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Comparative Study of Cryostripping and Endovenous Laser Therapy for Varicose Veins: Mid-Term Results

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Background: Conventional stripping is considered to be the standard procedure for great saphenous vein (GSV) varicosities, but many other alternative treatments such as cryostripping, endovenous laser therapy (EVLT), radiofrequency ablation, and ultrasound-guided foam sclerotherapy have been developed. Among them, both cryostripping and laser therapy have been reported to be less traumatic, with lower rates of complications and recurrences when compared to conventional stripping. To compare the efficacy of these treatments, we have analyzed and compared the mid-term clinical outcomes of cryostripping and EVLT. ***Methods:*** Patients diagnosed with varicose veins of the GSV and treated with cryostripping or laser therapy between September 2008 and April 2013 were enrolled in this study. Duplex ultrasonography was used for the diagnosis and evaluation of varicosity and reflux, and the clinical-etiology-anatomy-pathophysiology classification was used to measure the clinical severity. The symptoms, Venous Clinical Severity Score (VCSS), recurrence rates, and complication rates of the cryostripping and laser therapy groups were analyzed and compared. ***Results:*** A total of 68 patients were enrolled in this study. 32 patients were treated with cryostripping, and 36 patients were treated with laser therapy. The median follow-up period was 29.6 months. Recurrence was noted in three patients from the cryostripping group and in two patients from the EVLT group. There was no difference in the VCSS score, operative time, duration of hospital stay, and complication rate between the cryostripping group and the EVLT group. ***Conclusion:*** The mid-term clinical outcomes of cryostripping were not inferior to those of EVLT. Further, considering its cost-effectiveness, cryostripping seems to be a safe and feasible method for the treatment of varicose veins.

Key words: 1. Endovenous laser therapy
2. Cryostripping
3. Varicose veins
4. Venous disease

INTRODUCTION

Although conservative management such as compression therapy may improve the symptoms of varicose veins, surgery is considered the best way to eliminate incompetence [1]. High ligation at the saphenofemoral junction (SFJ) and stripping of the great saphenous vein (GSV) are considered to be the standard procedure for varicose veins caused by GSV incompetence [2].

The recent trend in the treatment of varicose veins is minimally invasive surgery, such as endovenous laser treatment (EVLT) and radiofrequency ablation (RFA). The mechanism

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of EVLT and RFA in the treatment of varicose veins is the application of thermal damage to the venous endothelium of GSV, resulting in thickening and fibrosis with non-thrombotic occlusion of incompetent veins [3].

Cryostripping is an alternative method of conventional stripping. It is less traumatic, with lower rates of complications and recurrence, than conventional stripping [2,4]. In addition, the cost-effectiveness of cryostripping has been reported to be better than that of EVLT, although both therapies yielded similar therapeutic results [5]. The purpose of this study was to compare the efficacy of cryostripping and EVLT by analyzing and comparing the mid-term clinical outcomes.

METHODS

1) Patient selection

Patients diagnosed with varicose veins of the GSV and treated with cryostripping or EVLT between September 2008 and April 2013 at Korea University Anam Hospital, were enrolled in this study. Each patient underwent duplex ultrasonography with an ultrasound system (Zone Ultra; Zonare Medical Systems, Mountain View, CA, USA) for the diagnosis of their GSV reflux, and the size and presence of perforator veins or other varicosities. The clinical-etiology- anatomy-pathophysiology (CEAP) classification was used to measure the clinical severity [6].

2) Inclusion and exclusion criteria

Only patients diagnosed with varicose veins together with GSV reflux confirmed under ultrasonography were included in our study. A downward flow at the SFJ lasting for more than 2 seconds, which was confirmed on Doppler ultrasonography, was considered a positive test for GSV reflux. For the evaluation of mid-term results, only patients with a follow-up period of more than 1 year were included in this study. For a proper evaluation, patients who underwent reoperation for recurrence after a previous operation for varicose veins and those who simultaneously had small saphenous vein varicosities were excluded.

3) Surgical procedure

All patients underwent the surgical procedure under intravenous anesthesia or monitored anesthesia care. For cryostripping, the SFJ was checked by duplex ultrasonography and the level just below the first branch of the GSV was marked. A small skin incision of about 1.5 cm was made about 1 cm below the SFJ, and standard high ligation of GSV was performed. After the insertion of a metal probe (diameter: 3.5 mm) into the GSV through the distal opening of the ligated GSV, the probe location inside the lumen was confirmed using duplex ultrasonography. A tumescent (0.1% lidocaine chloride, 12.5 mEq/L of sodium bicarbonate, and epinephrine at 1:100,000 in normal saline) solution was injected around the GSV where the cryoprobe was inserted for efficient thermal transfer to the vein wall and to minimize the freezing of the adjacent structures. After freezing (2–5 seconds at -80°C) by Cryo-S Classic (Metrum CryoFlex, Blizne, Poland), the GSV between the highly ligated portion and the level of the lower one-third of the thigh was stripped out. If necessary, additional microphlebectomy of non-truncal varicosities was performed through small incisions after the ablation.

EVLT was also performed under the guidance of duplex ultrasonography, and the 980-nm multidiode endolaser fiber was used to produce thermal damage to the venous endothelium of the GSV. After confirmation of reflux at the SFJ, the GSV was punctured in the ankle area using an 18G angioneedle, and a 5F angiocatheter was inserted. The endolaser fiber was inserted up to the SFJ, and the tip of the laser fiber was placed at 1 cm below the SFJ under the guidance of duplex ultrasonography. As in cryostripping, a tumescent solution was injected around the GSV. The power of the laser was 12 W from the SFJ to the mid-thigh, 10 W at the lower thigh, and 8 W in the upper 1/3 of the calf. The pullback velocity of the laser fiber was 5 mm/sec. Microphlebectomy was performed in the same manner as in the case of cryostripping.

In both groups, sufficient hemostasis was performed by compression to prevent hematoma formation, and routine wound closure was done when needed. We applied compression bandages at the end of the procedure. Patients were discharged on the day of surgery or on the next day after

Table 1. Patient characteristics

Characteristic	Category	Cryostripping (n=32)	Endovenous laser therapy (n=36)	p-value
Sex ratio (female:male)		20:12	21:15	0.806
Age (yr)		56.75±10.65	54.28±12.38	0.384
Symptoms	Asymptomatic	15 (46.9)	18 (50.0)	0.813
	Pain	14 (43.8)	10 (27.8)	0.208
	Heaviness	2 (6.2)	4 (11.1)	0.676
	Fatigue	1 (3.1)	4 (11.1)	0.360
CEAP[a)] clinical classification	C2	27 (84.4)	32 (88.9)	0.725
	C3	5 (15.6)	4 (11.1)	0.725

Values are presented as mean±standard deviation or number (%).
[a)]Clinical-etiology-anatomy-pathophysiology.

surgery and were asked to wear compression stockings for 6–8 weeks.

4) Follow-up

We recommended the patients revisit the hospital at 1 week, 1 month, 3 months, and 1 year after surgery. During follow-up, patient history and physical examination results possibly related to some postoperative complications were examined and recorded. Most importantly, remnant varicosity and reflux were evaluated through duplex ultrasonography. On the basis of the results of duplex ultrasonography, the recurrence of GSV was interpreted as either neovascularization or recanalization. Recurrence after cryostripping was diagnosed with the presence of neovascularization or the residual stump with the presence of valves. Further, recurrence after EVLT was defined when there was an open refluxing segment of the treated GSV longer than 5 cm. After collecting the data of both groups, we analyzed and compared clinical outcomes such as symptoms, Venous Clinical Severity Score (VCSS), recurrence rates, complication rates, operative time, and duration of hospital stay.

5) Statistical analysis

All data were entered into an MS Excel spreadsheet (Microsoft, Bellevue, WA, USA). Data were analyzed using IBM SPSS Statistics ver. 20.0 (IBM Co., Armonk, NY, USA) to compare the clinical outcomes of each treatment modality. The univariate data analysis included t-tests for continuous variables and Fisher's exact test for discrete variables. Data were reported as the mean±standard error of the mean. A value of $p < 0.05$ was considered statistically significant.

RESULTS

A total of 68 patients with GSV reflux were enrolled, and the median follow-up period was 29.6 months. Among them, 32 patients were treated with cryostripping and 36 patients were treated with EVLT. No patient had a history of previous operations for varicose veins. No difference was noted between the two groups with respect to patient age, sex, past history, CEAP classifications, or preoperative symptoms. The overall patient characteristics are summarized in Table 1.

With respect to the operative results, recurrence was observed in 5 (7.4%) of the 68 patients. Two of these five patients were from the EVLT group, and both of them complained of lower leg numbness. The other three were from the cryostripping group, and they showed no symptoms. After examination with duplex ultrasonography, we could confirm the presence of neovascularization in all cryostripping cases, and one recanalization and one neovascularization in the EVLT cases. There was no difference between the two groups with respect to postoperative complications including deep venous thrombosis, pulmonary embolism, pain, remnant varicosities, hyperpigmentation, and paresthesia. The postoperative results, VCSS score, and complications are listed in Table 2.

Additional clinical factors such as operative time and duration of hospital stay were also evaluated. The average operative time was 73.1±33.2 minutes in the EVLT group and 75.5±27.9 minutes in the cryostripping group. The average duration of hospital stay was 1.8±1.0 days in the EVLT

Table 2. Postoperative results

Complications	Category	Cryostripping (n=32)	Endovenous laser therapy (n=36)	p-value
Recurrences		3 (9.4)	2 (5.6)	0.660
Complications	Deep vein thrombosis	0	0	
	Pain	4 (12.5)	3 (8.3)	0.699
	Varicosities	10 (31.2)	6 (16.7)	0.252
	Hyperpigmentation	0	4 (11.1)	0.116
	Paresthesia	4 (12.5)	3 (8.3)	0.699
Average Venous Clinical Severity Score		1.50±1.21	1.14±1.29	0.241

group and 2.2±1.5 days in the cryostripping group. There was no significant difference in the operative time and the duration of hospital stay between the cryostripping and the EVLT groups.

DISCUSSION

High ligation at the SFJ and stripping of the GSV are considered to be the standard procedure for varicose veins caused by GSV incompetence [2]. However, conventional stripping has been reported to have a recurrence rate of 6% to 26% and to be accompanied with side effects such as scars, infections, bruising, and hematoma [2,4,7].

Recent trends in the treatment of varicose veins is minimally invasive surgery, such as EVLT and RFA [3]. EVLT for the GSV, which is being performed widely and is a relatively new procedure, has been reported to show advantages such as better cosmetic outcomes, less invasive anesthesia requirements, less postprocedural pain, less induration, and rapid resumption of normal activity [8-10].

However, some studies have also reported the disadvantages of minimally invasive surgery, stating that it is only suitable for non-tortuous and less enlarged veins. Obviously, to make it easy to pass a catheter through the vein, from the ankle to the groin, we need to ensure that the vein is not tortuous [11].

On the other hand, cryostripping, which is an alternative less-invasive method of conventional stripping, can also be used in cases of tortuous varicosities of certain degrees by carefully inserting a metal probe through the tortuous vessels. In fact, cryostripping has been reported to be less traumatic, with lower rates of complications and recurrences, than conventional stripping [2,12]. Further, according to the 5-year follow-up of a randomized clinical trial reported by Disselhoff et al. [12], no significant difference was seen in the outcome after EVLT or cryostripping for varicose GSV.

Our results did not differ from the results of previous studies in that both groups showed similar results with respect to the recurrence and complication rates. A slight difference in the procedure between the two methods was that for cryostripping, a small incision of about 1.5 cm was needed in the inguinal area for high ligation and insertion of the probe into the vein. However, we had no wound complications such as dehiscence or infection during the postoperative follow-up.

Focusing on the recurrence, which was the primary endpoint of our study, we had three recurrences in the cryostripping group (9.4%) and two in the EVLT group (5.6%). There are several reasons for the recurrence of varicose veins after surgery. Ravi et al. [13] reported that without SFJ ligation, EVLT has a risk for recanalization. In another study, recanalization following EVLT on 1,250 patients was observed in 3% of the cases after 3 years [13]. On the other hand, neovascularization has been reported to be the major cause of recurrence after cryostripping. Surgery-induced angiogenesis is supposed to reconnect superficial veins to the deep femoral vein around a ligated SFJ. The venous drainage interference may also promote new vessel formation [14,15]. The recurrences in our study also showed similar results in that both of our cryostripping recurrence cases were due to neovascularization, while one EVLT recurrence case was due to recanalization and the other due to neovascularization. Fortunately, we had no incompetent thigh perforator causing recurrence that needed additional treatment.

Postoperative complications, which were the secondary end-

point of our study, are an important factor that influences the quality of life of varicose vein patients. According to the literature, the common postoperative complications at the mid-term follow-up are pain, hyperpigmentation, paresthesia, and remnant varicosities. Disselhoff et al. [14] reported that EVLT patients showed slightly better results with respect to postoperative pain and induration than the cryostripping patients, but both procedures were equally effective in terms of quality of life, recurrence rate, and complication rate in most of the previous studies [7,8,12,14]. Our study also confirmed that the incidence of complications was similar in both the cryostripping and the EVLT groups.

An additional advantage of cryostripping over EVLT lies in its cost-effectiveness. According to a comparative study reported by Disselhoff et al. [5] in 2009, while the outcomes of cryostripping and EVLT were similar, the total cost of EVLT was significantly higher than that of cryostripping. Further, considering the conditions of insurance related to surgery in Korea, the cost of EVLT is significantly higher than that of cryostripping.

The retrospective nature of the study, relatively small number of cases considered, and the absence of an evaluation of the actual costs for each procedure are the limitations of this study. Our results should therefore be interpreted with caution. However, the overall clinical outcomes of cryostripping do appear to be comparable to those of EVLT, particularly in patients with tortuous varicosities that are not suitable candidates for laser therapy and when economic factors are strongly considered.

In conclusion, the mid-term clinical outcomes of cryostripping were not inferior to those of EVLT. Further, considering its cost-effectiveness, cryostripping seems to be a safe and feasible method for the treatment of varicose veins.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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