrasound assessment, which includes true recurrences and residual veins, as well as varicose veins as a consequence of disease progression.[5] The details of the methodology have been previously described.[13] In brief, consecutive patients with symptomatic varicose veins and GSV incompetence, CEAP $C_{2\text{-}6}E_pA_sP_r$, were randomized using sealed envelopes to RFA, EVLA, UGFS or HL/S. The four groups were well matched for demographic data, CEAP classification and GSV details.[13] Exclusion criteria were duplication of the saphenous trunk or an incompetent anterior accessory saphenous vein (AASV), small saphenous or deep venous incompetence, previous deep vein thrombosis, arterial insufficiency, or a tortuous GSV rendering the vein unsuitable for endovenous treatment. All treatments and assessments were performed by one of three vascular and general surgeons with several years of experience in the treatment of varicose veins including endovenous treatments. Bilateral treatment was permitted, provided both limbs received the same treatment during the same operation. Patients who had undergone previous high ligation or phlebectomies were included in the trial. The patients were treated with one of the following methods: RFA (ClosureFast; Medtronic, Minneapolis, MN, USA), EVLA (ELVES, Ceralas D 980 or D 1470, bare fiber; Biolitec, Bonn, Germany), UGFS with Aethoxysclerol 3%, 2-mL solution mixed with 8-mL air according to the method of Tessari [14] (Polidocanol; Kreussler, Wiesbaden, Germany), or pin stripping. All treatments were performed in a treatment room under tumescent local anesthesia using a solution of 0.1% lidocaine with adrenaline and bicarbonate. A light sedation with midazolam and alfentanil was administered intravenously in most cases.

Surgery

The surgical procedure was carried out through a 4- to 6-cm incision in the groin, with flush division and ligation of the GSV and division and ligation of tributaries. The GSV was then removed to just below the knee using a pin stripper.

Thermoablation

The RFA procedure was performed according to the manufacturer's recommendations.[15] The GSV was cannulated just below the knee, or at the lowest point of reflux on the thigh. The fiber or catheter was advanced to 1 to 2 cm below the saphenofemoral junction and withdrawn during ablation. The EVLA procedure was performed under duplex guidance with a 980-nm diode laser for the first 17 legs, and a 1470- nm for the rest using 12-watt power and a bare fiber aiming at delivering 70 joules/cm vein. Access to the GSV was performed similarly to the RFA procedure.

Foam sclerotherapy

Foam was injected through one or two intravenous cannulas in the GSV at knee level and in the thigh. Be-

fore injection of the foam, the patient was placed in Trendelenburg position. The progression of foam in the GSV was followed with ultrasound to ensure a complete filling to the junction and subsequent spasm of the vein. When this was achieved, further injection was terminated.

Our protocol allowed re-treatment with foam in the UGFS group within the first month after the initial treatment.

All visible varicose veins present on the leg were removed by miniphlebectomies during the same procedure in all patients including the UGFS group. A mean of 15 phlebectomies were performed in the groups and a mean of 8 mL foam was used as previously described.[13]

When a leg reached the primary end point, an open refluxing segment of the GSV of more than 10 cm, or developed recurrent varicose veins it was excluded from further follow-up, because the treatment in such cases was considered to have failed. The 10 cm cut of value of GSV reflux was chosen arbitrarily, because no universally accepted value exists.[13]

Patients who did not show up for a scheduled follow-up visit, received a reminding letter for each occasion.

The local ethics committee approved the study and all patients gave informed consent.

Assessments

The patients were examined at the time of randomization, and after 3 days, 1 month, 1, 3, 4 and 5 years. Because a high number of patients, particularly in the RFA group, did not show at 4 years, they were invited up to 2 times by letter or phone call at 5 years, if they did not show up. Examinations included clinical and ultrasound examination.

Any surgical or endovenous procedure for varicose veins after the primary operation was defined as a re-operation, but were only performed after the patient reached the primary or secondary endpoint. In previous publications we reported quality of life (QOL) findings, including disease specific Aberdeen Varicose Vein Symptom Severity Score (AVVSS) and the Medical Outcomes Study Short Form 36 (SF-36; Quality Metric, Lincoln, RI, USA) until 3 years after the procedure.[12, 13] In the present study however, we excluded such analyses, because we did not record the information in patients who had previously reached an endpoint of recanalization or clinical recurrence. The same is true for VCSS analyses. Thus, when a leg reached the primary or secondary endpoint it was excluded from further follow-up.

Statistical analysis

The study was designed as a superiority trial. *A priori* sample size calculations indicated that, to detect a 15 per cent difference in closed or absent GSVs between the groups with α=5 and β=20 (80% power), 120 legs would be needed in each group. The sample size was based on a χ^2 test for difference in proportions between, assuming incidence rates of 85% and 70% in two groups respectively. The sample size based on two groups and a χ^2 test served as a proxy for the more complicated power calculation based on Kaplan-Meier statistics. Analyses were assessed for the full analysis set, comprising all patients undergoing treatment. There were no imputations of missing values. The primary endpoint, closed or absent GSV, and secondary endpoints, recurrent varicose veins and frequency of reoperations, were analyzed by Kaplan-Meier (KM) and Cox survival methods as "time to first" endpoints. The P value represents a comparison across all treatment groups (*i.e*. testing the hypothesis that there are equal treatment effects across all groups). No multiple testing corrections were performed. The analysis was performed in SAS version 9.1 (SAS Institute, Cary, NC, USA).

Results

A total of 500 patients (580 legs) were randomized to the four groups, with 125 (148 legs) in the RFA group, 125 (144 legs) in the EVLA group, 125 (145 legs) in the UGFS group and 125 (143 legs) in the HL/S group. At 5-year follow-up there were 61 patients (68 legs) for analysis in the RFA group, 48 patients (53 legs) in the EVLA group, 42 patients (44 legs) in the UGFS group and 55 (58 legs) in the HL/S group. This is specified in the CONSORT diagram (Figure 1). Baseline patient characteristics are shown in Table I. The groups were comparable with regards to patient characteristics and CEAP classification of the treated legs. Seven, 9, 4, and 8 patients had undergone previous high ligation and/or phlebectomies in the RFA, EVLA, UGFS, and HL/S group, respectively. Five patients in the UGFS group received re-treatment with foam within the first month.[13]

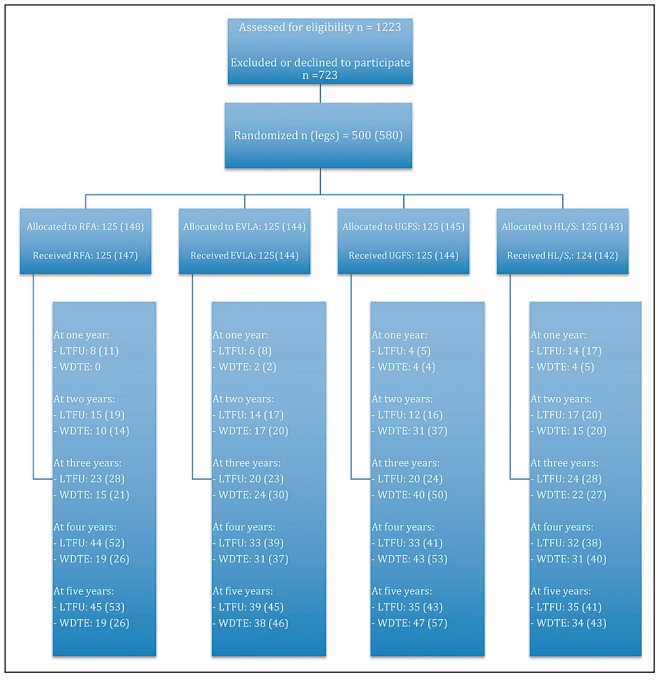

Figure 1.—CONSORT flow chart.
Numbers are in N.(legs), and are accumulated over time.
EVLA: endovenous laser ablation; RFA: radiofrequency ablation; UGFS: ultrasound guided foam sclerotherapy; HL/S: high ligation and stripping; LTFU: lost to follow-up; WDTE: withdrawn due to event.

Detailed information regarding treatment characteristics has been published before.[13]

GSV data

The KM plot of the open, refluxing GSVs are shown in Figure 2. The KM figures represent time to the event, and the probability on the plots is freedom from the event. The KM estimates are 1-KM and represent the

TABLE I.—*Baseline characteristics.*

	RFA	EVLA	UGFS	HL/S
N. patients/legs	125/147	125/144	125/144	124/142
N. bilateral	22	19	20	18
Age, years [a]	51 (23-77)	52 (18-74)	51 (18-75)	50 (19-72)
Male [b]	30	28	24	23
CEAP C2-C3 [c]	92	95	96	97
CEAP C4-C6 [c]	8	5	4	3

EVLA: endovenous laser ablation; RFA: radiofrequency ablation; UGFS: ultrasoundguided foam sclerotherapy; HL/S: high ligation and stripping; [a] Mean (range); [b] % of patients; [c] % of legs.

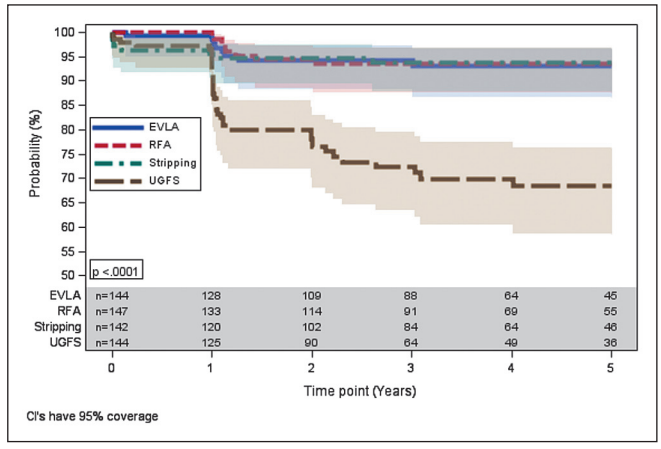

Figure 2.—Kaplan-Meier (KM) plot of open refluxing great saphenous veins (GSVs). The KM figures represent time to the event. CIs: confidence intervals; EVLA: endovenous laser ablation; RFA: radiofrequency ablation; UGFS: ultrasound guided foam sclerotherapy.

percentage of patients who had technical failure, recurrent varicose veins, or reoperation. During 5 years the highest failure rate was seen in the UGFS group. Thus 8 (KM estimate, 6.8%), 8 (KM estimate, 6.8%), 37 (KM estimate, 31.6%), and 8 (KM estimate, 6.3%) of GSVs were recorded as having open segments of 10 cm or more during the 5-year follow-up, in the RFA, EVLA, UGFS, and HL/S group respectively (P<0.001). Open GSV's without reflux were not observed. RFA, EVLA and HL/S were each tested against UGFS and there was a significant difference between UGFS and the other modalities separately (P<0.001). As a sensitivity analysis, the endpoint was analyzed using a Cox regression model, adjusted for whether or not patients had prior treatment of varicose veins. Such association was not found (Effect of prior teatments in cox model, P=0.3742).

Clinical recurrence and pattern of reflux

The KM plot of legs with recurrent varicose veins is shown in Figure 3. Recurrent varicose veins were recorded in 19 (KM estimate, 18.7%), 42 (KM estimate, 38.6%), 28 (KM estimate, 31.7%), and 38 (KM estimate 34.6%) legs during the 5 years in the RFA, EVLA, UGFS, and HL/S group, respectively (P<0.001). Table II shows the pattern of reflux and nature of sources in legs with recurrent varicose veins. More patients in the UGFS group had reflux in the groin compared with the

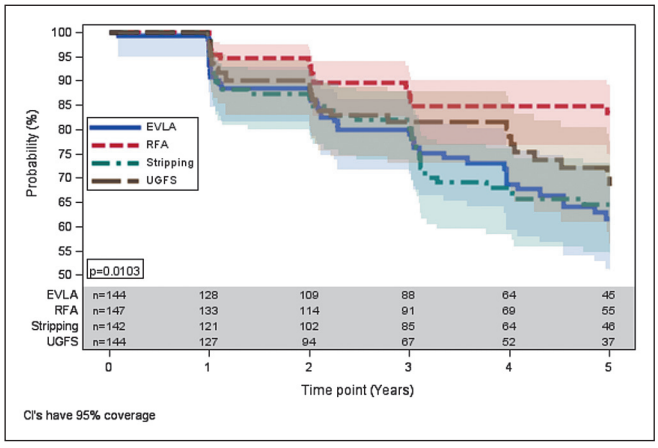

Figure 3.—Kaplan-Meier (KM) plot of recurrent varicose veins.
The KM figures represent time to the event. Cis: confidence intervals; EVLA: endovenous laser ablation; RFA: radiofrequency ablation; UGFS: ultrasound guided foam sclerotherapy.

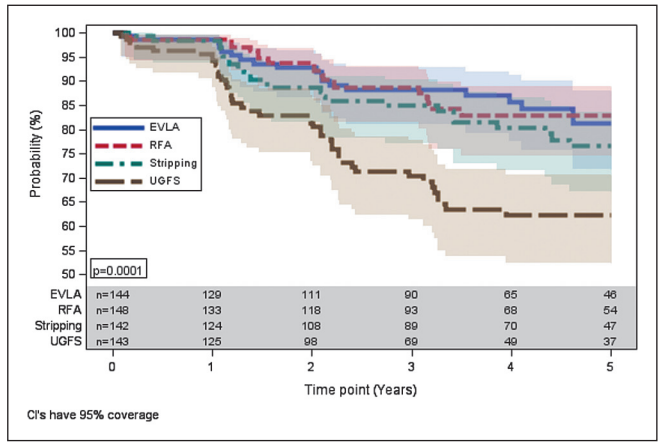

Figure 4.—Kaplan-Meier (KM) plot of reoperations.
The KM figures represent time to the event. CIs: confidence intervals; EVLA: endovenous laser ablation; RFA: radiofrequency ablation; UGFS: ultrasound guided foam sclerotherapy.

TABLE II.—*Topographical sites of REVAS. Number of recurrences, pattern of reflux and nature of sources.*

	RFA	EVLA	UGFS	HL/S	P [b]
N. of legs treated	147	144	144	142	
Clinical recurrence [a]	19 (13%)	42 (29%)	28 (19%)	38 (27%)	0.0032
Reflux in the groin [a]	0	2	12	2	<0.0001
Reflux in the thigh [a]	17	25	24	24	0.4817
Reflux in the popliteal fossa [a]	1	1	2	1	0.8942
Reflux in lower leg, ankle and foot [a]	19	31	21	24	0.2202
Other [a]	0	0	2	0	0.1099
Same site	10	14	23	13	0.068
Tech. failure	7	8	20	6	<0.0001
Tact. failure	0	0	0	2	0.1
Neovasc.	5	8	1	10	0.041
Uncertain	3	2	1	3	0.75
Mixed	0	1	2	0	0.297
Diff. site	14	24	13	29	0.01
persistent	0	1	3	3	0.26
New	19	29	13	29	0.016
Uncertain	0	0	0	3	0.027

REVAS: recurrence after varicose vein surgery; RFA: radiofrequency ablation; EVLA: endovenous laser ablation; UGFS: ultrasound-guided foam sclerotherapy; HL/S: high ligation and stripping; [a] N. of legs (% of total leg); [b] P values based on χ^2 test for the difference in proportions between groups.

other groups (P<0.001). There were significantly more patients with neovascularization in the HL/S group (P<0.05). As a sensitivity analysis, the clinical recurrence was analyzed using a Cox regression model, adjusted for whether or not patients had prior treatment of varicose veins. This was found to be statistically significant (P<0.001), with a hazard ratio 0.32, suggesting a higher probability of clinical recurrence had the patient had prior treatment. Whether patients were bilateral or not was also found to be statistically significant (P=0.006), with a hazard ratio of 0.60, suggesting a higher probability of clinical recurrence if the patient was bilateral.

Reoperations

The KM plot of legs with retreatment is shown in Figure 4. Nineteen (KM estimate, 17%), 19 (KM

estimate, 18.7%), 43 (KM estimate, 37.7%), and 25 (KM estimate, 23.4%) legs were retreated in the RFA, EVLA, UGFS, and HL/S group, respectively, during the 5-year follow-up (P<0.001). RFA, EVLA and HL/S were each tested against UGFS and there were significantly more reoperations in the UGFS group when compared to the other groups separately (P<0.001). Most patients were treated with UGFS, in some cases combined with phlebectomies, which is standard practice in our clinics.

Discussion

In the present study, significantly more patients in the UGFS group developed recanalization in the GSV, compared with the other groups. The majority of recanalizations appeared within the first year. These findings are in line with other studies.[16-18] A recent study compared conventional surgery, EVLA and UGFS with follow-up to 5 years.[10] The authors found a substantially higher failure rate after UGFS than our study. One explanation may be the small volume of foam, mean 4 ml per vein, which is only half of the amount used in our study.[13] Our protocol allowed re-treatment within the first month after the initial treatment, but only five patients received such treatment.[13] If we had allowed further treatments in the UGFS group, the occlusion rate would undoubtedly have improved. Recanalization in the HL/S group represents technical failures, such as snapping of the vein, and occurred in eight legs. We found no difference in failure rates between HL/S and thermo ablation. Other studies have reported such finding as well.[9, 17, 19, 20] The clinical recurrence, as defined by the presence of varicose veins after treatment (REVAS) [5] was high in all groups. This problem is well known and clinical recurrence has been shown to reach 65% eleven years after primary treatment.[21] In our study, the RFA group showed the lowest recurrence rates, with the HL/S and EVLA group showing the highest rates. The difference was statistically significant. Clinical recurrence may be caused by technical failure, strategic failure, neovascularization or progression of disease.[5] Our study was unable to show an association between clinical recurrence and recanalization of the GSV. Perhaps because legs reaching the primary end point were excluded. Others have shown, that clinical recurrence may be independent of the status of the GSV following stripping compared to high ligation.[21] However, if we had treated the GSV below the knee, clinical recurrence might have been less, but this was not routine treatment policy in our clinics, and we intended to simulate Pin stripping in the endovenous groups. Pin stripping is normally carried out to just below the knee.[22] Longer term follow-up could be justified to clarify such association. However, the topical site of REVAS might have been influenced by the fact that patients reaching the primary or secondary end points were excluded. Neither did clinical recurrence seem to be associated with the number of phlebectomies because there were no difference in the number of phlebectomies between the groups.[13] Thus, our data offer no explanation to the difference in clinical recurrence between the groups. If patients with clinical recurrence were more likely to attend for follow-up, this would make recurrence seem more frequent than it actually was. Significantly more patients in the UGFS group developed recurrence in the groin. This was a manifestation of GSV recanalization. We could not confirm previous reports that recurrence of reflux in the groin is more frequent after surgery compared to thermoablation.[23, 24] However, the source of recurrence was only sought for in legs with recurrent varicose veins, because our recordings were based on the REVAS classification.[5] Hence neovascularization was not investigated systematically in all legs.

There were more reoperations in the UGFS group compared with the other groups. This was due to more recanalizations. The vast majority of re-treatments were performed with foam sclerotherapy. In our clinics it is common practice to offer re-treatment to patients with recanalization of the GSV following primary treatment. Thus the patients receiving reoperations did not necessarily have symptoms or recurrent varicose veins.

Limitations of the study

A shortcoming of this study is the fact that it was not blinded. In practice it is not possible to blind the current treatments for the patients. However, blinding of the observer and leaving out traces of the treatment modality could potentially have been done. Another limitation is that legs would be excluded if the primary end point was reached or the leg developed re-

current varicose veins. Thus, the fact that legs were excluded when reaching one end point, might have influenced the analysis of the other. As a result, the study was not designed to investigate the longer term consequences of recanalization with regards to QOL and clinical recurrence. However, such information is considered important and frequently used in more recent and other studies.[9, 10, 17] A relatively high number of patients did not show up for all follow-up visits despite a scheduled visit and a reminding letter. This is also a limitation of the study. However, the number of patients who came for examination, is high compared to other studies.[9-11] Thus, our finding that RFA, EVLA and HL/S are more efficient methods technically than UGFS is robust.

According to our treatment methodology we did not treat the GSV below the knee. Treating the GSV from the lowest point of reflux might improve outcome.[22] GSV reflux below the knee in our study population was undoubtedly high as has been shown in other studies.[25, 26] Furthermore, the fact that some patients had undergone previous treatment for varicose veins influenced clinical recurrence. Still, it could not explain the higher frequency of REVAS in the EVLA group.

Conclusions

In conclusion, our study demonstrates, that recanalization of the GSV occurred frequently after UGFS, whereas no difference in the technical efficacy was observed in the other modalities in a 5-year period of follow-up. The higher frequency of clinical recurrence after EVLA requires confirmation in other studies.

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