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복재정맥 부전에 대한 980-nm 다이오드 레이저를 이용한 치료와 전통적인 발거술 간의 비교: VCSS 점수와 재발에 의한 중기 임상 결과

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Comparison of Endovenous Treatment Using a 980 nm Diode Laser versus Conventional Stripping for Truncal Saphenous Vein Incompetence: Mid-term Results by VCSS Score and Recurrence

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Background: The aims of the present study were to assess and compare mid-term clinical outcomes including recurrences between endovenous laser therapy (EVLT) and stripping. ***Material and Method:*** Between January 2007 and February 2010, 318 limbs in 237 patients with saphenous truncal varicosities were treated by laser energy using a 980 nm diode or were treated with conventional stripping. At the initial visit and at 1, 2, 6, 12, 18, 24, and 36 months postoperatively, clinical examination and questioning for Venous Clinical Severity Score (VCSS) as well as duplex ultrasonography were done. In order to compare clinical outcomes between the two treatment groups, EVLT versus stripping, all data were processed and analyzed. ***Result:*** There were no significant differences between the two treatment groups in the extent of the reflux and the number of insufficient perforating veins. The in EVLT and the stripping group at 12 months were 90.3±4.5% and 93.9±4.2%, respectively ($p>0.05$). Total recurrence rates were 4.4% in the EVLT group and 1.5% in the stripping group ($p>0.05$). In both groups, the VCSS scores were significantly reduced at week 1, 1 month, and 2 months after EVLT or stripping ($p<0.001$). ***Conclusion:*** Efficiency in eliminating truncal saphenous vein incompetence and reducing venous clinical severity were equal in the two treatment groups.

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Key words: 1. Venous disease
2. Saphenous vein
3. Varicose vein
4. Laser

INTRODUCTION

As a less invasive alternative to conventional stripping in the treatment of great saphenous vein (GSV) insufficiency, endovenous laser therapy (EVLT) has gained popularity rapidly due to its high degree of safety and efficiency in treating the primary varicose veins and reflux[1-3]. In addition, even for small saphenous vein (SSV) which has been much less

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frequent subject for EVLT or surgery than GSV, several good results of the endovenous laser ablation have been reported in recent years[4,5]. Many clinicians offer this EVLT as the treatment of choice to patients with venous reflux[6].

However, comparative data on the recurrence as well as clinical severity follow-up after EVLT and stripping have only been described to a limited extent[7,8]. In order to widely accept the EVLT as a proper replacement therapy to conventional stripping, much more data from well-performed clinical evaluation with adequate follow-up are essential. The present study describes the mid-term comparative result of the treatment with either EVLT or conventional stripping in a prospective manner.

The aims of the present study were to assess and compare the mid-term clinical outcomes including recurrences between EVLT and stripping.

MATERIAL AND METHOD

This prospective, non-randomized study included 237 patients with 318 limbs, among whom 133 patients with 183 limbs underwent endovenous laser therapy (EVLT) and 104 patients with 135 limbs underwent stripping. All patients enrolled in this study from January 2007 untill February 2010 had truncal saphenous incompetence in great saphenous vein (GSV) or small saphenous vein (SSV). All limbs had preoperative venous duplex ultrasound scanning performed by the surgeon who performed operation. Truncal saphenous vein incompetence was defined by reflux time >0.5 seconds by duplex imaging[9]. The reflux was examined in the standing position and measured after manual compression of the calf. Bilateral treatment was also included in this study, if both limbs received the same treatment during the same operation.

All the operations were performed under the spinal anesthesia by a single surgeon. In EVLT, 980-nm diode laser using pulse mode with 2.0-second impulse, 1-second pause was used. When the reflux lasting more than 0.5 second presented at the saphenofemoral junction, high ligation was done. If high ligation was not needed, the tip of the optic fiber was positioned 2 cm below the saphenofemoral junction[10]. In stripping group, invagination stripping was performed through an oblique groin incision. Most of the tributaries were not ligated or divided if they are not so large or tortuous. In both groups, non-truncal varicosities were removed by ambulatory phlebectomy at the time of operation.

The patients attended follow-up at 1week and at 1, 2, 6, 12, 18, 24, and 36 months postoperatively. At the initial visit to out-patient office, a clinical examination and questioning for VCSS record as well as duplex ultrasonography were performed, and the CEAP (Clinical severity, Etiology, Anatomy, Pathophysiology) stage was determined. At every follow-up visits, duplex ultrasound scanning and VCSS recording were performed. In order to compare the clinical outcomes between the two treatment groups, EVLT versus stripping, all data were processed and analyzed.

The definition of recurrence included the existence of a reconnection with the femoral vein on color-flow duplex ultrasound scanning concurrent with GSV insufficiency[11], re-canalization which means opened segment >5 cm in length, and newly detected non-truncal varicose vein and reflux. When the opened segment of the treated truncal vein was detected by duplex ultrasound at the first 1 month, it was taken for remnant reflux regardless of the lenghth of opened segment.

Statistical analysis was performed with the SPSS software package (version 11.0, SPSS Inc, Chicago, IL). Comparison between the two groups was performed using the unpaired Student's t-test and chi-square test (Pearson chi-square and Fisher exact tests) for categorical variables. For the VCSS, intergroup comparisons were made by Mann-Whitney U test and intra-group comparison by Friedman test. The time to recurrence was analysed using log-rank statistics. All results were expressed as the mean±standard deviation, and a p-value of less than 0.05 was considered statistically significant.

RESULT

The two groups were comparable and well matched for the demographic data, pretreatment C category of the CEAP classification (Table 1). The majority of the patients in both groups were C2 and less than 5% of the patients in each group were C4.

Details of the treated veins and laser energy profiles are summarized in Table 2. The numbers of treated GSVs were

Table 1. Patient characteristics and C catergory of the CEAP classification

Characteristics	EVLT	Stripping
No. of patients/legs	133/183	104/135
Age (yr)	49.3±12.0	50.4±13.8
Sex (F/M)	78/55	53/51
Weight (kg)	63.8±10.7	66.5±11.1
Height (cm)	161.9±8.5	163.2±9.1
BMI	24.3±3.0	24.9±3.6
CEAP, No. (%)		
C2	98 (73.7)	85 (81.7)
C3	25 (18.8)	15 (14.5)
C4a	6 (4.5)	2 (1.9)
C4b	2 (3.0)	2 (1.9)

EVLT=Endovenous laser therapy; BMI=Body mass index; CEAP=Clinical severity, Etiology, Anatomy, Pathophysiology.

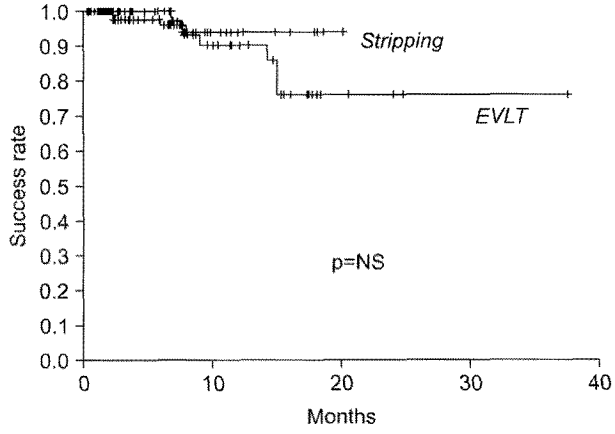


Fig. 1. Kaplan-Meier plot of recurrence indicating the successful maintenance of primary elimination of the truncal saphenous vein reflux (EVLT=Endovenous laser therapy).

Table 2. Details of treated veins and laser energy used

Characteristics	EVLT	Stripping	p-value
No. of limbs	183	135	-
Right GSV	60	61	-
Left GSV	71	44	-
Right SSV	23	17	-
Left SSV	29	13	-
Diameter, mm	7.2±1.9	8.3±2.0	0.006
Treatment extent (%)			
High ligation at SFJ/ total GSV	71/131 (54.2)	105/105 (100)	-
High ligation at SPJ/ total SSV	21/52 (40.4)	30/30 (100)	-
To distal thigh level/ total GSV	16/131 (12.2)	13/105 (12.4)	NS
To below knee level/ total GSV	94/131 (71.8)	66/105 (62.8)	NS
To ankle level/ total GSV	21/131 (16.0)	26/105 (24.8)	NS
Ligation of IPV (%)	56 (30.6)	44 (32.6)	NS
Ambulatory phlebectomy (%)	144 (78.7)	123 (91.1)	0.009
Laser energy density		-	-
Total energy, J	3076.8±1,507.9	-	-
Energy delivery, J/cm	82.4±25.1		

EVLT=Endovenous laser therapy; GSV=Great saphenou vein; SSV=Small saphenous vein; SFJ=Saphenofemoral junction; SPJ=Saphenopopliteal junction; IPV=Insufficient perforating vein.

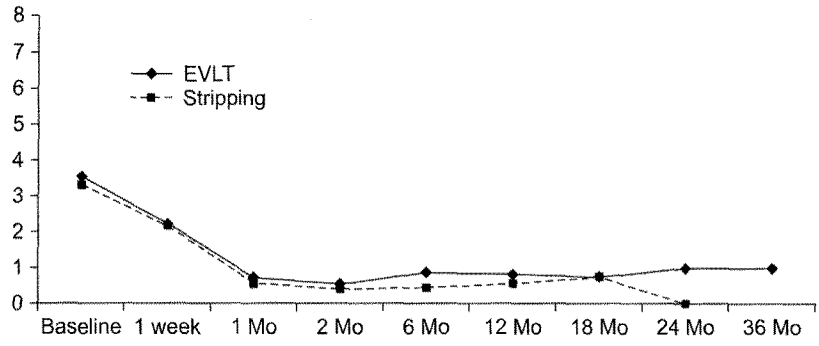
Table 3. Comparison of recurrence data in patients treated with stripping or EVLT

n=limbs	EVLTn =183	Strippingn =135	p-value
Recurrence proven by USG (%)	8 (4.4)	2 (1.5)	0.192
Recannalization	6		-
Reflux into the AAGSV	1	1	-
Reflux in the groin	0	1	-
Reflux in thigh perforators	0		-
Reflux in lower leg perforators	1		-
Residual focal reflux at postop. 1 month (%)	4 (2.2)	1 (0.7)	0.389

EVLT=Endovenous laser therapy; USG=Ultrasonography; AAGV=Anterior accessory great saphenous vein; postop.=Postoperative day.

much larger than those of SSVs; 131 (71.6%) in EVLT and 105 (77.8%) in stripping group. The mean diameter of saphenous truncal veins in stripping group which was measured at mid-thigh or proximal calf level was significantly larger than that in EVLT group (p=0.006). In stripping group, 100% of the patients underwent high ligation. Most of the truncal saphenous veins showed reflux to the below-knee level on duplex ultrasound examination in both groups. There were no significant difference in the extent of the reflux and the number of insufficient perforating veins between the two treatment groups. In terms of laser energy density, mean amounts of energy delivered to GSVs and SSVs were similar between them.

The successful maintenance rates of primary elimination of the truncal saphenous vein reflux were not significantly different over time between the two treatment modalities (Fig.



	Baseline	1 week	1 Mo	2 Mo	6 Mo	12 Mo	18 Mo	24 Mo	36 Mo
EVLT	3.56	2.25	0.74	0.54	0.87	0.82	0.77	1.00	1.00
Stripping	3.32	2.13	0.57	0.4	0.46	0.57	0.71	0.00	
Mann-Whitney p-value	0.318	0.445	0.183	0.078	0.028	0.034	0.158	0.343	

Fig. 2. Comparison of VCSS scores (mean) between EVLT and Stripping group (VCSS=Venous clinical symptoms score; EVLT=Endovenous laser therapy; Mo=Months).

1). The successful maintenance rates in EVLT and stripping group at 12 months were 90.3±4.5% and 93.94.2% respectively (p=NS). Total recurrence rates were 4.4% in EVLT and 1.5% in stripping group (p=NS)(Table 3).

The improvement of venous clinical severity was plotted on the VCSS graph in Fig. 2. In both groups, the VCSS scores were significantly reduced at the first 1 week, 1 month, and 2 months after EVLT or stripping ($p<0.001$). Comparing the VCSS score between the two treatments, the level of improvement of the venous symptom was significantly higher in stripping group than in EVLT at the first 6 months (p=0.028) and 12 months (p=0.034) after operation

DISCUSSION

The present study demonstrated that the recurrence rates of the two treatment groups, EVLT and stripping, were not significantly different. Although a maximum follow-up of the patient in this study was more than 3 years, the statistically reliable follow-up duration for appropriate comparison between the two groups was about 13 months and, at this time, the recurrence rates of EVLT and stripping were 6.1% and 9.7% respectively. In fact, the mid-to-long-term recurrence rates which have been recently reported show relatively large discrepancies between them, from 6.6% at 2 years to 51% at 5 years[7,12-14]. This discrepancy might be due to the different definitions of the recurrence taken by the different authors.

Comparing the characteristics of the treated veins, the diameters in stripping group were significantly larger than those in EVLT group. This results is partly due to surgeon's intention to treat. There are many times when the large veins, especially when their diameters are more than 8 mm, are running tortuous and superficial course. In those cases, the author recommended the patients to undergo stripping rather than EVLT because EVLT has the risks of skin burn and the puncture of the vein wall during the difficult advance of the optic fiber. The most patients of this study underwent the ambulatory phlebectomy simultaneously regardless of the treatment groups. However, because the vast majority of the patients in stripping group had the severe branch varicosities as well as truncal saphenous vein reflux, 91% of the patients underwent simultaneous ambulatory phlebectomy, which made statistical difference in phlebectomy rates between the two groups.

In the analysis of laser energy used in EVLT group, the mean energy delivery was 82.4 joules/cm. According to an experienced author[15], early re-canalization after EVLT can be avoided if the laser energy used for ablation is more than 80 joules/cm. However, the studies of the most efficient and appropriate laser energies needed for great or small saphenous veins under various conditions are still rarely available. In addition, the author insisted that using the laser in continuous mode instead of pulse mode might reduce re-canalization. Another thing to be mentioned in this study is the fact that there was no deep vein thrombosis associated with the use of

endovenous laser ablation, though some authors[16] have reported the extension of saphenous thrombus into the femoral vein.

In this report, VCSS has been chosen to evaluate and classify changing features of venous disease after stripping or EVLT. According to a well summarized review article[17], the choice of a valid and reliable assessment tool is crucial. In patient-generated assessment tools, the 36-Item Short Form Health Survey (SF-36) and the Nottingham Health Profile are generic surveys (NHP), while The Chronic Venous Insufficiency Questionnaire (CIVIQ 1, 2), the Venous Insufficiency Epidemiological and Economic Study (VEINES), the Aberdeen Varicose Vein Questionnaire (AVVQ) and the Charing Cross Venous Ulceration Questionnaire (CXVUQ) are disease-specific instruments. In physician-generated tools, there are Venous Clinical Severity Score (VCSS) and Venous Segmental Disease Score (VSDS). The VCSS parallels CEAP clinical class[18] and can generate a more dynamic score to sensitively reflect the greatest change of venous sequelae in response to therapy[19].

This study showed the statistically significant improvement of the VCSS scores at 1 weak, 1 month, and 2 months postoperatively. The VCSS score plot in Fig. 1. demonstrated that clinical severities of the disease were similarly reduced most markedly at 2 months after the operation and then started to rise again gradually in both treatments. This finding indicates that the two treatments are equally efficient in eliminating truncal saphenous vein incompetency and improving venous symptoms at least in a short-term after operation. This early outcome and the general pattern of VCSS score are similar to other studies comparing endovenous laser ablation and stripping[14,20,21]. The results comparing endovenous laser ablation with stripping using VCSS tool has been rarely reported. Our VCSS curve over time showed that the level of improvement of the venous symptom was significantly higher in stripping group than in EVLT at the first 6 months ($p=0.028$) and 12 months ($p=0.034$) after operation. This transient intergroup difference is against the other similar report[14]. In this study, the mean duration between recurrence and operation was 8.6 months and the venous symptom related with recurrent varicosity would have developed with high probability around this time including 6 and 12 months. Considering the fact that the recurrence rates of the two groups were not significantly different over time, the VCSS is quite a sensitive tool. The small rebound of VCSS score after 6 months is thought to be associated with minor recurrences causing occasional pain and venous edema in most cases. However, all of the recurrent varicosities were treated so immediately by foam sclerotherapy (9 cases) or laser ablation (1 case) that VCSS score rebound did not deepen further afterwards into statistical significance.

Five cases of residual focal reflux were detected in the treated vein by the regular ultrasound examination performed at 1 month postoperatively. All of them were completely and simply closed by a single foam sclerotherapy which was performed under the guidance of duplex ultrasound on the outpatient base. This remnant reflux should be treated differently from the recurrent incompetence. The patients with such a small and focal reflux did not develop any symptom in this study and the cause of remnant reflux would be mostly a technical error. Therefore the cases of residual reflux did not counted as the recurrence. In terms of recurrence, the major causes were re-canalization in 6 patients and reflux into the AAGSV in 2 patients. Because all the recurrences developed after the first 6 months except only one case in which the re-canalization occurred at 2.2 months, tactical or technical errors are not believed to be the causative mechanism.

The major shortcoming of this study is the fact that the number of follow-up loss was not small. This made the power of mid-term prospective data weak. As the clinical results of the treated primary varicose veins are usually so good that many patients frequently loose the drive to re-visit hospital especially after 2-month follow-up. Therefore, extra-efforts will be taken to avoid the follow-up loss for successful performance of longer-term prospective study afterwards. Another shortcoming of the present study is non-randomization. Actually, larger veins with great tortuosity tended to treated by stripping procedure. This fact might have induced a selection bias which is the major problem faced in the study with retrospective design though.

CONCLUSION

The efficiency in the elimination of the truncal saphenous

vein incompetence and the improvement in venous clinical severity were equal in both treatment groups. This study also showed that recurrent varicose veins were well treated and their progression were also well interrupted by foam sclerotherapy.

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=국문 초록=

배경: 이번 연구의 목적은 정맥내 레이저 응고술(EVLT)과 발거술의 재발을 포함한 중기 임상 결과를 비교 평가하는 것이다. **대상 및 방법**: 2007년 1월부터 2010년 2월까지 237명의 환자에서 대복재 및 소복재 정맥류 318개를 대상으로 980-nm 다이오드 레이저 또는 전통적인 발거술을 시행하였다. 첫 방문과 수술 후 1, 2, 6, 12, 18, 24, 36개월째 외래를 방문한 모든 환자를 대상으로 듀플렉스 초음파 검사와 Venous Clinical Severity Score (VCSS) 기록을 위한 임상검사 및 설문조사를 시행하였다. EVLT 및 정맥류 발거술의 두 치료군 간의 임상 결과를 비교하기 위해 수집된 모든 데이터를 이에 맞게 가공하여 분석하였다. **결과**: 두 치료군 간에 관통정맥 부전의 수나 정맥 역류의 정도는 차이가 없었다. EVLT나 발거술로 대복재 및 소복재 정맥의 역류가 제거된 후 이 역류 제거 상태의 성공적인 유지율은 양 군간에 차이가 없었으며 12개월째 성공적인 유지율은 EVLT군이 90.3±4.5%, 발거술군이 93.9±4.2%였다. 전체적인 재발율은 EVLT군이 4.4%, 발거술군이 1.5%로 두 군간의 통계적인 차이는 없었다. VCSS 점수는 두 군 모두에서 수술 후 1주와 1개월, 2개월에 유의한 감소를 보였다. **결론**: 대복재 및 소복재 정맥 부전의 제거에 대한 효율성이나 정맥 부전으로 인한 임상 경과의 수술 후 개선 능력 등에 있어 EVLT와 발거술은 비슷한 결과를 나타냈다.

중심 단어 : 1. 정맥질환
2. 대퇴정맥
3. 정맥류
4. 레이저