Preminary Report: Initial Experience of Endovascular Laser Therapy for Varicose Veins Due To Greater Saphenous Vein Incompetence in Thailand

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Background: *Surgical venous stripping (SVS) is a standard treatment for varicose veins (VV) due to greater saphenous vein incompetence (GSVI) but there are some disadvantages to and risks. Endovascular laser (EVL) has been introduced to overcome these disadvantages. The present study was designed to determine the effectiveness of EVL treatment for these patients.*
Material and Method: *The patients with VV due to GSVI diagnosed by duplex scan were recruited in the present study. The EVL-procedure was percutaneously approached guiding by ultrasound under monitor anesthetic care (MAC). Postoperative clinical and imaging assessment was assessed.*
Results: *There were 17 limbs with symptomatic VVs in 11 patients. Two patients were admitted for a reason not related to surgery. The others were day cases. There was no postoperative complication except a large echymosis in one case. At 3-month follow-up, no recanalization or recurrence was detected.*
Conclusion: *The authors' early results demonstrated that EVL could obliterate VVs due to GSVI and further showed some benefits over SVS. More studies with a longer period of follow-up are needed to further confirm the efficacy of EVL.*

Keywords: *Varicose vein, Endovascular laser, Endovascular therapy*

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Venous varicosity of the lower extremities can be caused by insufficiency of either superficial venous system itself or secondary to insufficiency of the perforator and deep venous system. Its natural course, whatever the etiology, is gradually progressive and results in a manifestation of chronic venous disease including heaviness, skin-hyperpigmentation, stasis dermatitis and ulceration. Treatment differs according to etiology.

For primary varicose veins of the saphenous system, there are several treatment modalities all with the same treatment principle; ablation of the diseased veins. SVS is a standard treatment option for primary varicose vein due to reflux of the saphenous main trunk[1,2]. Sclerotherapy or microphebectomy is used for the diseased veins of the non-saphenous system or side branches of the saphenous system with intact main trunk[1,2].

Venous stripping requires admitting the patient, undergoing general anesthesia or spinal anesthesia and also decreases the patient's postoperative comfort by limiting the patient's activity including body-cleaning. Significant wound pain, saphenous nerve injury, and poor cosmetic outcome can also occur. Modern endovascular (laser & radiofrequency) therapy has been introduced for in situ ablating the saphenous main trunk in an attempt to eliminate the drawback of SVS[3,4].

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The present cohort study aimed primarily to assess the long-term effectiveness and recurrence or recanalization after treatment of VV due to GSVI with EVL.

Material and Method

EVL was introduced in our unit in September 2004. All patients with GSVI recruited in the present study were counseled about the modalities of treatment including standard venous stripping and EVL. They had to fulfill the following inclusion criteria. All patients must undergo venous evaluation by color flow duplex scan (model HDI 5000, ATL company) to confirm the diagnosis of GSVI using the criteria of reflux time greater than 0.5 second[5] after valsava maneuver and no reflux in the deep or perforator system. Patients with a history of deep vein thrombosis or postphebitic syndrome, markedly tortuous saphenous main trunk, recurrent VV after previous surgery, unable to afford EVL, very poor health or refused EVL treatment were excluded.

Patients underwent routine preoperative check up for proper preoperative preparation. Patients fasted at least 6 hours before operation. The procedure was performed in the operating theater. The whole leg up to the groin of the diseased limb was cleaned with antiseptic and draped. Temporary tourniquet was applied at the mid thigh level before puncturing the distal part of the greater saphenous main trunk with puncture needle No. 18G under B-mode ultrasound guide. The puncture site was infiltrated with 1% lidocaine before puncturing. Hydrophilic angled guide wire (0.32 or 0.35 inches diameter) was accessed via the puncture needle to the proximal part of GSV and common femoral vein while the tourniquet was removed. Five or six French long-sheath (40 cm or 55 cm long) was inserted over the guide wire into the common femoral vein under visual guidance by B-mode ultrasound, followed by the withdrawal of its stylet. Six-hundred m laser fiber was inserted through the long-sheath into the common femoral vein and adjusted under intraoperative B-mode ultrasound. The laser beam in the present study was a diode laser of 980-nm wavelength(ELVeS^{TM} diode laser, biolitec) with 12-watt power and continuous pulse (3-second on time and 1-second off time). The tip of the laser fiber must be at about 2 cm distal to the saphenofemoral junction and out of the long-sheath before delivering the laser beam. To relieve pain and patients' discomfort, MAC with intravenous profofol and fentanil was used to sedate the patients during laser-beam delivery. Laser beam was delivered along the course of the GSV from the final position toward the initial puncture site. External compression was applied simultaneously at the area around the tip of laser probe to promote coaptation of the venous intima during laser-beam deployment. Tight compressive dressing wrapped the whole limb for 3-4 hours in the short stay using elastic bandages then changed to gradual compressive stocking class 2 before discharging the patients. Only paracetamol tablets were prescribed to the patients.

Patients were followed at 1, 4, 12, 24, 48, 72 weeks postoperatively. Clinical assessment (including symptom improvement, complications and recurrence) and serial venous imaging with color flow duplex scan (incomplete venous obliteration, recanalization and recurrence) were the outcome indicators.

Results

Between September and December 2004, there were 17 limbs with VVs due to GSVI in 11 patients. Nine patients were female. All VVs were symptomatic. Demographic data is presented in Table 1.

All patients underwent the procedure under MCA and more potent analgesia was given only before laser delivery. Nine patients with 13 VVs were day-case surgery. The first patient with unilateral VV was asked to be admitted to the hospital because of the authors' inexperience. One patient with bilateral VVs asked to be admitted to obtain insurance-reimbursement. The procedure was successful in all cases. The percutaneous approach was successfully

Table 1. Demographic data of 11 patients with 17 VVs due to GSVI

Age:	Mean $\pm$ SD	51.9$\pm$19.6 yrs
	Range	31-88 yrs
Gender:	(male/female)	2/9
Varicose:	Right/Left	9/8
	Unilateral/Bilateral	5/6
Clinical:		
- bleeding		1
- pain, heaviness		17
- superficial phlebitis of VV		1
- venous claudication		2
- hyperpigmentation, lipodermatosclerosis		2
- dermatitis, venous ulcer		1
Associated diseases:		
- hypertension		4
- COPD		1
- cervical spondylosis		1
- BPH		1
- bladder carcinoma		1

performed in 16 VVs while the first case required a small incision for opened canulation. None of the cases required conversion to SVS. The mean operative time for each VV was 51.67 $\pm$ 40.72 minutes while the laser treatment-time was 2.41 $\pm$ 0.86 minutes. The mean treatment energy used was 1890.9 $\pm$ 759.0 joules. Blood loss was very minimal. No immediate complication during and after the procedure occurred.

Follow-up time was 1-week in 11 patients (17 VVs), 4-weeks in 8 patients (10 VVs), 12-weeks in 2 patients (2 VVs). Puncture scars were noticed at the first postoperative visit in 16 limbs except a small linear surgical scar in the first case. One case had a large echymosis (around 15 cm in diameter) at the thigh with slight pain but no hematoma. No clinical sign of saphenous nerve injury was observed in all cases. Serial color duplex scan in all cases revealed a small non-compressible heterogenous strand of the main trunk of GSV except the 1 or 1.5 cm of the GSV that was still patent. No thrombosis was detected in the femoropopliteal venous system. No recanalization or recurrence detected by duplex scan was seen in the early follow up. All patients could return to work or normal activity the day after the procedure.

Discussion

Lower-limb venous varicosity due to GSVI is a common etiology of chronic venous insufficiency that can produce similar clinical manifestation as that caused by perforator and deep venous insufficiency. In the present study, all cases had chronic symptoms of heaviness and calf pain. Three out of 17 limbs had severe skin change or ulceration. Because of the limitation of making a definite diagnosis from clinical presentation alone and different management strategies for each etiology of chronic venous insufficiency, it is the authors' policy to perform color duplex scanning in all cases to confirm diagnosis and exclude the other causes.

SVS is a standard treatment option for the VV due to GSVI. There is strong evidence showing its efficacy superior efficacy to other treatment-methods such as high ligation alone or sclerotherapy[6-9]. Recently, the patients' quality of life has also been shown to be better after SVS than high ligation alone[10]. This implies a beneficial effect of GSV-removal in addition to saphenofemoral vein disconnection. The disadvantages of the operation are: 1) Patients have to be admitted to the hospital and require general anesthesia or spinal block. 2) Postoperatively, patients suffer wound pain and are limited in their life-style and normal activities for at least a week. 3) It has a risk of saphenous nerve injury and unsightly surgical scar.

Endovascular therapy for VVs is a new approach that obliterates the diseased GSV which is similar to SVS but leaves it in situ. There are 2 different sources of energy that destroy the vein wall: radiofrequency thermoablation (RFT) and endovascular laser (EVL). Theoretically, these new modalities are nearly equivalent to SVS. There are several studies[11-13] confirming this equivalence, unfortunately theses studies had only short term observation. Although SVS is accepted as a standard treatment option, there is still a high recurrent rate of up to 65% in longer follow-up[6,9].Therefore it is too early to fully endorse the endovascular therapy at present.

The authors have not had experience with RFT for treating VV because there is no representative for this instrument in Thailand and it is more costly than EVL. Regarding EVL[11,14-17], there are many types of lasers classified according to the wavelength ranging from 810 nm to 1320 nm. No specific wavelength has been proved to have the highest efficacy to obliterate the diseased veins. In the present study using the 980-nm diode laser showed EVL can effectively obliterate GSV as in other reports[11,14-17]. The most important indicator of EVL-efficacy is the recurrent rate that should at least be equal to that of SVS. No study has compared the efficacy EVL over SVS in treatment VV. In the present study the number of cases was too small with a short follow-up. More data and longer follow up are required to establish the efficacy and effectiveness of EVL compared to SVS.

Although the authors' experience is limited with 3 months follow up, it is quite clear that this modality is free from SVS-disadvantages. All patients underwent EVL as day-case surgery without the risk of general anesthesia or spinal block, and patients were able to work the next day. Six patients in the present study had associated diseases (hypertension, COPD and cervical spondylosis) that may increase the risk of general anesthesia or spinal block. MAC with local lidocaine injection can minimize the anesthetic risk.

That of the endovascular approach avoiding injury to the saphenous nerve was supported by the present report as in others[11,14-17] while there was an injury rate of 18-25% in a recent report of conventional SVS or power phebectomy[18]. None in the present study had nerve injury complication as in the other reports[15-18]. Compared to SVS, there was only a

small 2-3 mm puncture wound on the patients' leg that allowed the patients to clean their bodies easily and was also more aesthetic. In Thailand, where the hot weather decreases the patients' tolerance to wearing compressive stockings, EVL allows the patients more time to clean their bodies before putting the stockings on again.

Conclusion

The present early result demonstrates that EVL can effectively obliterate VVs due to GSVI similar to previous studies. The benefits of EVL include: day-case surgery, avoiding general anesthesia, increases the patients' comfort and is acceptable cosmetically. At present, EVL shows a trend to be an alternative to SVS for the treatment of VVs due to GSVI. More cases and a longer period of follow-up are needed to confirm the efficacy of this modality.

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รายงานระยะต้น: ประสบการณ์เบื้องต้นการรักษาหลอดเลือดดำขอดด้วยวิธีเอนโดวาสคูล่าร์เลเซอร์ในประเทศไทย

สุรศักดิ์ ลีลาอุดมลิปี, สุทัศน์ ศรีพจนารถ, ภาณุวัฒน์ เลิศสิทธิชัย, ธีรพล อังกูลภักดีกุล, ปิยนุช พูตระกูล, สุทัศน์ ฮ้อศิริมานนท์, โสภา หลิ่วโรจน์ทรัพย์, เสงี่ยม ไตรหัตถทรัพย์

จุดประสงค์: *ศึกษาประสิทธิภาพการรักษาหลอดเลือดดำขอดที่เกิดจากการไหลย้อนในหลอดเลือดดำซาฟีนัสด้วยวิธีเอ็นโดวาสคูลาร์เลเซอร์*

วัสดุและวิธีการ: *คัดเลือกผู้ป่วยที่มีหลอดเลือดดำขอดที่เกิดจากมีการไหลย้อนของหลอดเลือดดำซาฟีนัสโดยใช้เครื่องตรวจอัลตราซาวด์และรักษาด้วยวิธีเอ็นโดวาสคูลาร์เลเซอร์ โดยใช้ยาระงับปวดชนิดตื้น ประเมินติดตามการรักษาโดยการตรวจร่วมกับตรวจความเปลี่ยนแปลงของหลอดเลือดดำด้วยอัลตราซาวด์เป็นระยะ*

ผลการศึกษา: *ได้ทำการรักษาโดยวิธีเอ็นโดวาสคูลาร์เลเซอร์หลอดเลือดขอดที่ขาที่มีอาการจำนวน 17 ข้างในผู้ป่วย 11 ราย ผู้ป่วย 2 รายจำเป็นต้องรับไว้ในโรงพยาบาลเนื่องจากเหตุผลด้านอื่นไม่เกี่ยวเนื่องกับการผ่าตัด ขณะที่ผู้ป่วยที่เหลือรักษาแบบผู้ป่วยนอก ไม่พบข้อแทรกซ้อนยกเว้นมีจ้ำพรายย้ำในผู้ป่วย 1 ราย ไม่พบมีการเป็นซ้ำของหลอดเลือดขอดในผู้ป่วยเมื่อติดตามการรักษา 3 เดือน*

สรุป: *จากผลการรักษาแสดงให้เห็นว่าเอ็นโดวาสคูลาร์เลเซอร์สามารถรักษาหลอดเลือดดำขอดจากการไหลย้อนในหลอดเลือดดำซาฟีนัสได้ สำหรับผลระยะยาวต้องรอประเมินการรักษาเพิ่มเติม*